STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED

PUBLIC HEARING
REVIEW STANDARDS FOR MRI, PANCREAS AND PSYCH BEDS

BEFORE ANDREA MOORE, DEPARTMENT TECHNICIAN TO CON COMMISSION

201 Townsend Street, Lansing, Michigan

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Lansing, Michigan
Thursday, July 23, 2009 - 9:02 a.m.

MS. MOORE: Good morning. As all of you know, I am Andrea Moore, a departmental technician for the Certificate of Need Commission from the CON Health Policy section of the Department of Community Health. Chairperson Ed Goldman has directed the Department to conduct today's hearing. Please be sure that you have completed the sign-in log, located on the back table. Copies of the standards and comment cards can be found on the back table. A comment card needs to be completed and provided to me if you wish to give testimony today.

The proposed review standards for MRI services are being reviewed and modified to include the following: A streamlining of Section 1; technical edits to Section 2; the addition of an exclusion in Section 2, sub 1, (dd), for MRI simulators; the streamlining and reorganization of Sections 3 through 7; the addition of an exception to the criteria for conversion of a mobile to fixed MRI in Section 3, sub 2(B) (III) to 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; elimination of the draft contract requirement within the expansion and replacements for mobile services; modification of the expansion criteria for mobile services to utilize only historical utilization adjusted procedures not physician commitments available adjusted procedures; elimination of the exception for relocating outside the relocation zone, but within the planning area, as this exception is obsolete and not utilized; modification of the project delivery req1uirement; and other technical edits, including those based on administrative practices.

The proposed CON review standards for pancreas transplantation services are being reviewed and modified to include the following: The definitions of initiator, implement and license site have been clarified based on current Department practice; implementation plan has been moved to Section 3 (2); the projected and maintenance volume for pancreas transplantation procedures is changed from 12 to 2. These changes occur in Section 3, sub 3 and 4, sub 1, (i). This conforms with OPTN requirements of one every six months. In addition to the changes, the maintenance requirement of 80 kidney transplants and/or pancreas transplants biennially (every two years). This change can be found in Section 4 (1) (c) (II); and additional technical changes.

The proposed CON review standards for psychiatric beds and services are being reviewed and modified to include the following: Based on administrative practice, the high occupancy language in Section 7 (3) is revised to clarify that the planning area must be at a bed need of zero or overbedded to use this provision. Additional criteria has been added at Section 11 (2) that requires all outstanding debt obligations owed to the State of Michigan for Quality Assurance Assessment Program, or called QAAP, or civil monetary penalties have been paid in full. Added criteria at Section 11, sub 3, that requires that the health facility for the proposed project has not been cited for a State or Federal code deficiency within the 12 months prior; and the bed needs numbers have been updated in Appendix A through D.

If you wish to speak on any of these proposed standards, please provide a comment card to me. Additionally, if you have written testimony please provide a copy as well. Just as a reminder, all cellular phones and pagers need to be turned off or set to vibrate during the hearing. As indicated on the notice of public hearing, written testimony may be provided to the Department via our website at www.michigan.gov/con through Thursday, July 30th, 2009, at 5:00 p.m.

Today is Thursday, July 23rd, 2009. We will begin the hearing by taking testimony on MRI and will continue with Pancreas and Site Beds until all testimony has been given, at which time we will adjourn. Starting this morning will be Monica Harrison from Oakwood.

MS. HARRISON: Good morning. My name is Monica Harrison, senior planning analyst at Oakwood Healthcare System. Oakwood Healthcare, Inc., is located in Dearborn, Michigan, and 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 psych 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 South Shore 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 South Shore 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, South Shore could provide enhanced teaching capabilities with a 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 of 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.

MS. MOORE: Thank you. Mark Mailloux from the University of Michigan.

MR. MAILLOUX: Good morning. My name is Mark Mailloux, senior health system planner at the University of Michigan Health System. I'd like to thank you for the opportunity to appear here today and to offer our comments on the proposed CON review standards for 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 as yet un-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 intraoperative utilization of MRI, or 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 the 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 nontraditional use of an existing tool; an existing tool that is measured as a stand-alone modality but is not being used as such. As has happened in the past, a rear-guard action will then be required to again clarify that, quote, "This isn't what we meant," closed quote, 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 piecemeal approach. Thank you.

MS. MOORE: Thank you. Dennis McCafferty from Economic Alliance of Michigan.

MR. McCaFFERTY: I have some oral remarks today. I'm going to paraphrase the written remarks that we'll be submitting in the next few days. Regarding MRI for MRT simulation, our members have concern regarding proposed changes in these standards for exempting MRIs that are used for MRT simulation. The major cancer programs that could justify the expense of an additional MRI that's used solely for MRT simulation already have multiple MRI machine units used for diagnostic purposes. The proposed standards would result in these major cancer programs being able to acquire yet another MRI machine that's limited in its availability for just the simulations. We anticipate that in a few years when its discovered that these machines are under-utilized, that these health systems will be back at the CON Commission asking that they also be able to use them for diagnostic because they're underutilized technology and they're very expensive and it's a shame that they're left idle a certain amount of time.

