

POSITRON EMISSION TOMOGRAPHY STANDARD ADVISORY COMMITTEE (PETSAC) MEETING

Friday, June 9, 2006

Capitol View Building
201 Townsend Street
MDCH Conference Room B/C
Lansing, MI 48913

APPROVED MINUTES

I. Call to Order

Chairperson Nagle called the meeting to order at 9:02 a.m.

A. Members Present and Organizations Represented:

Dr. Kevin Berger, Michigan State University
Dr. Kirk Frey, University of Michigan Health System (Arrived at 9:14 a.m.)
Chad Grant, Detroit Medical Center
John Helmer, Saint Mary's Health/ Spectrum Health (Filled-in at 10:48 a.m.)
Dr. David Kellam, Economic Alliance of Michigan
Dr. Conrad Nagle, Beaumont Hospitals
Dr. Kevin O'Brien, St. John Health
Loren Rhoad, Hospital Network Healthcare Services
Dr. Anthony F. Shields, Karmanos Cancer Institute (Left at 1:00 p.m.)
Dr. Paul Shreve, Saint Mary's Health/Spectrum Health (Left at 10:48 a.m.)
Jo Ann Sting, Blue Cross Blue Shield of Michigan
Carl VerBeek, Alliance for Health (Left at 12:46 p.m.)

B. Members Absent and Organizations Represented:

Dr. Kastytis Karvelis, H.F. Health System

C. CON Commission Liaison Absent:

Dr. Michael Sandler

D. Staff Present:

Sallie Flanders
John Hubinger
Matt Jordan
Irma Lopez
Andrea Moore (Left at 10:00 a.m.)
Stan Nash
Taleitha Pytlowanyj
Brenda Rogers

II. Review Agenda and Distributed Materials

Motion by Dr. Kellam, seconded by Dr. Shreve, to accept the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None were stated.

IV. Review of Minutes – May 9, 2006

Motion by Dr. Kellam, seconded by Mr. VerBeek, to accept the minutes as proposed. Motion Carried.

V. Review of Final Draft Language

Motion by Dr. O'Brien, seconded by Dr. Shreve, to look at the language section by section with the exception of saving Section Y and XX for last. Motion Carried.

Section 1

Motion by Mr. VerBeek, seconded by Dr. Kellam, to approve Section 1 as proposed. Motion Carried.

Section 2

Motion by Mr. VerBeek, seconded by Dr. Frey, to approve Section 2 as proposed.

Motion by Mr. Grant, seconded by Ms. Sting, to amend VerBeek/Frey Motion to change the relocation zone so that it is 25 miles for Micropolitan/Rural areas and 10-miles for Metropolitan areas. Motion Carried.

Motion by VerBeek/Frey. Motion Carried.

Public comment received during discussion:
Barbara Jackson, Economic Alliance of Michigan
Terry Gerald, Detroit Medical Center

Section 3

Motion by Mr. Rhoad, seconded by Dr. Shields, to approve Section 3 as proposed. Motion Carried.

Section 4

Motion by Dr. Berger, seconded by Dr. Frey, to modify Section 4(2)(b)(ii)(f) to read at line 302; "NETWORK OR A MOBILE PET NETWORK THAT HAS BEEN APPLIED FOR UNDER SECTION 5(3)". Motion Carried.

Motion by Chairperson Nagle, seconded by Dr. Berger, to approve Section 4 as modified. Motion Carried.

Section 5

Motion by Mr. VerBeek, seconded by Dr. Frey, to approve Section 5 as proposed with the technical change to Section 5(3)(D) at the end to read; "Subject to Section 4(3)". Also to insert the word "simultaneously" on line 385 after the word "submitted." Further, to add a sub-section (G) to read; "THE APPLICANT AGREES TO COMPLY WITH SECTIONS 11 AND 12 PROJECT DELIVERY REQUIREMENTS."

Motion by Dr. Frey, seconded by Dr. O'Brien, to amend VerBeek/Frey Motion to add another sub-section (h) to read; "THE MOBILE NEEDS TO OPERATE WITHIN 20 MILES OF THE CURRENT FIXED UNIT."

Mr. Rhoad proposes a friendly amendment to Frey/O'Brien Motion to change it so there is no mile radius, but instead use "planning area." Sub-section (H) should read; "MOBILE UNIT NEEDS TO OPERATE IN THE SAME PLANNING AREA AS THE CURRENT FIXED UNIT." Motion Carried.

Motion of Frey/O'Brien. Motion Carried.

Motion of VerBeek/Frey. Motion Carried.

Public comment received during discussion:
Barbara Jackson, Economic Alliance of Michigan

Section 6

Motion by Dr. Shields, seconded by Mr. VerBeek, to approve Section 6 as proposed. Motion Carried.

Section 7

Motion by Mr. Rhoad, seconded by Chairperson Nagle, to clarify the language in Section 7 so that the language corresponds with the title of this Section. Motion Carried.

