

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISSION MEETING**

Thursday, March 24, 2011

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

APPROVED MINUTES

I. Call to Order

Chairperson Goldman called the meeting to order @ 9:42 a.m.

A. Members Present:

Edward B. Goldman, Chairperson
James B. Falahee, Jr., JD, Vice-Chairperson
Peter Ajluni, DO
Charles Gayney
Robert Hughes
Brian Klott
Gay L. Landstrom, RN
Michael A. Sandler, MD
Michael W. Young, DO

B. Members Absent

Bradley Cory
Marc Keshishian, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Melanie Brim
Linda Collins
William Hart, Jr.
Larry Horvath
Joette Laseur
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Vice-Chairperson Falahee and seconded by Commissioner Landstrom to approve the agenda as presented. Motion carried in a vote of 9-Yes; 0-No; and 0-Abstain.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of January 26, 2011

Motion by Commissioner Sandler and seconded by Commissioner Ajluni to approve the minutes of January 26, 2011. Motion carried in a vote of 9-Yes; 0-No; and 0-Abstain.

V. Computed Tomography (CT) Scanner Services Standard Advisory Committee (SAC) Report

A. Dr. Mukherji gave a brief summary of the final report from the CT SAC (See attachment A).

B. Ms. Rogers gave a brief summary of the proposed CT draft language (See attachment B).

C. Public Comment:

Melissa Cupp, Weiner Associates (See attachment C)
Milan P. Gaudlin, Northern Radiology

Discussion followed.

Motion by Commissioner Sandler and seconded by Commissioner Ajluni to approve the proposed draft language and move forward to a public hearing and the Joint Legislative Committee (JLC). Motion carried in a vote of 9-Yes; 0-No; 0-Abstain.

VI. Positron Emission Tomography (PET) Scanner Services - MDCH Status Report

Ms. Rogers gave a brief summary of the Department's PET Status report (See attachment D).

VII. Magnetic Resonance Imaging (MRI) Services - Intra-Operative MRI (iMRI) - MDCH Report

Ms. Rogers gave a brief summary of the iMRI Report (See attachment E).

VIII. Megavoltage Radiation Therapy (MRT) Services/Units - MDCH Report

Ms. Rogers gave a brief summary of the MRT Report (See attachment F).

Motion by Vice-Chairperson Falahee and seconded by Commissioner Sandler to accept all three (3) reports and recommendations provided by the Department and move forward. Motion carried in a vote of 9-Yes; 0-No; and 0-Abstain.

IX. Cardiac Catheterization Standard Advisory Committee (CCSAC) - Status Update

Chairperson Goldman and Ms. Rogers gave a verbal update on behalf the CCSAC.

X. Standing New Medical Technology Advisory Committee (NEWTAC)

Chairperson Goldman gave a verbal update on behalf of Dr. Keshishian.

Mr. Potchen commented that the Commission can expand the historical role of the NEWTAC to look at items before FDA approval and after the one-year time frame that is identified in statute.

XI. Legislative Report

Ms. Brim gave a verbal report, including HB 4441 regarding swing beds.

XII. Administrative Report

A. Health Policy Section

Ms. Rogers gave a verbal update on the Health Policy Section.

B. CON Evaluation Section Update

Mr. Horvath gave a brief summary of the Quarterly Report (see Attachment G) and the Compliance Report (see attachment H). He also gave a verbal report on the Administrative Rules and the annual CON Seminar.

XIII. Legal Activity Report

Mr. Potchen gave a brief summary on the legal activity report (see Attachment I).

XIV. Future Meeting Dates

A. June 9, 2011

B. September 22, 2011

C. December 15, 2011

XV. Public Comment

Bob Meeker, Spectrum Health

XVI. Review of Commission Work Plan

Ms. Rogers gave a summary of the draft work plan (see Attachment J).

A. Commission discussion

B. Commission Action

Motion by Commissioner Hughes and seconded by Commissioner Klott to accept the draft work plan as presented. Motion carried in a vote of 9-Yes; 0-No; and 0-Abstain.

XVII. Election of Officers

Motion by Commissioner Sandler and seconded by Commissioner Ajluni to nominate and elect Commissioner Falahee as Chairperson for the Commission.

A vote on the motion to nominate and elect Commissioner Falahee as Chairperson occurred. 8-Yes; 0-No; and 1-Abstained. Motion Carried.

Motion by Commissioner Ajluni and seconded by Commissioner Young to nominate and elect Commissioner Sandler as Vice-Chairperson for the Commission.

Motion by Commissioner Gayney and seconded by Commissioner Hughes to nominate and elect Commissioner Goldman as Vice-Chairperson for the Commission.

A vote on the motion to nominate and elect Commissioner Sandler as Vice-Chairperson occurred. 4-Yes; 5-No; and 0-Abstained. Motion Failed.

A vote on the motion to nominate and elect Commissioner Goldman as Vice-Chairperson occurred. 5-Yes; 4-No; and 0-Abstained. Motion Failed.

Commissioner Sandler withdrew his nomination.

A re-vote on the motion to nominate and elect Commissioner Goldman as Vice-Chairperson occurred. 6-Yes; 2-No; and 1-Abstained. Motion Carried.

Chairperson Falahee mentioned that Commissioner Sandler will also be included in monthly conference calls with the Department.

XVIII. Adjournment

Motion by Commissioner Sandler and seconded by Vice-Chairperson Goldman to adjourn the meeting at 11:41 a.m. Motion Carried.

CTSAC Final Report January 2011

This is the final report of the CTSAC that was given the charge of reviewing the Standards for Computed Tomography (CT) Scanner Services. Interim reports were provided for the September 2010 and December 2010 Certificate of Need Commission meetings.

The CTSAC met 7 times between July 2010 and January 2011. We addressed all the issues in the charge given to us by the Commission. Below is a summary of the action.

Charge 1: Whether or not dental CT scanners should continue to be regulated under CON. If regulation of dental CT scanners should be maintained, make recommendations, if necessary, regarding any modification to the requirements.

Action: The committee recommends that dental CT scanners continue to be regulated under CON, using the current standards, with one exception. Due to the lack of dental CT scanners in the entire Upper Peninsula (Health Service Area 8), in order to encourage the establishment of a dental CT scanner service in that region, the CTSAC recommends that the minimum volume requirements be dropped for HSA 8 only.

Charge 2: Whether or not portable point of care and mini CT scanners should continue to be regulated under CON. If regulation of portable point of care and mini CT scanners should be maintained, then make recommendations as to the requirements.

