



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ADMINISTRATIVE APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 04-17A

Applicant: Kenneth C. Arakawa, M.D., Inc.
1329 Lusitana Street, Suite 206
Honolulu, HI 96813
Phone: 808-528-3888

Project Title: Establish an outpatient extremity MRI for early diagnosis of
Rheumatoid Arthritis

Project Address: same

1. TYPE OF ORGANIZATION: (Please check all applicable)

- Public _____
- Private _____ **X**
- Non-profit _____
- For-profit _____ **X**
- Individual _____
- Corporation _____ **X**
- Partnership _____
- Limited Liability Corporation (LLC) _____
- Limited Liability Partnership (LLP) _____
- Other: _____

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2. PROJECT LOCATION INFORMATION

A. Primary Service Area(s) of Project: (please check all applicable)

- Statewide: _____
- O`ahu-wide: _____ **X**
- Honolulu: _____
- Windward O`ahu: _____
- West O`ahu: _____
- Maui County: _____
- Kaua`i County: _____
- Hawai`i County: _____

3. DOCUMENTATION (Please attach the following to your application form):

A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)

Equipment and leasing quotations attached

B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)

No permits required/Not applicable

C. Your governing body: list by names, titles and address/phone numbers

D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:

- Articles of Incorporation
- By-Laws
- Partnership Agreements
- Tax Key Number (project's location)

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over \$400,000)	New/Upgraded Medical Equip. (over \$1 million)	Other Capital Project (over \$4 million)	Change in Service	Change in Beds
Inpatient Facility					
Outpatient Facility				X	
Private Practice					

Not Applicable: actual cost of new equipment for private practice is \$229,900

5. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
TOTAL			

6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:

AMOUNT:

1.	Land Acquisition	<u>0</u>
2.	Construction Contract	<u>0</u>
3.	Fixed Equipment	<u>0</u>
4.	Movable Equipment	<u>0</u>
5.	Financing Costs	<u>\$ 9,980</u>
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	<u>\$229,900</u>
7.	Other: _____	<u>0</u>

TOTAL PROJECT COST: \$239,880

B. Source of Funds

1.	Cash	<u>\$ 3,998</u>
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt	<u>\$ 235,882</u>
6.	Other: _____	_____

TOTAL SOURCE OF FUNDS: \$239,880

- 7. **CHANGE OF SERVICE:** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please reference the Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

The new service to be provided consists of an in-office MRI imaging device for hand, wrist and/or feet extremities only, for purposes of identifying and staging early Rheumatoid Arthritis as well as monitoring response to TNF-alpha inhibitor therapies. The equipment utilized consists of a compact extremity MRI system designed specifically for rheumatologic applications, including acquisition and display protocols not generally available on other MRI systems such as 1.0 mm T1 and STIR slices without gaps as well as 3-D volume, side-by-side T1/STIR slice displays in axial, sagittal and coronal views. The MRI device provides comfortable positioning for patients suffering from the painful effects of arthritis who would otherwise have difficulty undergoing an MRI procedure in a conventional magnet due to the need for them to be positioned in a "swimmers position."

- 8. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

- a) Date of site control for the proposed project,

6/11/04

- b) Dates by which other government approvals/permits will be applied for and received,

Not applicable

- c) Dates by which financing is assured for the project,

6/15/04

- d) Date construction will commence,

Not applicable

- e) Length of construction period,

Not applicable

- f) Date of completion of the project,

6/21/04

- g) Date of commencement of operation

9. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the certificate of need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

- a) Relationship to the Hawai'i Health Performance Plan (H2P2), also known as the State of Hawai'i Health Services and Facilities Plan.
- b) Need and Accessibility
- c) Quality of Service/Care
- d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
- e) Relationship to the existing health care system
- f) Availability of Resources.

The 2000 HSDH "Behavioral Risk Factor Surveillance System" documented that nearly 25,000 Hawaiians (12.2% of 204,000 total arthritis patients) suffer from rheumatoid arthritis. Early detection of synovitis, osteitis and bone erosions followed by timely and aggressive treatment in patients diagnosed with rheumatoid arthritis has emerged as the new clinical paradigm, taking advantage of what is now commonly referred to as the "window of opportunity." Plain film radiography, along with certain lab tests, has been used in the past to identify and stage RA patients. Unfortunately, the sensitivity of X-Ray is poor, with telltale disease indicators not appearing for up to two years. It is well documented in the clinical literature that the majority of damage to joints from RA occurs within the first year after onset. MRI can detect changes in the joint, including bone erosions, as early as 4-6 months after onset of the disease. By initiating aggressive biologic therapy, joint damage from RA can be arrested, even healed, resulting in significantly improved outcomes and quality of life for the RA patient.

