

**Public Testimony Regarding MRI Standards
Presented at Public Hearing – July 23, 2009
By: Oakwood Healthcare, Inc.**

Good Morning,

My name is Monica Harrison, Sr. Planning Analyst at Oakwood Healthcare System.

Oakwood Healthcare, Inc., located in Dearborn, Michigan, operates four licensed hospitals with 1281 inpatient hospital beds in west and southwest Wayne County and offers an array of hospital outpatient, diagnostic, physician, and other medical services, including inpatient psychiatric services.

Oakwood supports the proposed changes to the MRI standards relative to the conversion of a mobile to a fixed MRI found in Section 3 of the standards. Specifically, the language would allow a hospital with 3,000 MRI adjusted procedures, 24-hour emergency care services, and at least 20,000 emergency room visits within a 12-month period to convert from a mobile to a fixed unit.

Mobile MRI service is currently provided at two of Oakwood's hospital facilities: Oakwood Heritage Hospital and Oakwood Southshore Medical Center. In the last several years, MRI has become an important component of quality patient care. Now mainstream, MRI is a vital service for all hospitals and the communities they serve. The cost of providing mobile service is significantly more expensive than those associated with a fixed scanner.

MRI capabilities have also evolved rapidly over the last five years. Increasingly, MRI is becoming the modality of choice for emergent cases, in particular cardiac MRI. Cardiology volumes have steadily increased at our Southshore facility with the onset of the emergency PCI program. Also, as a trauma center designation, the need for emergent MRI for neurology is an absolute. Also, as a teaching hospital, Southshore could provide enhanced teaching capabilities with the 24-hour availability of a fixed MRI.

We feel the proposed change in the MRI standards would allow us the opportunity to save lives and better serve our patients and community.

I would also like to thank the Commission, Dr. Sandler, and staff at the Department for their work on this issue. I would also urge their support in the final approval of these proposed changes in September.

Thank you for the opportunity to provide these comments.

Memo

To: CON Commissioners
From: David W Kondas, Director of Operations, Alliance Imaging
Date: 7/22/2009
Re: Proposed changes to the MRI Standards

This comment is in reference to the proposed MRI language that is being considered by the CON Commission and the Michigan Department of Community Health. There are 2 primary subjects in the proposed language that will be addressed: The use of MRI to support emergency department needs and the use of MRI in treatment planning. Alliance Imaging does not support the proposed language in Section 3(2)(b)(iii) which would allow for a hospital with 3,000 MRI adjusted procedures, 24-hour emergency care services, and at least 20,000 emergency room visits within a 12-month period, to convert from a mobile to a fixed MRI. Although Alliance Imaging supports the proposed language in Section 2 (1)(dd) for MRI Simulators, we are opposed to the timing of the review of these standards as there is no urgent need and the proposed changes should therefore be reviewed during the regular scheduled review period. We will expand on our reasoning below.

Regarding the language being proposed in Section 3(2)(b)(iii), our primary concern is that the proposed language is incomplete and not well supported by underlying data. The language is incomplete because it does not include the same base criteria as other exclusions to the 6000 adjusted procedure threshold that are in the current standard. The following should be added to be consistent with the current logic for exclusions:

- (A) IS LOCATED IN A COUNTY THAT HAS NO FIXED MRI MACHINES THAT ARE PENDING, APPROVED BY THE DEPARTMENT, OR OPERATIONAL AT THE TIME THE APPLICATION IS DEEMED SUBMITTED.
- (B) THE NEAREST FIXED MRI MACHINE IS LOCATED MORE THAN 15 RADIUS MILES FROM THE APPLICATION SITE.

The proposed language is not well supported because the appropriate volume of emergency room visits that would require 24/ 7 MRI coverage has not been established. Why should the threshold be set at 20,000 visits? No evidence has been submitted justifying this number. Since the appropriate number of emergency room visits has not been established, the CON Commission would be making an irrational and inappropriate policy decision if it simply pulled the number of 20,000 visits from out of thin air. How could the Commission later support this decision in the face of a future request by a facility with only 15,000 annual visits? A policy change of this nature should not be taken lightly. Additionally, the data specific to Oaklawn is not compelling with regards to the need to have full time coverage and appropriate utilization. In data submitted to the MDCH in 2008, Oaklawn showed 2296 MRI visits with 182 inpatients, of

these only a fraction were from the emergency department. The May 2009 adjusted procedures data showed Oaklawn has 2294 MRI visits or 3350 adjusted procedures utilizing 5 days of mobile MRI service per week. Oaklawn, which had less than 3,000 MRI visits last year and only 8 MRI patients per day, is now requesting that the CON Commission revise the CON Standards so that it can convert its less than fully utilized mobile MRI to a fixed MRI. Oaklawn's self-serving attempt to amend the CON MRI standards should be rejected by the CON Commission because there is no established need for such a fixed MRI and to allow it would result in an unneeded expenditure to treat a small number of patients. It should be of interest that Oaklawn is also presently exploring reducing their service to 4 days per week in order to get better utilization of the MRI. This type of utilization is not consistent with the CON Commission's goals for equipment utilization and justification of a mobile host site to fixed MRI conversion. Finally, it is not necessary for Oaklawn to operate an MRI on a 24/7 basis to cover its emergency department. We have contacted other fixed site MRI operators and have documented that many of these do not operate their MRI 24/7 in order to cover their emergency department. The fixed sites we contacted were: Bronson Methodist Hospital, Garden City Hospital, Owosso Memorial, and St. Mary Mercy in Livonia. It is our suggestion that better data be gathered to support the actual need for MRI as a supporting service for emergency departments.