Action: The committee decided to separate the portable point of care (POC) and mini CT scanners. Regarding the POC CT scanners, the committee recommends extending the current pilot project for these units until December 31, 2013 in order to obtain sufficient data to fully evaluate the use of these scanners. It is recommended that eligibility for the pilot project be extended to those facilities that performed >100 craniotomies in the prior 12 month period, in addition to Level I and Level II trauma centers as in the original pilot project. The committee also recommends additional metrics be collected for evaluation.

Regarding the mini-CT (or office-based CT scanner), the committee recommended that a separate category not be made for this type of scanner. These scanners must meet all the requirements of a fixed CT scanner.

Charge 3: The methodology, e.g., volume requirements and CT equivalents in regards to CT proliferation, and make any necessary recommendations.

Action: The committee recommends that the volume requirements and CT equivalents remain the same with one exception: the “excess capacity” of a scanner that can be committed to starting a new scanner service be raised from the current 7500 to 10,000. Currently if a scanner service wishes to expand, it must demonstrate that each scanner is generating 10,000 CT equivalents before it can count any additional CT equivalents as “excess” for the purpose of committing to a new scanner. However, if a new service wished to start, it could count all CT equivalents over 7500 towards its own commitments. This recommendation uses the same volume for both expansion of an existing service and initiation of a new service.

Charge 4: Any technical or other changes from the Department, e.g., updates consistent with other ON Review Standards, radiation safety issues, consistency of initiation language with Public Health Code.

Action: The committee was concerned about obsolete CT scanners that cannot be replaced under the current standards because they are not generating sufficient CT equivalents. Generally these older scanners provide higher radiation doses to the patient and are not receiving sufficient referrals to meet their volume requirements. The committee recommends that there be a one time exemption of volume requirements for a hospital to replace a CT scanner with <16 multidetector rows as long as the machine is fully depreciated and is being replaced by a scanner with at least 16 multidetector rows.

The committee also reviewed the language of the CT Scanner Services Review Standards and made some recommendations of changes in wording to bring these Review Standards into conformance with other Review Standards.

Respectfully submitted

Sharon L. Brooks, DDS, MS, Chair, CTSAC
Suresh Mukherji, MD, FACR, Vice-Chair, CTSAC

Supplement to CTSAC Final Report

During the course of the SAC, the Department sought legal guidance regarding two issues. At the time the SAC completed its duties, guidance was still pending. The SAC moved its recommendation forward with the understanding that changes may need to be made to the language pending the guidance received by the Department. The questions and answers are:

- 1) Whether the new standards could be applied retroactively to those who have been approved under prior CON standards. **Answer:** The proposed CON standards cannot be applied retroactively to current CON holders. [Section 19(5)]
- 2) Whether the language requiring revocation of the CON for failure to comply is necessary. **Answer:** The language requiring revocation is not necessary or recommended. [Section 19(5)]

In addition, the AG guidance stated concern with the pilot language end date [Section 13(7)].

Based on the legal guidance the Department received and with support from the Vice-Chairperson of the SAC, Dr. Mukherji, and Chairperson Goldman, the language has been modified to address the concerns and has been included in the language under consideration for proposed action.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval ~~and OF THE INITIATION, EXPANSION, REPLACEMENT, RELOCATION, OR ACQUISITION OF CT SERVICES AND THE~~ delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve CT scanners.

~~(2) CT scanner is a covered clinical service for purposes of PURSUANT TO Part 222 of the Code. CT IS A COVERED CLINICAL SERVICE.~~

~~(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 21, and 22, as applicable, THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

(4) ~~The Department shall use sections 19 and 20, as applicable, in applying AND~~ Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of an existing CT scanner service" means obtaining possession or control of an existing fixed or mobile CT scanner service or existing CT scanner(s) by contract, ownership, or other comparable arrangement. For proposed projects involving mobile CT scanners, this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit, and performed in Michigan.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

(e) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(g) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(h) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 21.

(i) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators

53 used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-
54 operative guidance tomographic units.

55 (j) "CT scanner services" means the con-approved utilization of a CT scanner(s) at one site in the
56 case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

57 (k) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures
58 are performed on patients under 18 years of age.

59 (l) "Dental CT examinations" means use of a CT scanner specially designed to generate CT images
60 to facilitate dental procedures.

61 (m) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or
62 maxillary surgical procedures, or temporal mandibular joint evaluations.

63 (n) "Department" means the Michigan Department of Community Health (MDCH).

64 (o) "Emergency room" means a designated area physically part of a licensed hospital and
65 recognized by the Department as having met the staffing and equipment requirements for the treatment
66 of emergency patients.

67 (p) "EXCESS CT EQUIVALENTS" MEANS THE NUMBER OF CT EQUIVALENTS PERFORMED
68 BY AN EXISTING CT SCANNER SERVICE IN EXCESS OF 10,000 PER FIXED CT SCANNER AND
69 4,500 PER MOBILE CT SCANNER OR EITHER AN EXISTING FIXED OR MOBILE CT SCANNER
70 SERVICE, THE NUMBER OF CT SCANNERS USED TO COMPUTE EXCESS CT EQUIVALENTS
71 SHALL INCLUDE BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CT SCANNERS.
72 IN THE CASE OF A CT SCANNER SERVICE THAT OPERATES OR HAS A VALID CON TO OPERATE
73 THAT HAS MORE THAN ONE FIXED CT SCANNER AT THE SAME SITE, THE TERM MEANS
74 NUMBER OF CT EQUIVALENTS IN EXCESS OF 10,000 MULTIPLIED BY THE NUMBER OF FIXED CT
75 SCANNERS AT THE SAME SITE. FOR EXAMPLE, IF A CT SCANNER SERVICE OPERATES, OR HAS
76 A VALID CON TO OPERATE, TWO FIXED CT SCANNERS AT THE SAME SITE, THE EXCESS CT
77 EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 20,000 (10,000 X 2) CT EQUIVALENTS. IN
78 THE CASE OF AN EXISTING MOBILE CT SCANNER SERVICE, THE TERM MEANS THE SUM OF
79 ALL CT EQUIVALENTS PERFORMED BY THE SAME MOBILE CT SCANNER SERVICE AT ALL OF
80 THE HOST SITES COMBINED THAT IS IN EXCESS OF 4,500. FOR EXAMPLE, IF A MOBILE CT
81 SCANNER SERVICE SERVES FIVE HOST SITES WITH 1 MOBILE CT SCANNER, THE TERM MEANS
82 THE SUM OF CT EQUIVALENTS FOR ALL FIVE HOST SITES COMBINED THAT IS IN EXCESS OF
83 4,500 CT EQUIVALENTS.

84 (Q) "Existing CT scanner service" means the utilization of a CON-approved and operational CT
85 scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a
86 mobile CT scanner service.