Because of the discomfort and limited mobility associated with arthritic conditions, conventional MRI's are difficult to utilize with rheumatology patients, as they must place their arm over their head for extended periods of time in what is called the "swimmers position" in order for their hands and wrists to be imaged. Additionally, the specific clinical acquisition, processing and display protocols previously referred to in Section 7 above, so critical to this specialized application, are not generally available on conventional MRI's.

By combining the benefits associated with the convenience of a relatively inexpensive in-office extremity MRI device, along with the design-specific capabilities for rheumatologic applications, we shall be able to better serve rheumatoid arthritis patients.

- a) Relationship to the Hawai'i Health Performance Plan (H2P2), also known as the State of Hawai'i Health Services and Facilities Plan.

Included among the many goals and objectives of H2P2 "Vision and Guiding Principles" are:

- *Increase the span of healthy life for Hawaii residents*
- *Early detecting and diagnosing of treatable diseases*
- *Reducing the effects of chronic diseases and prolonging quality of life*
- *Reducing morbidity and pain through timely and appropriate treatment*
- *Establishing delivery systems that are cost effective and foster improved access to quality health care*

Additionally, the Healthy People 2010 Measures includes the goal to "prevent illness and disability related to arthritis and other rheumatic conditions."

Implementation of this in-office extremity MRI will accomplish all of these goals. By identifying and intervening during the "window of opportunity" with rheumatoid arthritis patients, we shall be able to increase the span of healthy life for Hawaii residents. The MRI device is designed for the express purpose of early detection and diagnosis of rheumatoid arthritis which, when caught early enough with this methodology, is a treatable disease. Use of the MRI to identify and treat rheumatoid arthritis earlier than previously possible will reduce the effects of this chronic disease and prolong quality of life, minimizing and/or eliminating the chronic pain associated with this disease. It will also reduce the morbidity and pain associated with rheumatoid arthritis by identifying those patients who can benefit from timely and appropriate treatment. This new in-office MRI will help establish cost effective delivery systems by differentiating actual rheumatoid arthritis patients from those whose symptoms merely mimic rheumatoid arthritis. This will allow the withholding of costly therapeutic treatments from those patients for whom they are not necessary. In the Journal of Rheumatology 2004; 31:4 Dr. Charles Peterfy states "while MRI is a relatively expensive procedure, its use in RA may prove cost-effective if it can reduce unnecessary treatment of patients with costly biological therapies. As noted above, this may apply to more than 30% of RA patients on initial presentation." Dr. Peterfy also writes in the 2004 online Annals of the Rheumatic Diseases May 2004; 63: 473-477 "the availability of effective structure modifying treatment has stimulated a trend towards early, aggressive treatment before the development of joint damage. Some have advocated treating all patients aggressively in order to avoid missing those who might progress. However, 30%-40% of cohorts with early RA do not progress (develop erosions) and therefore may not require aggressive treatment." While it is impossible to be completely accurate in assessing the savings associated with the withholding of treatment, as this will be a function of the total number of patients who fit this category, it can be said that the savings will amount to between \$10,000 and \$20,000 per patient per year as this is the cost of the biological therapies that would be withheld. (Finally, it will foster improved access to quality healthcare by providing MRI imaging capability during in-office appointments which is more timely, more comfortable and more convenient for the patient. It will also guarantee that a patient will not be bumped from a scheduled exam using a traditional MRI on which procedures related to more critical medical needs always take priority.

b) Need and Accessibility

As previously mentioned, approximately 25,000 Hawaiians are currently diagnosed with rheumatoid arthritis. Very few of these patients, many of whom are being treated with costly biologic therapies, are undergoing MRI exams to confirm the presence of bone erosions and/or to monitor their response to therapy. New RA patients are identified at the office every month. Conventional MRI systems are typically reserved for studies of a more critical nature such as trauma, cardiac, large organ, etc. Additionally, the specific acquisition and display protocols required to accurately detect and monitor small erosions are not generally found on conventional MRI's. This new extremity MRI is needed to provide comfortable, convenient and timely point of care exams that will accurately diagnose and monitor treatment of RA. By providing the service in-office, accessibility is maximized for the patients as they can be imaged during routine initial or follow up appointments or during a therapeutic infusion session.