We believe that there's an alternative approach within the standards that hasn't been explored in the one meeting of the work group. The MRI standards already contain a provision that allows the weighting of different procedures depending on their complexity and the amount of time that it uses to take -- it uses the machines. It seems to us that it would be more appropriate that the use of MRIs for MRT simulation could be addressed by this weighting process, thereby allowing the multiple existing machines to be used for this purpose, not require the purchase of yet an additional machine. We think that this is a more reasonable use of the time and expense of these machines and was not explored by the work group. We're suggesting that this proposal not be approved by the Commission and that it be reported back to the work group to consider other alternatives for addressing this need.

Replacing MRIs for -- mobile MRIs with fixed MRIs for high volume, our group also has concerns regarding this. Is there a need for 24/7 services in an emergency room? We're aware that there are many hospitals that have fixed MRIs that don't operate them 24/7 because they can't justify the expense of staff in the off-hours when their utilization is so very low. So even if this hospital is claiming that they need one now for 24/7, they're not likely to be staffing it for 24/7. Are the 3,000 adjusted procedures per year too low to justify a fixed MRI? That works out to roughly eight scans per day. The current standards for acquiring an MRI machine is 16 scans per day. This is half the level. No information was provided that indicates that the adjusted procedures per year of 3,000 is the appropriate number; all we know for sure is that it's enough for Oaklawn to get their machine. Doesn't this leave the standards open to challenges for the next hospital that has just a slightly lower number of procedures so that they can get a machine?

Why are 2,000 emergency room visits per year the appropriate number for a hospital to qualify for a mobile MRI -- to replace their mobile MRI with a fixed MRI? No information was provided indicating that 2,000 ER visits is the appropriate number. All we know for sure is that it was just enough for Oaklawn to qualify for their machine. Again, doesn't it leave the standards open to the next hospital that has just a slightly fewer number to say that the standards need to be adjusted so that they can get one?

We believe that the proposed standards was developed to address the perceived needs of a specific provider. Revising the CON standards for specific providers is detrimental to the -- good public policy and the proposed changes will result in undermining the basis for the MR standards in making it more difficult to defend against further requests to erode these standards.

MS. MOORE: Thank you, Dennis. Next, I have David Kondas from Alliance Imaging.

MR. KONDAS: Good morning. I thank everybody for giving me the time to present our comments in this public hearing. They've also been submitted online, so I'll paraphrase some of the points in here. My name is David Kondas, I'm from Alliance Imaging. I am the director of operations for Alliance, and I would have it be known that we're the service for Oakwood Hospital -- or, Oaklawn Hospital, excuse me, in this particular case.

We have two primary areas of concern with regards to the proposal that is founded around the need for emergency room coverage. The first predominant one is that the language is incomplete, inconsistent with the current language that we've used and supported for the MRI standards. There's no language in there that includes language that would be consistent with the fact that there's no fixed MRI machines that are in the same county that are already in operation in -- CON approved, and also the language that there's nothing within 15 miles radius from that particular site, which is consistent with other exceptions that are in the current standards. So I think there's some incompletion there.

The other component that we're against with regards to this is there's really no support-- underlying support for this particular proposal. Why should the threshold be set at 20,000 ER visits per year? If you look at the data from Oaklawn last year, they did about 2,296 MRI visits of which about 182 were inpatients; not classified out of that are the number of those that were actual ER visits. So a very small fraction of patients are actually coming from the emergency room. We'd like to see some data -- in a policy decision like this, we'd like to see some data that the State could later support when another hospitals pops up and says that, "We think 15,000 is the appropriate number of ER visits that a fixed MRI could support." So that is one of the predominant issues with the proposed language that's here is how we support that for future questions that come up from other hospitals that feel that they need emergency room coverage as well.

And then the final point that we have is around utilization as it applies. This is a facility that currently is utilizing a scanner five days a week, and only doing about eight scans per day. The standards are much higher than that. It's definitely an attempt, a fairly self-serving one at that, to fix the language around a particular need for this particular client. We've reached out to a number of hospitals -- Bronson Methodist, Garden City Owosso, St. Mary's Livonia -- and looked at their use of MRI to cover their emergency room. And what we found is that most of those do not staff the MRI in the off hours to cover the emergency room need.

And then the other component that I think is of interest at the current time is, you know, right now we cover the facility for four days of -- or, for five days of service. They've actually asked us to scale back service to four days. So if there's such a large impending need, it's curious to me that we'd be moving in the opposite direction on the amount of coverage that is needed.

With regards to the MRI standard change around therapy planning, I think a primary concern here is that there is supposed to be a regularly scheduled review of the MRI standards. It seems like we're starting to set a precedence around reviewing these upon these types of requests. And this doesn't seem to be an urgent need. It's not that we're necessarily against its use in MRT by any means, but just kind of the frequency and the precedent it's being set around in how we review the standards. Thank you.