87 (qR) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
88 scanner services.

89 (rS) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and
90 transporting equipment operated by a central service coordinator serving two or more host sites.

91 (sT) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an
92 existing CT scanner service.

93 (tU) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or
94 posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

95 (V) "HEALTH SERVICE AREA" OR "HSA" MEANS THE GROUPS OF COUNTIES LISTED IN
96 SECTION 24.

97 (wW) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

98 (xX) "Hospital-based portable CT scanner OR PORTABLE CT SCANNER" means a CT scanner
99 capable of being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide
100 high-quality imaging of critically ill patients.

101 (wY) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner
102 services.

103 (xZ) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or
104 mobile, at a site that does not perform CT scans as of the date an application is submitted to the

105 Department. The term does not include the acquisition or relocation of an existing CT scanner service or
 106 the renewal of a lease.

107 (yZAA) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
 108 and 1396r-8 to 1396v.

109 (zBB) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as
 110 that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by
 111 the statistical policy office of the office of information and regulatory affairs of the United States office of
 112 management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

113 (aaCC) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as
 114 that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by
 115 the statistical policy office of the office of information and regulatory affairs of the United States office of
 116 management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

117 (bbDD) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a
 118 central service coordinator and which must serve two or more host facilities.

119 (eeEE) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is
 120 authorized to serve.

121 (ddFF) "Pediatric patient" means any patient less than 18 years of age.

122 (eeGG) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the
 123 existing site to a different site within the relocation zone.

124 (ffHH) "Relocate an existing CT scanner service" means a change in the geographic location of an
 125 existing fixed CT scanner service from an existing site to a different site.

126 (ggII) "Relocation zone," means a site that is within a 10-mile radius of a site at which an existing fixed
 127 CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan
 128 statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or
 129 micropolitan statistical area county.

130 (hhJJ) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that
 131 requires a change in the radiation safety certificate, proposed by an applicant which results in that
 132 applicant operating the same number of CT scanners before and after project completion, at the same
 133 geographic location.

134 (iiKK) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
 135 statistical areas as those terms are defined under the "standards for defining metropolitan and
 136 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
 137 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as
 138 shown in Appendix A.

139 (jjLL) "Sedated patient" means a patient that meets all of the following:

140 (i) Patient undergoes procedural sedation and whose level of consciousness is either moderate
 141 sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the
 142 American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care
 143 Organizations, or an equivalent definition.

144 (ii) Who requires observation by personnel, other than technical employees routinely assigned to the
 145 CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support
 146 (PALS).

147 (kkMM) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of
 148 the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
 149 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
 150 disorders, and other conditions that make the patient unable to comply with the positional requirements of
 151 the exam.

152
 153 (2) The definitions in Part 222 shall apply to these standards.

154
 155 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service**
 156 **other than a dental CT scanner service or hospital-based portable CT scanner service**
 157

158 Sec. 3. An applicant proposing to initiate a CT scanner service shall demonstrate each of the
 159 following, as applicable:

160 (1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the
 161 following:

162 (a) The proposed site is a hospital licensed under Part 215 of the Code.

163 (b) The hospital operates an emergency room that provides 24-hour emergency care services as
 164 authorized by the local medical control authority to receive ambulance runs.

165
 166 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
 167 proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT
 168 equivalents per year for the second 12-month period after beginning operation of the CT scanner.

169
 170 (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of
 171 at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the
 172 CT scanner.

173
 174 **Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner**
 175 **service**

176
 177 Sec. 4. An applicant proposing to initiate a dental CT scanner service shall demonstrate each of the
 178 following, as applicable:

179
 180 (1) An applicant is proposing a fixed CT scanner service for the sole purpose of performing dental
 181 CT examinations.

182
 183 (2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

184
 185 (3) An applicant proposing to initiate a dental CT scanner service, **OTHER THAN AN APPLICANT**
 186 **THAT IS PROPOSING A DENTAL CT SCANNER SERVICE IN HSA 8**, shall project an operating level of
 187 at least 200 dental CT examinations per year for the second 12-month period after beginning operation of
 188 the dental CT scanner.

189
 190 (4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g.,
 191 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by
 192 one of the following groups, as recognized by the Department: a dental radiology program in a certified
 193 dental school, an appropriate professional society, or a dental continuing education program accredited
 194 by the American Dental Association.

195
 196 (5) The applicant has demonstrated to the satisfaction of the Department that the dental CT
 197 examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s)
 198 trained and/or certified by one of the following groups, as recognized by the Department: a dental
 199 radiology program in a certified dental school, an appropriate professional society, or a dental continuing
 200 education program accredited by the American Dental Association.

201
 202 **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**
 203 **service other than a dental CT scanner service or hospital-based portable CT scanner service**
 204

205 Sec. 5. (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate
 206 that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 13
 207 and 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most
 208 recent continuous 12-month period preceding the applicant's request. In computing this average, the
 209 Department will divide the total number of CT equivalents performed by the applicant's total number of
 210 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

211
 212 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to
 213 Section 17 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed
 214 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent
 215 continuous 12-month period preceding the applicant's request. In computing this average, the
 216 Department will divide the total number of CT equivalents performed by the applicant's total number of
 217 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated
 218 pediatric CT scanners.

219
 220 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
 221 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500
 222 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
 223 applicant's request. In computing this average, the Department will divide the total number of CT
 224 equivalents performed by the applicant's total number of mobile CT scanners, including both operational
 225 and approved but not operational mobile CT scanners.

226
 227 **Section 6. Requirements for approval for applicants proposing to expand an existing dental CT**
 228 **scanner service**

229
 230 Sec. 6. An applicant proposing to expand an existing fixed dental CT scanner service shall
 231 demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300
 232 dental CT examinations per fixed dental CT scanner for the most recent continuous 12-month period
 233 preceding the applicant's request. In computing this average, the Department will divide the total number
 234 of dental CT examinations performed by the applicant's total number of fixed dental CT scanners,
 235 including both operational and approved but not operational fixed dental CT scanners.

236
 237 **Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner**
 238 **other than a dental CT scanner or hospital-based portable CT scanner**

239
 240 Sec. 7. An applicant proposing to replace an existing CT scanner shall demonstrate each of the
 241 following, as applicable:

242
 243 (1) An applicant, other than an applicant meeting all of the applicable requirements of subsection (a),
 244 (b) or (c) below, proposing to replace an existing fixed CT scanner shall demonstrate that the fixed CT
 245 scanner(s) performed at least an average of 7,500 CT equivalents per fixed CT scanner in the most
 246 recent 12-month period for which the Department has verifiable data.

