

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
COMPUTED TOMOGRAPHY (CT) STANDARD ADVISORY COMMITTEE (SAC)  
MEETING**

Wednesday, September 5, 2007

Capitol View Building  
201 Townsend Street  
MDCH Conference Center  
Lansing, Michigan 48913

**APPROVED MINUTES**

**I. Call To Order**

Chairperson Shumaker called the meeting to order at 9:20 a.m.

A. Members Present:

Gerrie Baarson, Battle Creek Health System  
Sharon Brooks, DDS, Self  
Dale M. Downes, Sparrow Hospital  
William C. Granger, MD, Blue Care Network of Michigan  
Chad M. Grant, Detroit Medical Center  
Jeffrey Hinman, MD, Spectrum Health  
Dean J. Jackson, Marquette General Health System  
Calvin C. Johnson, MidMichigan Health  
Alice W. Mailhot, Consumer Health Care Coalition  
Kathleen A. McManus, Vice-Chairperson, Munson Medical Center  
Cassandra R. Saunders, Economic Alliance for Michigan  
Daniel B. Shumaker, MD, Chairperson, Michigan Radiological Society  
Kristin J. Tesner, Genesys Regional Medical Center

B. Members Absent:

None.

C. Michigan Department of Community Health Staff Present:

Umbrin Ateequi  
Larry Horvath  
John Hubinger  
Irma Lopez  
Andrea Moore  
Brenda Rogers  
Taleitha Pytlowanyj  
Matt Weaver

## **II. Declaration of Conflicts of Interests**

None were stated at this time.

## **III. Review of Agenda**

Chairperson Shumaker stated that the Committee would skip item V of the agenda, MDCH Program Update (on enforcement and compliance), for the time being due to Mr. Horvath being in another meeting.

Motion by Dr. Granger, seconded by Mr. Johnson, to approve the agenda as amended. Motion Carried.

## **IV. Review of Minutes – August 9, 2007**

Motion by Dr. Brooks, seconded by Ms. Baarson, to approve the minutes as presented.

Dr. Granger requested that the minutes show more of the discussion that takes place during the meeting. Under item V of the minutes, he would like the minutes to reflect that his concern was that the CT data was not presented in a manner that allowed the members to analyze it (due to it being emailed in pdf format).

Brooks/Baarson Motion. Motion Carried.

## **V. Review and Discussion of Charge**

### **A. Potential Pediatric and Special Needs Criteria and Need for Specific Weighting**

#### Public Comment

J. Michael Zerin, MD, Detroit Medical Center  
Conrad Nagle, William Beaumont

Motion by Mr. Grant, seconded by Mr. Dziejdzic, that the Committee adopt the language presented (Attachment A) for Specially Dedicated Pediatric CT Scanners, as well as a pediatric conversion factor for institutions not meeting the dedicated CT language and the weighting factor .25 be added to the existing CT weights.

#### Public Comment

J. Michael Zerin, MD, Detroit Medical Center  
Robert Meeker, Spectrum Health  
Conrad Nagel, William Beaumont

Dr. Zerin raised concern with the Grant/Dziejdzic Motion regarding defining a dedicated pediatric scanner and its requirements, versus a non-dedicated scanner that's used for kids with the additional weighting. There should also be appropriate protocols (in regards to ALARA training, PALS training, etc.) for a non-pediatric center where they're being given an additional weighting. Chairperson Shumaker stated that most of the quality control issues in the Standards fall under the Project Delivery Requirements and recommended that Dr. Zerin review the Project Delivery Requirements and possibly recommend changes/additions to that language.

Mr. Weaver recommended that in the proposed pediatric language, under the section regarding Requirements for Approval of an Applicant Proposing to Establish Dedicated Pediatric CT, the word "annual" be removed in the third to last line of that section and

have that concept be placed under the Project Delivery Requirements. Chairperson Shumaker requested that Dr. Zerlin consider the recommended change while he looks at the Project Delivery Requirements to make sure that it is consistent with the rest of the language.

Grant/Dziedzic Motion. Motion Carried.

## **VI. MDCH Program Update**

Chairperson Shumaker summarized the statewide reviews conducted by the Department, stating that the four services; Air Ambulance, Swing Beds, Open Heart and Transplant, have all had a comprehensive review done. He also stated that enforcement action has taken place with five facilities in Open Heart and two facilities in Transplant. Mr. Horvath provided a brief background on the enforcement that the Program Section has taken in the past. He stated the three ways in which the Department monitors. An investigation is triggered if an allegation is made of non-compliance, if someone submits an application and they are not meeting volume, and also, as the Department does a statewide comprehensive review of all facilities performing a certain CON covered clinical service to determine if they are meeting their project delivery requirements. Discussion followed.