In particular to access to this MRI for the sole purpose of establishing a diagnosis, low income persons, racial and ethnic minorities, women, persons with disabilities and other underserved groups, and the elderly will be served via referral system from other physicians.

c) Quality of Service/Care

Ken Arakawa, MD is licensed in the state of Hawaii and board certified in the specialty of rheumatology. All MRI studies will be performed by a trained and certified operator. All MRI studies will be transmitted to and interpreted by a board certified radiologist. The extremity MRI system known as "Applause" from GE Medical Systems is recognized as the device of choice for this specialized exam. It is currently in use at highly regarded research and physician office locations around the mainland and is often the device of choice with pharmaceutical companies for clinical trials involving RA patients. The most recent study documenting the effectiveness of the extremity MRI device was lead-authored by the internationally recognized musculoskeletal radiologist, Dr. John Crues and published in the Journal of Rheumatology 2004; 31:4. Entitled "Identification of Wrist and Metacarpophalangeal Joint Erosions Using a Portable Magnetic Resonance Imaging System Compared to Conventional Radiographs," this article concludes that "the findings in a large group of patients indicated that there was superior sensitivity to bone damage using the portable MR system compared to radiographs, suggesting this MR scanner is extremely promising in the assessment of patients with RA or other erosive arthropathies." Similarly, in the Journal of Rheumatology April 31 (4): 640-4, lead author JL Hoving writes in his article entitled "A comparison of magnetic resonance imaging, sonography, and radiography of the hand in patients with early rheumatoid arthritis" that "MRI appears to be the most sensitive modality for erosive disease compared with sonography and radiography."

- d) Cost and Finances (include revenue/cost projections for the first and third year of operation)

The total cost over 5 years for the MRI device is projected to be about \$240,000 for equipment and \$80,000 for service. Positive cash flow of about \$60,000 is expected in the first year assuming bilateral scans are performed. Positive cash flow should continue for all years, including year three, as patient exam volumes are projected to remain stable. A sample financial analysis is attached demonstrating revenue projections based on our estimates of one patient exam every other day.

According to Medicare and HMSA, the following procedure code will be reimbursed as detailed below:

CPT Code	Description	HMSA	Medicare
73218	MRI upper extremity other than joint; w/o contrast	\$668.15	\$449.65
73221	MRI any joint of upper extremity; w/o contrast	\$668.15	\$449.65
73718	MRI lower extremity other than joint; w/o contrast	\$668.15	\$449.65
73721	MRI any joint of lower extremity; w/o contrast	\$668.15	\$449.65

Due to HIPAA regulations, other medical facilities will not share information about fees and reimbursements. At this time, I am not able to draw a parallel as far as charges and /or reimbursements and costs of the conventional MRI unit for the same procedure.

- e) Relationship to the existing health care system

As very few patients are now being referred for MRI exams for early detection of rheumatoid arthritis due to the aforementioned limitations with currently available MRI services, we expect very little impact on existing healthcare providers should this application be approved. Current in-state radiologists will be offered the opportunity to interpret and report the MRI exams we perform. If their existing workloads are prohibitive, we shall have the ability to transmit these studies via the internet to a board certified radiologist licensed to practice in the state of Hawaii.

- f) Availability of Resources

Management and human resources are available in-office from Dr. Arakawa and his staff for the implementation and continued operation of this new service. Professional resources are available from either existing radiology services on the island or from mainland board certified radiologists licensed to practice in Hawaii. Financial resources are available from the current

operation of Ken C. Arakawa, MD, Inc. as well as secured funding from GE Healthcare Financial Services. Initiation of the new service will be accomplished with a modest cash investment of only \$3,998; subsequent debt will be supported by procedural revenues and backed by personal guarantees. The operation of the MRI unit requires that a State certified radiology technician is required. We currently employ a radiology tech who is now in charge of our existing digital X-ray equipment in-house. As this unit is magnetic, no special certification will be necessary aside from the hands-on training that will be provided upon installation of equipment.

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10. Eligibility to file for Administrative Review. This project is eligible to file for Administrative review because: (Check all applicable)

It involves bed changes, which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.

It involves service changes which will have a capital expense of \$1,000,000 or less, and which will have an increased annual operating expense of less than \$500,000.

It is an acquisition of a health care facility or service, which will result in lower annual operating expenses for that facility, or service.

It is a change of ownership, where the change is from one entity to another substantially related entity.

It is an additional location of an existing service or facility.

The applicant believes it will not have a significant impact on the health care system.