247 (a) A hospital proposing to replace an existing CT scanner which is the only fixed CT scanner
 248 operated at that site by the hospital shall demonstrate each of the following:

249 (i) The proposed site is a hospital licensed under Part 215 of the Code.

250 (ii) The hospital operates an emergency room that provides 24-hour emergency care services as
 251 authorized by the local medical control authority to receive ambulance runs.

252 (iii) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

253 (b) An applicant proposing to replace an existing fixed CT scanner shall be exempt once from the
 254 volume requirements if the existing CT scanner demonstrates that it meets all of the following:

255 (i) The existing CT scanner has performed at least 5,000 CT equivalents in the most recent 12-
 256 month period for which the Department has verifiable data.

257 (ii) The existing CT scanner is fully depreciated according to generally accepted accounting
 258 principles.

259 (iii) The existing CT scanner has at one time met its minimum volume requirements.

260 (c) An applicant proposing to replace an existing fixed CT scanner on an academic medical center
 261 campus, at the same site, shall be exempt once, as of the effective date of the standards MAY 5, 2008,
 262 from the minimum volume requirements for replacement if the existing CT scanner is fully depreciated
 263 according to generally accepted accounting principles.

264 (D) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER HAVING A
 265 CONFIGURATION OF LESS THAN 16 MULTIDETECTOR ROWS SHALL BE EXEMPT ONCE, AS OF
 266 THE EFFECTIVE DATE OF THE STANDARDS, FROM THE MINIMUM VOLUME REQUIREMENTS
 267 FOR REPLACEMENT IF IT MEETS BOTH OF THE FOLLOWING:

268 (I) THE PROPOSED CT SCANNER TO BE OBTAINED WILL HAVE A CONFIGURATION OF
 269 SIXTEEN (16) OR MORE MULTIDETECTOR ROWS, AND

270 (ii) THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY
 271 ACCEPTED ACCOUNTING PRINCIPLES.

272
 273 (2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the
 274 mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile
 275 CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more
 276 than one mobile CT scanner for the same mobile CT scanner network, in the most recent 12-month
 277 period for which the department has verifiable data.

278
 279 (3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall
 280 demonstrate that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT
 281 equivalents per dedicated pediatric CT scanner in the most recent 12-month period for which the
 282 Department has verifiable data.

283
 284 (4) An applicant under this section shall demonstrate that the existing CT scanner(s) proposed to be
 285 replaced is fully depreciated according to generally accepted accounting principles, or, that the existing
 286 equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT
 287 scanner offers technological improvements which enhance quality of care, increase efficiency, and/or
 288 reduce operating costs and patient charges.

289
 290 **Section 8. Requirements for approval for applicants proposing to replace an existing dental CT**
 291 **scanner**

292
 293 Sec. 8. An applicant proposing to replace an existing dental CT scanner shall demonstrate each of the
 294 following:

295 (1) An applicant proposing to replace an existing fixed dental CT scanner shall demonstrate that the
 296 fixed dental CT scanner(s) performed at least an average of 200 dental CT examinations per fixed dental
 297 CT scanner in the most recent 12-month period for which the Department has verifiable data.

298
 299 (2) An applicant under this section shall demonstrate that the existing dental CT scanner(s)
 300 proposed to be replaced is fully depreciated according to generally accepted accounting principles, or,
 301 that the existing equipment clearly poses a threat to the safety of the public, or that the proposed
 302 replacement dental CT scanner offers technological improvements which enhance quality of care,
 303 increase efficiency, and/or reduce operating costs and patient charges.

304
 305 **Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner**
 306 **service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT**
 307 **scanner(s) or hospital-based portable CT scanner(s)**

308
 309 Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate
 310 that the proposed project meets all of the following:

311 (a) The existing fixed CT scanner service to be relocated has been in operation for at least 36
 312 months as of the date an application is submitted to the Department.

313 (b) The proposed new site is in the relocation zone.

314 (c) The requirements of sections 5 or 7, as applicable, have been met.

315 (d) The CT scanner service to be relocated performed at least an average of 7,500 CT equivalents
 316 per fixed scanner in the most recent 12-month period for which the Department has verifiable data.

317 (e) The applicant agrees to operate the CT scanner service in accordance with all applicable project
318 delivery requirements set forth in Section 19 of these standards.

319
320 (2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service shall
321 demonstrate that the proposed project meets all of the following:

322 (a) The existing CT scanner service from which the CT scanner(s) is to be relocated has been in
323 operation for at least 36 months as of the date an application is submitted to the Department.

324 (b) The proposed new site is in the relocation zone.

325 (c) The requirements of sections 5 or 7, as applicable, have been met.

326 (d) Each existing CT scanner at the service from which a scanner is to be relocated performed at
327 least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which
328 the Department has verifiable data.

329 (e) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all
330 applicable project delivery requirements set forth in Section 19 of these standards.

331
332 **Section 10. Requirements for approval for applicants proposing to relocate an existing dental CT**
333 **scanner service and/or dental CT scanner(s)**

334
335 Sec. 10. (1) An applicant proposing to relocate an existing fixed dental CT scanner service shall
336 demonstrate that the proposed project meets all of the following:

337 (a) The existing fixed dental CT scanner service to be relocated has been in operation for at least 36
338 month as of the date an application is submitted to the Department.

339 (b) The proposed new site is in the relocation zone.

340 (c) The requirements of sections 6 or 8, as applicable, have been met.

341 (d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT
342 examinations per fixed dental CT scanner in the most recent 12-month period for which the Department
343 has verifiable data.

344 (e) The applicant agrees to operate the dental CT scanner service in accordance with all applicable
345 project delivery requirements set forth in Section 19 of these standards.

346
347 (2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner
348 service shall demonstrate that the proposed project meets all of the following:

349 (a) The existing dental CT scanner service from which the dental CT scanner(s) is to be relocated
350 has been in operation for at least 36 months as of the date an application is submitted to the Department.

351 (b) The proposed new site is in the relocation zone.

352 (c) The requirements of sections 6 or 8, as applicable have been met.

353 (d) Each existing dental CT scanner at the service from which a scanner is to be relocated
354 performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most
355 recent 12-month period for which the Department has verifiable data.

356 (e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with
357 all applicable project delivery requirements set forth in Section 19 of these standards.

358
359 **Section 11. Requirements for approval for applicants proposing to acquire an existing CT**
360 **scanner service or an existing CT scanner(s) other than an existing dental CT scanner service**
361 **and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)**

362
363 Sec. 11. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service shall
364 demonstrate that a proposed project meets all of the following:

365 (a) The requirements of sections 5, 7, or 9, as applicable, have been met.