### Public Comment

Jim Potchen, MD, MSU Radiology

## **V. Review and Discussion of Charge - Continued**

### **B. Replace/Upgrade Criteria and Definitions**

The Committee restated the two Motions that were Tabled at the previous meeting.

Motion by Dr. Granger, seconded by Dr. Brooks, to remove from the table the Grant/Johnson Motion "that the applicant proposing to replace/upgrade an existing CT scanner be exempt once from the volume threshold if the current machine is performing at least 5000 CT equivalents in the preceding 12 months and is a fully depreciated asset." Motion Carried.

### Public Comment

Conrad Nagle, William Beaumont  
Dennis McCafferty, Economic Alliance for Michigan  
Monica Harrison, Oakwood  
Robert Meeker, Spectrum Health

Motion by Mr. Grant, seconded by Dr. Brooks, to amend the Grant/Johnson Motion by adding language that the applicant proposing to replace/upgrade an existing CT Scanner has met the minimum volume requirement at one point. Motion Carried.

The Committee asked that the Grant/Johnson Motion be restated with the amendment.

Motion by Mr. Grant, seconded by Mr. Johnson, that the applicant proposing to replace/upgrade an existing CT scanner be exempt once from the volume threshold if the current machine is performing at least 5000 CT equivalents in the preceding 12 months and is a fully depreciated asset and at one point met the minimum volume requirements. Motion Carried.

Motion by Dr. Brooks, seconded by Ms. Tesner, to remove from the table the Brooks/Jackson Motion "that an underperforming system can replace the CT scanner if it is completely depreciated and obsolete if it is over 8 years old." Motion Carried.

Dr. Brooks withdrew the Brooks/Jackson Motion.

Motion by Mr. Grant, seconded by Mr. Downes, that the applicant proposing to replace/upgrade an existing free-standing CT Scanner on a medical school campus shall be exempt once, as of the effective date of the standards, from the volume threshold if the current machine is a fully depreciated asset. Motion Carried.

Lunch Break from 12:17 p.m. to 1:43 p.m.

**C. Commitment Process**

The Department provided proposed language for Section 16 of the standards (Attachment B), related to the documentation of projections. Mr. Horvath explained that the basic principle behind this language is that an applicant should not be able to take commitments from a facility that is not itself able to meet its current volume requirements. This language would require that a facility has excess volume that it is able to commit. Mr. Horvath informed the Committee that the Department enforces regulation as Standards are written. He stated that the Department only uses physician commitments as an acceptable methodology for projections. Discussion followed.

The Committee stated that they need more time to review the proposed language and would address it at the next meeting.

**D. Criteria and Processes for Addressing Emerging Specialty Use Scanners**

Dr. Brooks provided a brief background on Dental CT Scanners. Susan Vestevich of Xoran Technologies provided a brief slide-show presentation on Specialty Use Scanners. Discussion followed.

Public Comment

Jean Aldrich, Eye and ENT Specialists

Motion by Dr. Brooks to remove Dental CT Scanners from being regulated by the CON process. Motion Failed due to lack of a second.

The Committee decided they need to look at thresholds for Dental CT's and to address language for expansion, relocation, replacement, or acquisition of a dental CT scanner service.

**VII. MDCH – Review of Draft Language (More Technical Changes)**

Ms. Ateequi provided a brief overview of the technical changes made to the Standards. Discussion followed.

**VIII. Public Comment**

Matt Jordan, Xoran Technologies  
Dennis McCafferty, Economic Alliance for Michigan

**IX. Next Steps**

Ms. Ateequi provided a brief summary of the meeting. The Committee will be looking at the recommendations by Dr. Zerlin regarding the Project Delivery Requirements at the next meeting. The Committee was requested to review the Draft Language to prepare for the next meeting; additional language will be drafted into the standards based on today's recommendations.

**X. Future Meeting Dates 2007**

October 10  
November 14

Dr. Shumaker requested committee members to email staff regarding their availability in October and November for a potential additional meeting.

**XI. Adjournment**

Motion by Dr. Granger, seconded by Dr. Hinman, to adjourn the meeting at 3:24 p.m. Motion Carried.

## ***For CTSAC Review: Pediatric Sections of CT***

### **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

Proposed changes:

- 1) Create a dedicated pediatric CT CON for qualifying institutions
- 2) Creates new replacement, upgrade and expansion thresholds for dedicated pediatric CT scanners.

#### **Definitions**

"Dedicated pediatric CT" means an CT unit on which at least 70% of the CT procedures are performed on patients under 18 years of age

"Pediatric patient," for purposes of these standards, except for Section 10, means a patient who is 18 years of age or less.