On a final note, we are concerned that the CON Commission appears to be setting a new precedent regarding the timing of CON standards review in this case. Why are revisions to the MRI standards being considered out of sync with the Commission work plan? There is no urgent need to review the MRI Standards at this time. There may be a "want" by one facility, but that does not mean there is a true and urgent need.

Regarding the second proposal for the use of MRI for radiation treatment planning and the proposed language change in Section 2 (1)(dd), we support this concept. However, we are not in support of the timing of this change to the MRI Standards. Review of the MRI Standards is scheduled to occur on a regular cycle every other year. The exception to this would be an urgent need to review the standard and to modify the language therein. Given the fact that CT is still considered the gold standard for treatment planning and this request is directed toward facilities performing proton beam therapy, of which none will be operational prior to the next scheduled regular review, it appears that the CON commission is setting a new precedent regarding the timing of the review and revision of CON standards.



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MAGNETIC RESONANCE IMAGING (MRI) SERVICES

July 23, 2009

Good Morning. My name is Mark Mailloux, Sr. Health System Planner at the University of Michigan Health System (UMHS). I'd like to thank you for the opportunity to appear here today to offer our comments on the proposed Certificate of Need (CON) Review Standards for Magnetic Resonance Imaging (MRI) Services.

UMHS supports the adoption of the proposed revisions to the MRI standards, particularly as they relate to the use of MRI, not as a primary diagnostic tool, but rather in its capacity as an adjunct to another treatment modality.

In this broader context, UMHS believes that the use of a diagnostic tool in a subsidiary capacity, whether that be MRI as in this instance, or PET, CT (or even some other yet-to-be-envisioned tool), should be exempted from the volume-driven need methodologies which are not designed to address these situations.

Recently, these same standards were modified in order to facilitate the inclusion of a pilot project for the intra-operative utilization of MRI (IMRI). Each new instance of this sort of fusion of a diagnostic modality with another treatment in a novel arena causes the need for an after-the-fact modification of standards which were never intended to address these sorts of 'off-label' usage of existing technology.

In short, it is not possible to anticipate what the next new fusion will involve. But it is almost certain that it will be a non-traditional use of an existing tool; an existing tool that is measured as a stand-alone modality, but not being used as such. As has happened in the past, a rear-guard action will then be required to again clarify that "this isn't what we meant" in the existing standards, which were designed to measure and regulate the stand-alone diagnostic capacity of the modality in question.

So, while UMHS believes that these proposed MRI standards should be adopted, we also believe that it is time to address a broader exemption consideration instead of the current piece-meal approach.



MICHIGAN ORGAN & TISSUE DONATION PROGRAM



A Donate Life Organization

COMMENTS REGARDING THE PANCREAS TRANSPLANT SERVICES STANDARDS

Gift of Life Michigan supports the pancreas transplant standards as presented today. We feel that the main thrust of the rewritten standards, that of patient access to care and taking into consideration cost and quality issues, will increase the number of transplants that occur in our state. We thank the Commission for bringing these standards forward for review and the collegial environment through which they were drafted by the informal workgroup.

There is one place where language, as used in the standards, is open to interpretation. This section, page 4, line 164 (Section 4(c).i.II), pertains to the number of kidney and pancreas transplants a center shall perform. Line 164 reads that procedures are to be performed, "biennially (every two years)". Gift of Life Michigan respectfully requests that the Commission recognize the unique reporting and quality monitoring that exists today for transplant data. The federal reporting mechanisms for transplant centers occur monthly. Therefore, we request the Commission to adopt wording appearing in parentheses, to read "biennially (a consecutive 24-month period)". This will allow for different self-reporting periods that exist between federal and state regulatory agencies.

Finally, in the interest of transplanting more pancreata in our state, we ask the Commission to consider the adoption of an administrative "fast-track" for those programs inactive under federal OPTN regulations due to current CON requirements. These programs voluntarily surrendered their state certificate for pancreas transplants and are now inactive. This consideration could re-qualify a Michigan center to potentially open sooner under the new standards. Gift of Life Michigan respectfully asks that the Commission charge the Department staff to create a process by which these programs can begin to re-list and transplant patients as quickly as possible, to the benefit of Michigan residents.

I'd like to again thank the Commission for taking up this important issue, and Gift of Life also extends its gratitude to the staff of MDCH for their willingness to become knowledgeable of the many donation process issues over the past year.

July 23, 2009

Richard Pietroski, Executive Director

Gift of Life Michigan

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