Motion by Mr. VerBeek, seconded by Mr. Rhoad, to approve Section 7 as modified. Motion Carried.

Public comment received during discussion:
Mark Hutchinson, St. Mary's Health Care

Section X

Motion by Mr. VerBeek, seconded by Dr. Shields, to approve Section X as proposed. Motion Carried.

Section 8

Motion by Mr. VerBeek, seconded by Dr. Kellam, to approve Section 8 as proposed. Motion Carried.

Section 9

Motion by Dr. Berger, seconded by Dr. Frey, to approve Section 9 as proposed. Motion Carried.

Section 10

Motion by Dr. Shields, seconded by Dr. Berger, to approve Section 10 as proposed. Motion Carried.

Section 11

Motion by Mr. VerBeek, seconded by Mr. Helmer, to approve Section 11 as proposed. Motion Carried.

Section 12

Motion by Mr. Rhoad, seconded by Dr. Shields, to approve Section 12 as proposed. Motion Carried.

Section 13

Motion by Dr. Shields, seconded by Mr. Helmer, to approve Section 13 as proposed. Motion Carried.

Section 14

Motion by Mr. VerBeek, seconded by Dr. Kellam, to approve Section 14 with the modification at subsection (1)(b) to replace "CMS" with "National Coverage Determination". Motion Carried.

Section 15

Motion by Mr. VerBeek, seconded by Dr. O'Brien, to modify Section 15(d) by keeping the 75-mile radius for Micropolitan/Rural areas, but add 25-mile radius to apply to Metropolitan areas. Also, to modify line 869 by taking out the word "and" and replacing it with the word "or." Motion Carried.

Motion by Mr. VerBeek, seconded by Dr. O'Brien, to approve Section 15 as modified. Motion Carried.

Section 16

Motion by Ms. Sting, seconded by Dr. Kellam, to approve Section 16 as proposed. Motion Carried.

Section 17

Motion by Dr. Berger, seconded by Mr. Grant, to modify Section 17(1)(c) by keeping the 75-mile radius for Micropolitan/Rural areas, but add 25-mile radius to apply to Metropolitan areas. Also, to modify line 869 by taking out the word "and" and replacing it with the word "or." Motion Carried.

Motion by Dr. Shields, seconded by Dr. Kellam, to accept Section 17 as modified. Motion Carried.

Section 18

Motion by Dr. Berger, seconded by Dr. Frey, to modify Section 18(1)(c) by keeping the 75-mile radius for Micropolitan/Rural areas, but add 25-mile radius to apply to Metropolitan areas. Also, to modify line 869 by taking out the word "and" and replacing it with the word "or." Motion Carried.

Motion by Dr. Frey, seconded by Mr. Helmer, to approve Section 18 as modified. Motion Carried.

Sections 19, 20, 21, 22, 23

Motion by Dr. Berger, seconded by Dr. Kellam to approve Sections 19, 20, 21, and 22 as proposed and to approve the deletion of Section 23. Motion Carried.

Public comment received during discussion:
Lynn Bosscher, Spectrum Health

Section Y

Motion by Mr. VerBeek, seconded by Dr. O'Brien, to modify Section Y (1) to read; "AN APPLICANT PROPOSING TO OPERATE AN INCREMENTAL FIXED PET SCANNER AT THE SITE OF AN EXISTING FIXED PET CLINICAL SCANNER TO BE USED FOR BOTH RESEARCH AND CLINICAL PURPOSES SHALL DEMONSTRATE EACH OF THE FOLLOWING." Motion Carried.

Motion by Mr. VerBeek, seconded by Dr. Shields, to approve Section Y as amended.

Public comment received during discussion:
Melissa Cupp, Wiener Associates
Mark Hutchinson, St. Mary's Health Care

Recessed from 11:58 a.m. to 12:10 p.m.

Motion by Mr. VerBeek, seconded by Ms. Sting, to strike Section Y as amended and replace as follows with keeping the original language of Section Y(1)(E) and (F):

Section Y. Requirements for approval for applicants proposing a combined clinical/research fixed PET Scanner

Sec. Y. (1) AN APPLICANT PROPOSING TO OPERATE AN INCREMENTAL FIXED PET SCANNER TO BE USED FOR BOTH RESEARCH AND CLINICAL PURPOSES SHALL DEMONSTRATE EACH OF THE FOLLOWING:

- (A) THE APPLICANT FACILITY HAS A CLINICAL FIXED PET SERVICE.
- (B) THE APPLICANT'S EXISTING FIXED CLINICAL PET SERVICE HAS REACHED THE NECESSARY VOLUME TO JUSTIFY ADDITIONAL CLINICAL CAPACITY AS FOLLOWS:
 - (I) THE APPLICANT IDENTIFIES THE PERCENTAGE OF SERVICE ON THE PROPOSED UNIT THAT WILL BE FOR CLINICAL SERVICE. THIS IS CALLED % CLINICAL.
 - (II) IF THE APPLICANT FACILITY IS LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, THE APPLICANT'S EXISTING VOLUME MUST BE EQUAL TO $(5,500 \times \% \text{ CLINICAL}) + 500$.
 - (III) IF THE APPLICANT FACILITY IS LOCATED IN A MICROPOLITAN STATISTICAL AREA COUNTY OR A RURAL COUNTY, THE APPLICANT'S EXISTING VOLUME MUST BE EQUAL TO $(5,500 \times \% \text{ CLINICAL}) + 500$.
- (C) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 8(1)(A), (B), AND (C).
- (D) THE APPLICANT MUST AGREE TO LIMIT THE CLINICAL USE OF THE PROPOSED UNIT TO % CLINICAL UNTIL SUCH TIME AS THEY APPLY FOR AN ADDITIONAL CON TO INCREASE % CLINICAL. [THIS SECTION COULD BE INCORPORATED INTO THE PROJECT DELIVERY REQUIREMENTS INSTEAD OF HERE.]
- (E) ALL USES OF THE COMBINED CLINICAL/RESEARCH PET SCANNER WILL BE REPORTED TO THE DEPARTMENT AS CLINICAL ACTIVITY ACCORDING TO SECTIONS 11(1)(III) AND 13, UNLESS USE MEETS THE CRITERIA BELOW IN SECTION Y(1)(F).
- (F) USE OF THE COMBINED CLINICAL/RESEARCH PET SCANNER WILL BE REPORTED TO THE DEPARTMENT ACCORDING TO SECTIONS 11(1)(III) AND 13 AS RESEARCH ACTIVITY WHEN IT MEETS BOTH OF THE FOLLOWING REQUIREMENTS:
 - (I) THE SCAN IS CONDUCTED WITH APPROVAL FROM THE APPLICANT'S INSTITUTIONAL REVIEW BOARD.
 - (II) THE SUBJECT SCANNED IS INFORMED OF THE INVESTIGATIONAL NATURE OF THE STUDY.

APPLY TO A NEW OR EXISTING UNIT.
Motion Carried.

Motion by VerBeek/Shields. Motion Carried.

Public comment received during discussion:
Melissa Cupp, Wiener Associates
Mark Hutchinson, St. Mary's Health Care
Barbara Jackson, Economic Alliance of Michigan

Section XX

Motion by Mr. VerBeek, seconded by Mr. Rhoad, to accept Section XX with the modification of adding sub-letters and sub-sections. The additions will read as follows;

(D) 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 ANESTESIOLOGY
- (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

(E) THE APPLICATION 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

(2) AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (1) SHALL BE EXEMPT FROM MEETING THE REQUIREMENTS OF SECTION 4 OR SECTION 5 OF THESE STANDARDS; APPLYING TO SECTION 6.

(3) PEDIATRIC UNIT BE EXCLUDED FROM ADULT COUNT FOR FACILITY.

Motion by Dr. Frey to table the VerBeek/Rhoad motion. Motion Carried.

Public comment received during discussion:
Lynn Bosscher, Spectrum Health
Barbara Jackson, Economic Alliance of Michigan

Section 13

Motion by Dr. Berger, seconded by Dr. Shields, to modify Section 13(b) to read as follows:

“FOR EACH PEDIATRIC PATIENT VISIT, THE PET EQUIVALENT(S) DETERMINED PURSUANT TO SUBDIVISION (a) SHALL BE MULTIPLIED AS FOLLOWS:

Patient ≤ 5 years of age multiply by 4.0

Patient $> 5 \leq 10$ years of age multiply by 3.0

Patient $> 10 \leq 17$ years of age multiply by 2.0”

Motion Carried.

Motion by Dr. Frey, seconded by Dr. Kellam, to remove the VerBeek/Rhoad motion regarding Section XX from the table. Motion Carried.

Section XX

Motion of VerBeek/Rhoad. Motion Carried.

VI. Public Comment

None.

VII. Future Meeting Dates

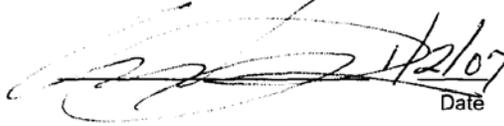
None at this time.

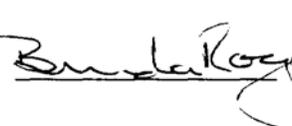
Language tentatively scheduled to be presented by the Chair at the September 19, 2006 CON Commission Meeting.

VIII. Adjournment

Motion by Chairperson Nagle, seconded by Dr. O'Brien, to adjourn the meeting at 1:02 p.m.
Motion Carried.

MINUTES APPROVED AND ACCEPTED BY:

 12/07
Date

 12-21-06
Date

Dr. Conrad Nagle, Chairperson
Positron Emission Tomography SAC

Brenda Rogers
Special Assistant to CON Commission