"Sedated patient" means a patient that meets all of the following:

- (i) patient undergoes procedural sedation and whose level of consciousness is either moderate sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care Organizations, or an equivalent definition.
- (ii) who requires observation by personnel, other than technical employees routinely assigned to the CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support (PALS).

#### **Requirements for approval of an applicant proposing to establish dedicated pediatric CT**

(1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the following:

- (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.
- (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.
- (c) The applicant shall have an active medical staff, at the time the application is submitted to the Department that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:
  - (i) pediatric radiology (at least two)
  - (ii) pediatric anesthesiology
  - (iii) pediatric cardiology
  - (iv) pediatric critical care
  - (v) pediatric gastroenterology
  - (vi) pediatric hematology/oncology
  - (vii) pediatric neurology
  - (viii) pediatric neurosurgery
  - (ix) pediatric orthopedic surgery
  - (x) pediatric pathology

- (xi) pediatric pulmonology
- (xii) pediatric surgery
- (xiii) neonatology

(d) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:

- (i) pediatric bone marrow transplant program
- (ii) established pediatric sedation program
- (iii) pediatric open heart program

Additionally, the applicant must be able to prove that all Radiologists, Technologists and Nursing staff working with CT patients have annual continuing education or in-service training on pediatric low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

- (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of routine CT initiation standards.

**Requirements for approval of an applicant proposing to upgrade or replace a pediatric CT**

CT scanner units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 2,500 CT equivalents per unit for dedicated pediatric CT.

**Requirements for approval of an applicant proposing to expand a pediatric CT**

CT scanner units shall be operating at a minimum average annual level of utilization during the previous 12 months of operation of 3,000 CT equivalents per unit for dedicated pediatric CT.

PROPOSED LANGUAGE (Charge 4: CT Physician Commitment Process)

**Section 16. Documentation of projections**

Sec. 16. ~~(1)~~ An applicant required to project volumes ~~of service~~ under sections 3, 4 and 5 shall DEMONSTRATE THE FOLLOWING, AS APPLICABLE: specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation the Department shall determine whether the projections are reasonable.

(1) AN APPLICANT REQUIRED TO PROJECT UNDER SECTION 3 SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON HISTORICAL PHYSICIAN REFERRALS THAT RESULTED IN AN ACTUAL SCAN FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION.

(2) An applicant required to project ~~volumes of service~~ under Section 4 shall demonstrate that the projection is based on a combination of the following for the most recent 12-month period immediately preceding the date of the application:

(a) the number of dental procedures performed by the applicant, and

(b) the number of committed dental procedures performed by referring licensed dentists.

~~(3)~~ FURTHER, THE applicant and the referring licensed dentists shall substantiate the numbers ~~in subsection (2)~~ through the submission of HIPAA compliant billing records.

(3) AN APPLICANT REQUIRED TO PROJECT UNDER SECTION 5 SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON HISTORICAL UTILIZATION AT THE APPLICANT'S SITE FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION.

(4) AN APPLICANT SHALL DEMONSTRATE THAT THE PROJECTED NUMBER OF REFERRALS TO BE PERFORMED AT THE PROPOSED SITE UNDER SUBSECTIONS (1) AND (2) ARE FROM AN EXISTING CT SCANNER SERVICE THAT IS IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE, AND WILL CONTINUE TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE SUBSEQUENT TO THE INITIATION OF THE PROPOSED CT SCANNER SERVICE BY AN APPLICANT. IN DEMONSTRATING COMPLIANCE WITH THIS SUBSECTION, AN APPLICANT SHALL PROVIDE EACH OF THE FOLLOWING:

(A) A WRITTEN COMMITMENT FROM EACH REFERRING PHYSICIAN THAT HE OR SHE WILL REFER AT LEAST THE VOLUME OF CT SCANS TO BE TRANSFERRED TO THE PROPOSED CT SCANNER SERVICE FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE CT SCANNER SERVICE PROPOSED BY AN APPLICANT.

(B) THE NUMBER OF REFERRALS COMMITTED MUST HAVE RESULTED IN AN ACTUAL CT SCAN OF THE PATIENT AT THE EXISTING CT SCANNER SERVICE FROM WHICH REFERRAL WILL BE TRANSFERRED, DURING THE MOST RECENT 12-MONTH PERIOD PRIOR TO THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT. THE COMMITTING PHYSICIAN MUST MAKE AVAILABLE HIPAA COMPLIANT AUDIT MATERIAL IF NEEDED UPON DEPARTMENT REQUEST TO VERIFY REFERRAL SOURCES AND OUTCOMES.