

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED

PUBLIC HEARING
REVIEW STANDARDS FOR
BONE MARROW TRANSPLANTATION SERVICES (BMT)
HEART/LUNG & LIVER (HLL) TRANSPLANTATION SERVICES
MAGNETIC RESONANCE IMAGING (MRI) SERVICES

BEFORE IRMA LOPEZ, MANAGER HEALTH POLICY SECTION OF THE
DEPARTMENT OF COMMUNITY HEALTH
201 Townsend Street, Lansing, Michigan
Wednesday, February 10, 2010, 9:30 a.m.

Also Present: Michael Berrios

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TABLE OF CONTENTS

PAGE

Statement by Ms. Lopez. 3

Lansing, Michigan

Wednesday, February 10, 2010 - 9:35 a.m.

MS. LOPEZ: Good morning. I'm Irma Lopez, section manager for the Health Policy Section of the Department of Community Health. Chairperson Ed Goldman has directed the Department to conduct today's hearing. Today is Wednesday, February 10th. It is 9:32, and if there is no objection from anyone in the room, I would like to delay the beginning of the actual – of hearing any testimony for approximately 20 minutes, given the weather conditions today. This will allow a little extra time for anyone else who may be coming in to provide testimony.

(Off the record)

MS. LOPEZ: Good morning again. This is Irma Lopez, and we are resuming the public hearing scheduled for Wednesday, February 10th, having postponed the start time approximately 20 minutes. Please be sure that you have completed the sign-in log. Copies of the standards and comment cards can be found on the back table with the sign-in log. A comment card needs to be completed and provided to me if you wish to give testimony. The proposed CON Review Standards for Bone Marrow Transplantation (BMT) Services are being reviewed and modified to include the following changes. As I'm reading through here I will be referencing any subsections that may be applicable. For exact location of changes, I will refer you to the public notice -- or the Notice of Public Hearing. There are some extra copies at the back of the table. Under Section 1, modified the language consistent with recent changes in other CON review standards. Definition for "licensed site" is clarified based on current Department practice. Under Section 2(1), redefined planning area to add a second adult planning area. Under Section 2(1), added a definition for Tumor Registry as referenced in Section 8. "Implementation plan" is moved to Section 3(4). Under Section 3(5), identified a cap of three in planning area one and a cap of one in planning area two. Under Section 3(6), the volume projection for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant

procedures. Under Section 3(10), added language to clarify that the written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular therapy, acronym FACT, accredited transplant unit that performs both allogeneic and autologous transplants for either adult and/or pediatrics. Under Section 3(10), reduced the number of site visits to three. Under Sections 3(10), 7(1) and 7(1)(c)(i) and (B) -- and Section 7(1)(c) modified language based on the recommendation that autologous only programs would no longer be allowed. Acquisitions language, previously Section 8, is moved to Section 4. For administrative feasibility, changed language, "the CON granted pursuant to this Section shall automatically expire," "the Department may expire the CON granted pursuant to this Section," Under Section 5(3), modified to award points based on the straight-line distance to the nearest existing BMT program of the type applied for, adult or pediatric, instead of being based on the number of BMT services within the health service area. Also it clarified Section 5(3) based on administrative practice. Under Section 5(3) added language to award points based on the number of necessary support services and personnel as identified in Section C (sic), which are the project delivery requirements, that the applicant has available on site on the date the application is submitted to the Department. Based on current administrative practice, modified the language in Section 5(4) consistent with recent changes in other CON review standards. Split Section 7 into two subsections. Under 7(1), the volume maintenance for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures. Under Section 8, added language to identify the source of data for documentation of projection. And finally, other technical changes were made to the language. And, again, for the specific location of these changes, I refer back to the Notice of Public Hearing.

The proposed CON review standards for Heart/Lung and Liver Transplantation Services are being reviewed and modified to include the following: Under Section 1, modified the language consistent with recent changes in other CON review standards. "Implementation plan" is moved to Section 3(2). The

definition for "licensed site" is clarified based on current Department practice. Removed the definition for "transplant and health policy center" as it is no longer referenced in the standards. Removed the definition for "transplant support program" as it is no longer referenced in the standards. Under Section 3(5) added "Liver Transplantation Services" to the joint sharing arrangement language. Under Section 5(1) and (2) added language relevant to the joint sharing agreement which are consistent with Sections 4(1) and (2). Based on current administrative practice, modified the language in Section 6(4) consistent with recent changes in other CON review standards. We've added language under Section 7(1) to clarify the requirements to comply with the Organ Procurement and Transplantation Network, OPTN. Removed Sections 8, 9 and 10, as they are no longer needed, given the clarification to Section 7(1), We've updated the language under Section 7(1) as required by the federal OPTN. And finally, we've included other technical changes. And again, for the specific location, I refer back to the Notice of Public Hearing.

The proposed CON Review Standards for Magnetic Resonance Imaging (MRI) Services are being reviewed and modified to include the following: Added a definition for "no charge." Added clarifying language under Sections 2(1) and 3(6). Added an exception to the criteria for a conversion of a mobile to a fixed MRI in Section 3(2) to allow for a for-profit freestanding facility with 2,000 MRI adjusted procedures and at least 25 percent of the MRI visits having a payer source of Medicaid and/or no charge to convert from a mobile to a fixed. Added acquisition language under Section 7(1) to acquire a fixed MRI service and its unit, or units, that were initiated under Section 3(2). Under Section 12(3) added a project delivery requirement to require an applicant approved under Section 3(2) to agree to continue to provide at least 25 percent of the MRI visits with the payer source of Medicaid and/or no charge during the first 12 months of operation and annually thereafter for at least 10 years. And the last modification noted, based on administrative practice, and for consistency, changed the phrase "deemed complete" to the phrase "deemed submitted" throughout the entire standards.

If you wish to speak on the proposed BMT, Heart/Lung and Liver or MRI standards, please provide your comment card to me. Additionally, if you have written testimony, please provide a copy as well. As a reminder, all cellular telephones and pagers need to be turned off or set to vibrate during the hearing. As indicated on the Notice of Public Hearing, written testimony will be accepted by the Department via our website at www.michigan.gov/con through Wednesday, February 17th, 2010 at 5:00 o'clock p.m. Again, today is Wednesday, February 10th, 2010. We will begin the hearing by taking testimony and will continue until all testimony has been given, at which time we will adjourn.

At this time I don't have any cards in front of me. If anyone would like to speak on the record, I will accept cards. Although we've postponed the hearing a little bit longer, I think we can adjourn for another 15 minutes. And in the event anyone comes in during those 15 minutes, they will be allowed to provide testimony. We'll resume back in 15 minutes.

(Off the record)

MS. LOPEZ: We'll go ahead and adjourn this public hearing.

(Proceedings concluded at 10:14 a.m.)