MS. MOORE: Is there anybody else that would like to provide testimony on MRI?

ALL: (No response)

MS. MOORE: Seeing none, we'll move on to pancreas, and I have Dennis McCafferty.

MR. McCAFFERTY: I failed to introduce myself; that needs to be done. Dennis McCafferty, health policy director for Economic Alliance of Michigan. We're a statewide business/labor coalition. We are involved mostly in CON efforts to represent our members who we perceive as purchasers and consumers.

Regarding the pancreas transplant proposed changes in the standards, we support those. We believe that these strengthen the standards. The requirement to secure and retain pancreas transplants for hospitals that have done at least 80 kidney and pancreas transplants in the last two years, the new standards require that you both do that volume to not only obtain your CON for pancreas transplants, but that you maintain that. Previously you needed only to have done at least 80 kidney transplants to qualify for the CON, so we see this as strengthening. The dropping of the annual minimum from 12 to 2, because the evidence supports that this is not a quality issue, our members are in favor of doing this as long as it continues to be tied to facilities that have this high volume of -- kidney transplant volume.

MS. MOORE: Thank you, Dennis. Mark Mailloux from the University of Michigan.

MR. MAILLOUX: Good morning. As you suspect, my name is Mark Mailloux; I'm the senior health system planner at the University of Michigan Health System. And, again, I'd like to thank you for the opportunity to appear here to offer our comments on the proposed CON review standards for pancreas transplantation services. UMHS strongly supports the proposed revision to these standards and believe that they should be adopted for several reasons.

Because of the nature of the pancreas organ itself, it's fragility and it's poor shelf life, as well as the current state of the art for dealing with those factors, pancreas transplant is, and for the foreseeable future will continue to be, an extremely low volume service. At the same time, the technical knowledge and equipment required, such as the highly trained transplant physicians and other personnel required to perform such transplants, are difficult to attract and obtain as well as expensive to retain solely for an extremely low volume service such as this.

From both a personnel as well as a technique standpoint, there is a close affinity between pancreas and kidney transplants, a connection that would continue to exist informally even if it were never formalized, as accomplished in these standards. As a result the establishment of a substantial volume standard for kidney transplants as a requirement for the establishment and ongoing maintenance of a pancreas transplant program secures that link. Despite the fact that kidney transplant is not a CON-covered service, we believe that basing pancreas transplant standards on an underlying kidney transplant program will do more to secure a successful pancreas transplant program than any pancreas volume requirement. So while UMHS believes these proposed -- I think it ends there. I did a mistake on my text and copied some wrong text in here. So I will submit online the correct copy. Thank you.

MS. MOORE: Thank you. Next is Rich Pietroski, from Gift of Life Michigan.

MR. PIETROSKI: Good morning, everyone. My name is Rich Pietroski; I'm the executive director for Gift of Life Michigan. 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 will 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 work group.

There is one place in the language, however, that we feel the standards are open to misinterpretation. The Section on page 4, line 164, Section 4, (c), i.II, pertains to the number of kidney and pancreas transplants that a center shall perform. The line reads that procedures are to be performed, quote, "biennially (every two years)," end quote. Gift of Life Michigan continues to respectfully request 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, and therefore we request that the Commission seek to adopt wording appearing in the parentheses to read, "(any consecutive 24-month period)." This would allow different self-reporting periods that exist between Federal and State regulatory agencies.

And finally, in the interest of transplanting more pancreata in our state, we ask the Commission to respectfully consider the adoption -- again, an administrative "fast-track" for those programs that are inactive under Federal OPTN regulations during current CON requirements. These programs voluntarily surrendered their State certificate of pancreas transplants and are now inactive. Similarly, however, it should be anticipated in the future that centers will undergo periods of inactivity due to temporary lapses caused by the loss of a single transplant surgeon, a medical director for the transplant program or other reasons as outlined under Federal regulation. And it would be an unfortunate lapse for these centers to remain inactive because the data could not be reported on a month-to-month basis as compared to annually.

This consideration would re-qualify a Michigan center to potentially open sooner. Under current -- we have two centers that are closed but, again, in the future there are other centers that could potentially lapse in their qualification to remain open under Federal requirements. Gift of Life respectfully asks the Commission charge the Department staff to create a process by which these programs can be relisted -- begin to relist -- excuse me -- begin to relist and transplant patients as quickly as possible to benefit the Michigan residents.

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

MS. MOORE: Thank you. Is there anybody else that would like to provide testimony on pancreas?

ALL: (No response)

MS. MOORE: Seeing none, is there anybody that would like to provide testimony on psych?

ALL: (No response)

MS. MOORE: Seeing none, we are going to go ahead and adjourn for today. I just want to remind anybody that if you'd like to submit additional written testimony you can do that via the Department link at www.michigan.gov/con until 5:00 p.m. on Thursday, July 30th. Have a wonderful day.

(Proceedings concluded at 9:32 a.m.)