366 (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner
367 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service
368 to be acquired shall not be required to be in compliance with the volume requirement applicable to the
369 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the

370 applicable volume requirements set forth in Section 19 of these standards in the second 12 months after
 371 the date the service is acquired, and annually thereafter.

372 (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an
 373 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least
 374 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.

375
 376 (2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or
 377 mobile CT scanner service shall demonstrate that the proposed project meets all of the following:

378 (a) The requirements of sections 5, 7 or 9, as applicable, have been met.

379 (b) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an
 380 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate that the fixed
 381 or mobile CT scanner(s) to be acquired performed at least 7,500 CT equivalents in the most recent 12-
 382 month period for which the Department has verifiable data.

383

384 **Section 12. Requirements for approval for applicants proposing to acquire an existing dental CT**
 385 **scanner service or an existing dental CT scanner(s)**

386

387 Sec. 12. (1) An applicant proposing to acquire an existing fixed dental CT scanner service shall
 388 demonstrate that a proposed project meets all of the following:

389 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.

390 (b) For an application for the proposed first acquisition of an existing fixed dental CT scanner
 391 service, for which a final decision has not been issued after the effective date of these standards, an
 392 existing dental CT scanner service to be acquired shall not be required to be in compliance with the
 393 volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT
 394 scanner service shall be operating at the applicable volume requirements set forth in Section 19 of these
 395 standards in the second 12 months after the date the service is acquired, and annually thereafter.

396 (c) For any application for proposed acquisition of an existing fixed dental CT scanner service, an
 397 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least
 398 200 dental CT examinations in the most recent 12-month period, for which the Department has verifiable
 399 data.

400 (2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed
 401 dental CT scanner service shall demonstrate that the proposed project meets all of the following:

402 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.

403 (b) For any application for proposed acquisition of an existing fixed dental CT scanner(s) of an
 404 existing fixed dental CT scanner service, an applicant shall be required to demonstrate that the fixed
 405 dental CT scanner(s) to be acquired performed at least 200 dental CT examinations in the most recent
 406 12-month period for which the Department has verifiable data.

407

408 **Section 13. Pilot program requirements for approval of a hospital-based portable CT scanner for**
 409 **initiation, expansion, replacement, and acquisition**

410

411 Sec. 13. As a pilot program, an applicant proposing to initiate, expand, replace, or acquire a hospital-
 412 based portable CT scanner shall demonstrate that it meets all of the following:

413

414 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two
 415 hospital-based portable CT scanners.

416

417 (2) The proposed site is a hospital licensed under Part 215 of the Code.

418

419 (3) The hospital has been certified as a level I or level II trauma facility by the American College of
 420 **Surgeons, OR HAS PERFORMED >100 CRANIOTOMIES IN THE MOST RECENT 12- MONTH**
 421 **PERIOD VERIFIABLE BY THE DEPARTMENT.**

422

423 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all
 424 applicable project delivery requirements set forth in Section 19 of these standards.

425
 426 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.
 427

428 (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner
 429 to demonstrate need or to satisfy CT CON review standards requirements.
 430

431 (7) **THE COMMISSION MAY DECIDE TO HAVE THE REQUIREMENTS OF THE PILOT**
 432 **PROGRAM DESCRIBED IN THIS SECTION BECOME A PERMANENT PART OF THE CT SCANNER**
 433 **SERVICES STANDARDS. IF THE COMMISSION DOES NOT TAKE ACTION TO MAKE THE PILOT**
 434 **PROGRAM A PERMANENT PART OF THE STANDARDS, The-~~THE~~ provisions of Section 13, are aS**
 435 **part of a pilot program, approved by the CON Commission and shall ~~WILL~~ expire ON DECEMBER 31,**
 436 **2016 and be of no further force and effect AFTER DECEMBER 31, 2016. ANY APPLICANT SEEKING**
 437 **TO BE PART OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION MUST SUBMIT ITS**
 438 **APPLICATION ON OR BEFORE DECEMBER 1, 2013, and THESE PROVISIONS shall not be**
 439 **applicable to any application which has not been submitted by ~~October~~ DECEMBER 1, 20082013.**
 440

441 **Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,** 442 **and acquisition**

443
 444 Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall
 445 demonstrate that it meets all of the following:
 446

447 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance
 448 with all applicable project delivery requirements as set forth in the CON review standards for PET.
 449

450 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project
 451 delivery requirements set forth in Section 19 of these standards.
 452

453 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.
 454

455 (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services
 456 and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid
 457 scanner to demonstrate need or to satisfy CT CON review standards requirements.
 458
 459

460 **Section 15. Additional requirements for approval of a mobile CT scanner service**

461
 462 Sec. 15. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall
 463 demonstrate that it meets all of the following:

464 (a) A separate CON application shall be submitted by the central service coordinator and each
 465 Michigan host facility.

466 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all
 467 potential contracts related to the mobile CT scanner service shall be included in the CON application
 468 submitted by the central service coordinator.

469 (c) The requirements of sections 3, 5, or 7, as applicable, have been met.
 470

471 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall
 472 demonstrate that it meets all of the following:

473 (a) Approval of the application will not result in an increase in the number of operating mobile CT
 474 scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.

475 (b) A separate CON application has been filed for each host facility.

476
 477 (3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner
 478 network shall demonstrate that approval of the application will not replace the CT scanner and
 479 transporting equipment unless the applicable requirements of Section 7 have been met.
 480

481 **Section 16. Requirements for approval of an applicant proposing a CT scanner used for the sole**
 482 **purpose of performing dental CT examinations exclusively for research**
 483

484 Sec. 16. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT
 485 examinations exclusively for research shall demonstrate each of the following:

486 (a) The applicant operates a dental radiology program in a certified dental school.
 487 (b) The research dental CT scanner shall operate under a protocol approved by the applicant's
 488 institutional review board.

489 (c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of
 490 approval in Section 19(4).
 491

492 (2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with
 493 the requirements of sections 4(2), 4(4) and 4(5).
 494

495 **Section 17. Requirements for approval of an applicant proposing to establish dedicated pediatric**
 496 **CT**
 497

498 Sec. 17. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the
 499 following:

500 (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges
 501 (excluding normal newborns) in the most recent year of operation.

502 (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most
 503 recent year of operation.

504 (c) The applicant shall have an active medical staff, at the time the application is submitted to the
 505 Department that includes, but is not limited to, physicians who are fellowship-trained in the following
 506 pediatric specialties:

- 507 (i) pediatric radiology (at least two)
- 508 (ii) pediatric anesthesiology
- 509 (iii) pediatric cardiology
- 510 (iv) pediatric critical care
- 511 (v) pediatric gastroenterology
- 512 (vi) pediatric hematology/oncology
- 513 (vii) pediatric neurology
- 514 (viii) pediatric neurosurgery
- 515 (ix) pediatric orthopedic surgery
- 516 (x) pediatric pathology
- 517 (xi) pediatric pulmonology
- 518 (xii) pediatric surgery
- 519 (xiii) neonatology

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

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

525
 526 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the
 527 requirements of Section 3 of these standards.
 528

529 **Section 18. Requirements for approval -- all applicants**
 530

531 Sec. 18. An applicant shall provide verification of Medicaid participation. An applicant that is a new
 532 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
 533 to the Department within six (6) months from the offering of services, if a CON is approved.
 534

535 **Section 19. Project delivery requirements -- terms of approval for all applicants**
 536

537 Sec. 19. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s)
 538 shall be delivered in compliance with the following terms of CON approval:

539 (a) Compliance with these standards

540 (b) Compliance with applicable safety and operating standards

541 (c) Compliance with the following quality assurance standards:

542 (i) The approved CT scanners shall be operating at the applicable required volumes within the time
 543 periods specified in these standards, and annually thereafter.

544 (ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so
 545 that:

546 (A) The screening of requests for CT procedures and interpretation of CT procedures will be
 547 performed by physicians with training and experience in the appropriate diagnostic use and interpretation
 548 of cross-sectional images of the anatomical region(s) to be examined, and

549 (B) The CT scanner is operated by physicians and/or is operated by radiological technologists
 550 qualified by training and experience to operate the CT scanner safely and effectively.

551 For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a
 552 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the
 553 screening of requests for and interpretations of CT procedures to be performed by physicians who are
 554 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional
 555 imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it
 556 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the
 557 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the
 558 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical
 559 Radiography Technologists (ARCRT). However, the applicant may submit and the Department may
 560 accept other evidence that the applicant has established a mechanism to assure that the CT scanner
 561 facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT
 562 scanner.

563 (iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of
 564 the operation of the CT scanner.

565 (iv) The applicant shall assure that at least one of the physicians responsible for the screening and
 566 interpretation as defined in subsection (ii)(A) will be in the CT facility or available on a 24-hour basis
 567 (either on-site or through telecommunication capabilities) to make the final interpretation.

568 (v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so
 569 authorized by the applicant to interpret initial scans will be on-site or available through telecommunication
 570 capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation
 571 of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A)
 572 within 24 hours.

573 (vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical
 574 emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other
 575 appropriate emergency interventions, and a physician on site in or immediately available to the CT
 576 scanner at all times when patients are undergoing scans.

577 (vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency
 578 patients.

579 (viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed
 580 practitioners.

581 (ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its
582 equivalent) requirement that provides for the medical and administrative control of the ordering and
583 utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.
584 These responsibilities may be assigned to an existing body of the applicant, as appropriate.

585 (x) An applicant approved under Section 17 must be able to prove that all radiologists, technologists
586 and nursing staff working with CT patients have continuing education or in-service training on pediatric
587 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

588 (xi) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan
589 population, shall:

590 (A) not deny CT scanner services to any individual based on ability to pay or source of payment;

591 (B) provide CT scanning services to any individual based on the clinical indications of need for the
592 service; and

593 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
594 source provided annually.

595 Compliance with selective contracting requirements shall not be construed as a violation of this term.

596 (xii) The applicant shall participate in a data collection network established and administered by the
597 Department or its designee. The data may include, but is not limited to, annual budget and cost
598 information, operating schedules, through-put schedules, demographic and diagnostic information, the
599 volume of care provided to patients from all payor sources, and other data requested by the Department,
600 and approved by the Commission. The applicant shall provide the required data on a separate basis for
601 each separate and distinct site as required by the Department; in a format established by the Department;
602 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
603 review of appropriate records.

604 (xiii) Equipment to be replaced shall be removed from service.

605 (xiv) The applicant shall provide the Department with a notice stating the date the approved CT
606 scanner service is placed in operation and such notice shall be submitted to the Department consistent
607 with applicable statute and promulgated rules.

608 (xv) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
609 of operation and continue to participate annually thereafter.

610 (d) An applicant approved under Section 4 shall not be required to be in compliance with subsection
611 (c) but shall be in compliance with the following quality assurance standards:

612 (i) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month
613 period after beginning operation of the dental CT scanner and annually thereafter.

614 (ii) The CT scanner will be used for the sole purpose of dental CT examinations.

615 (iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g.,
616 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by
617 one of the following groups, as recognized by the Department: a dental radiology program in a certified
618 dental school, an appropriate professional society, or a dental continuing education program accredited
619 by the American Dental Association.

620 (iv) The applicant shall demonstrate to the satisfaction of the Department that the dental CT
621 examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained
622 and/or certified by one of the following groups, as recognized by the Department: a dental radiology
623 program in a certified dental school, an appropriate professional society, or a dental continuing education
624 program accredited by the American Dental Association.

625 (v) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the
626 dental CT examinations for performing dental procedures has had the appropriate training and/or
627 experience certified by one of the following groups, as recognized by the Department: a dental radiology
628 program in a certified dental school, an appropriate professional society, or a dental continuing education
629 program accredited by the American Dental Association.

630 (vi) The applicant, to assure that the dental CT scanner will be utilized by all segments of the
631 Michigan population, shall:

632 (A) not deny dental CT scanner services to any individual based on ability to pay or source of
633 payment;

634 (B) provide dental CT scanning services to any individual based on the clinical indications of need for
635 the service; and

636 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
637 source provided annually. Compliance with selective contracting requirements shall not be construed as
638 a violation of this term.

639 (vii) The applicant shall participate in a data collection network established and administered by the
640 Department or its designee. The data may include, but is not limited to, annual budget and cost
641 information, operating schedules, through-put schedules, demographic and diagnostic information, the
642 volume of care provided to patients from all payor sources, and other data requested by the Department,
643 and approved by the Commission. The applicant shall provide the required data on a separate basis for
644 each separate and distinct site as required by the Department; in a format established by the Department;
645 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
646 review of appropriate records.

647 (viii) Equipment to be replaced shall be removed from service.

648 (ix) The applicant shall provide the Department with a notice stating the date the approved dental CT
649 scanner service is placed in operation and such notice shall be submitted to the Department consistent
650 with applicable statute and promulgated rules.

651 (x) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
652 of operation and continue to participate annually thereafter.

653

654 (2) The agreements and assurances required by this section shall be in the form of a certification
655 agreed to by the applicant or its authorized agent.

656

657 (3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
658 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

659

660 (4) An applicant for a CT scanner used for dental research under Section 16(1) shall agree that the
661 services provided by the CT scanner approved pursuant to Section 16(1) shall be delivered in compliance
662 with the following terms of CON approval:

663 (a) The capital and operating costs relating to the CT scanner used for dental research pursuant to
664 Section 16(1) shall be charged only to a specific research account(s) and not to any patient or third-party
665 payor.

666 (b) The CT scanner used for dental research approved pursuant to Section 16(1) shall not be used
667 for any purposes other than as approved by the institutional review board unless the applicant has
668 obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section
669 16.

670

671 (5) An applicant approved under Section 13 shall be in compliance with the following:

672 (A) PORTABLE CT SCANNER CAN ONLY BE USED IN ADULT OR PEDIATRIC INTENSIVE CARE
673 UNITS (ICU) BY QUALIFYING PILOT PROGRAM INSTITUTIONS AND MUST BE LIMITED TO BRAIN
674 SCANNING OF THOSE PATIENTS WHO ARE BEING TREATED IN AN ICU. —

675 _(aB) The APPROVED applicant agrees to MUST provide quarterly-ANNUAL reports to the Department
676 within one month following the end of each calendar quarter, starting with the quarter the applicant
677 initiates use of the hospital-based portable CT scanner BY JANUARY 31ST OF EACH YEAR FOR THE
678 PRECEDING CALENDAR YEAR;-. THIS REQUIREMENT APPLIES TO ALL APPLICANTS APPROVED
679 UNDER SECTION 13 AND BEGINS WITH 2010 DATA WHICH IS TO BE REPORTED IN 2011.

680 (C) THE FOLLOWING DATA MUST BE REPORTED TO THE DEPARTMENT:

681 (b) The Department will develop a questionnaire to be used by the applicant for the quarterly report.
682 This questionnaire, at a minimum, will include information regarding the utilization, cost, and benefit for
683 patient care as compared to the use of full-body CT scanners. NUMBER OF ADULT STUDIES
684 (AGE >= 18)

685 (II) NUMBER OF PEDIATRIC STUDIES (AGE < 18)

686 (III) NUMBER OF STUDIES PERFORMED USING A PORTABLE CT ON THE SAME PATIENT
687 WHILE THAT PATIENT IS IN AN ICU

688 (IV) NUMBER OF PATIENTS SCANNED ON A PORTABLE CT THAT UNDERWENT SUBSEQUENT
689 SCANNING ON A FIXED CT WITHIN 12 HOURS OF THE PORTABLE CT SCAN

690 (c) The Department will summarize the information from the quarterly reports and provide an
691 assessment to the Commission prior to the March 2010 Commission meeting. The Commission may
692 request updates on the status of the pilot program at its discretion.

693
694 **Section 20. Project delivery requirements -- additional terms of approval for applicants involving**
695 **mobile CT scanners**

696
697 Sec. 20. (1) In addition to the provisions of Section 19, an applicant for a mobile CT scanner shall
698 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
699 following terms of CON approval:

700 (a) A host facility shall submit only one CON application for a CT scanner for review at any given
701 time.

702 (b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community
703 Health prior to ending service with an existing host facility.

704 (c) A CON shall be required to add a host facility.

705 (d) A CON shall be required to change the central service coordinator.

706 (e) Each host facility must have at least one board certified or board eligible radiologist on its medical
707 staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion
708 protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

709 (f) Each mobile CT scanner service must have an Operations Committee with members
710 representing each host facility, the central service coordinator, and the central service medical director.
711 This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route
712 schedule, identify the process by which changes are to be made to the schedule, develop procedures for
713 handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a
714 quarterly basis.

715 (g) The central service coordinator shall arrange for emergency repair services to be available 24
716 hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition,
717 to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on
718 the CT scanner at least once each work day and routine maintenance services shall be provided on a
719 regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

720 (h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of
721 sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for
722 patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host
723 facility must also provide the capability for processing the film and maintaining the confidentiality of
724 patient records. A communication system must be provided between the mobile vehicle and each host
725 facility to provide for immediate notification of emergency medical situations.

726 (i) A mobile CT scanner service shall operate under a contractual agreement that includes the
727 provision of CT scanner services at each host facility on a regularly scheduled basis.

728 (j) The volume of utilization at each host facility shall be reported to the Department by the central
729 service coordinator under the terms of Section 19(1)(c)(xi).

730
731 (2) The agreements and assurances required by this section shall be in the form of a certification
732 agreed to by the applicant or its authorized agent.

733
734 **Section 21. Determination of CT Equivalents**

735
736 Sec. 21. CT equivalents shall be calculated as follows:

737 (a) Each billable procedure for the time period specified in the applicable section(s) of these
738 standards shall be assigned to a category set forth in Table 1.

739 (b) The number of billable procedures for each category in the time period specified in the applicable
740 section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to
741 determine the number of CT equivalents for that category for that time period.

742 (c) The number of CT equivalents for each category shall be summed to determine the total CT
743 equivalents for the time period specified in the applicable section(s) of these standards.

744 (d) The conversion factor for pediatric/special needs patients does not apply to procedures
745 performed on a dedicated pediatric CT scanner.

747 Table 1	Number of		Conversion		CT
748 Category	Billable CT		Factor		Equivalents
749	Procedures				
750					
751 Head Scans w/o Contrast	_____	X	1.00	=	_____
752 (includes dental CT examinations)					
753 Head Scans with Contrast	_____	X	1.25	=	_____
754 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
755 Body Scans w/o Contrast	_____	X	1.50	=	_____
756 Body Scans with Contrast	_____	X	1.75	=	_____
757 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
758					
759 Pediatric/Special Needs Patient					
760 Head scans w/o Contrast	_____	x	1.25	=	_____
761 (includes dental CT examinations)					
762 Pediatric/Special Needs Patient					
763 Head Scans with Contrast	_____	x	1.50	=	_____
764 Pediatric/Special Needs Patient					
765 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
766 Pediatric/Special Needs Patient					
767 Body Scans w/o Contrast	_____	x	1.75	=	_____
768 Pediatric/Special Needs Patient					
769 Body Scans with Contrast	_____	x	2.00	=	_____
770 Pediatric/Special Needs Patient					
771 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
772					
773 TOTAL CT EQUIVALENTS					_____

774

775 Section 22. Documentation of projections

776

777 Sec. 22. An applicant required to project volumes under sections 3, 4 and 5 shall demonstrate the
778 following, as applicable:

779 (1) An applicant required to project under Section 3 shall demonstrate that the projection is based on
780 historical physician referrals that resulted in an actual scan for the most recent 12-month period
781 immediately preceding the date of the application. Historical physician referrals will be verified with the
782 data maintained by the Department through its "Annual Hospital statistical survey" and/or "Annual
783 Freestanding Statistical Survey."

784

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

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

789 (b) the number of committed dental procedures performed by referring licensed dentists. Further,
790 the applicant and the referring licensed dentists shall substantiate the numbers through the submission of
791 HIPAA compliant billing records.

792

793 (3) An applicant required to project under Section 5 shall demonstrate that the projection is based on
794 historical utilization at the applicant's site for the most recent 12-month period immediately preceding the
795 date of the application.

796

797 (4) An applicant shall demonstrate that the projected number of referrals to be performed at the
 798 proposed site under subsections (1) and (2) are from an existing CT scanner service that is in compliance
 799 with the volume requirements applicable to that service, and will continue to be in compliance with the
 800 volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner
 801 service by an applicant. **ONLY EXCESS CT EQUIVALENTS EQUAL TO OR GREATER THAN WHAT IS**
 802 **BEING COMMITTED PURSUANT TO THIS SUBSECTION MAY BE USED TO DOCUMENT**
 803 **PROJECTIONS UNDER SUBSECTION (1).** In demonstrating compliance with this subsection, an
 804 applicant shall provide each of the following:

805 (a) A written commitment from each referring physician that he or she will refer at least the volume of
 806 CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to
 807 the initiation of the CT scanner service proposed by an applicant.

808 (b) The number of referrals committed must have resulted in an actual CT scan of the patient at the
 809 existing CT scanner service from which referral will be transferred. The committing physician must make
 810 available HIPAA compliant audit material if needed upon Department request to verify referral sources
 811 and outcomes. Commitments must be verified by the most recent data set maintained by the Department
 812 through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

813 (c) The projected referrals are from an existing ct scanner service within a 75-mile radius for rural
 814 and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.
 815

816 Section 23. Effect on prior CON review standards; comparative reviews

817
 818 Sec. 23. (1) These CON review standards supersede and replace the CON Review Standards for
 819 Computed Tomography Scanner Services approved by the CON Commission on **March 11 APRIL 30,**
 820 **2008 and effective ~~May 5~~ JUNE 20, 2008.**

821
 822 (2) Projects reviewed under these standards shall not be subject to comparative review.
 823

824 SECTION 24. HEALTH SERVICE AREAS

825
 826 **SEC. 24. COUNTIES ASSIGNED TO EACH OF THE HEALTH SERVICE AREAS ARE AS**
 827 **FOLLOWS:**

828 HSA	829 COUNTIES			
830	831 1 - SOUTHEAST	LIVINGSTON	MONROE	ST. CLAIR
832		MACOMB	OAKLAND	WASHTENAW
833		WAYNE		
834	835 2 - MID-SOUTHERN	CLINTON	HILLSDALE	JACKSON
836		EATON	INGHAM	LENAWEE
837	838 3 - SOUTHWEST	BARRY	CALHOUN	ST. JOSEPH
839		BERRIEN	CASS	VAN BUREN
840		BRANCH	KALAMAZOO	
841	842 4 - WEST	ALLEGAN	MASON	NEWAYGO
843		IONIA	MECOSTA	OCEANA
844		KENT	MONTCALM	OSCEOLA
845		LAKE	MUSKEGON	OTTAWA
846	847 5 - GLS	GENESEE	LAPEER	SHIAWASSEE
848	848 6 - EAST	ARENAC	HURON	ROSCOMMON
849		BAY	IOSCO	SAGINAW

850		CLARE	ISABELLA	SANILAC
851		GLADWIN	MIDLAND	TUSCOLA
852		GRATIOT	OGEMAW	
853				
854	7 - NORTHERN LOWER	ALCONA	CRAWFORD	MISSAUKEE
855		ALPENA	EMMET	MONTMORENCY
856		ANTRIM	GD TRAVERSE	OSCODA
857		BENZIE	KALKASKA	OTSEGO
858		CHARLEVOIX	LEELANAU	PRESQUE ISLE
859		CHEBOYGAN	MANISTEE	WEXFORD
860				
861	8 - UPPER PENINSULA	ALGER	GOGEBIC	MACKINAC
862		BARAGA	HOUGHTON	MARQUETTE
863		CHIPPEWA	IRON	MENOMINEE
864		DELTA	KEWEENAW	ONTONAGON
865		DICKINSON	LUCE	SCHOOLCRAFT

APPENDIX A

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**CON REVIEW STANDARDS
FOR CT SCANNER SERVICES**

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget



Improving the health of the people in our communities by
providing quality, compassionate care to everyone, every time

March 24, 2011

Mr. Edward B. Goldman, JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend, 7th Floor
Lansing, Michigan 48913

Re: CON Standards for CT Services

Dear Chairman Goldman,

I apologize for not being able to attend today's CON Commission meeting in person, and appreciate the opportunity to provide input regarding the CON Standards for CT Services. Sparrow Health System wants to first take this opportunity to commend the hard work and dedication of the members of the CT SAC and express our support for most of the proposed changes. However, in reviewing the proposed language posted on the CON website, I want to share with you my concern regarding the proposed modifications to the project delivery requirements for CT scanners approved under the pilot for hospital-based portable CT scanners (Section 13).

The project delivery requirements for the pilot program are located in Section 18(5) (page 13). Our concern is specifically with the requirement found on lines 672-674, limiting use of the portable CT to only adult or pediatric intensive care units. During the last revision to these standards the Commission approved a change to the definition of "CT scanner" to exempt CT scanners to be used in the OR for intraoperative imaging. Sparrow hospital is potentially interested in purchasing a portable CT to be used both in the OR for intraoperative CT or in the ICU to provide diagnostic images for patients too unstable to move. It would appear that the language in Section 18(5)(a) would prohibit us from purchasing one CT unit that could serve both functions.

Because Sparrow could clearly purchase two separate units and meet all CON requirements, we feel it is in the best interest of good public policy, to modify this language to make it clear that a facility who qualifies under the pilot could use that same scanner in the OR where a CON is not necessary in the first place. There is no reason to encourage facilities to purchase two CTs when one is sufficient to meet the needs of their patients and staff.

Sparrow Health System strongly supports the Certificate of Need program. I thank you for your time in considering my request and ask for your support.

Respectfully,

A handwritten signature in cursive script that reads 'Joy Szilagyi'.

Joy Szilagyi
Administrative Director, Radiology
Sparrow Hospital

1215 E. Michigan Avenue
P.O. Box 30480
Lansing, Michigan 48909-7980

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MEMORANDUM

Date: March 17, 2011
 To: Certificate of Need (CON) Commission
 From: Natalie Kellogg
 RE: March 24, 2011 Commission Meeting

This memo gives an overview of the highlights and the materials discussed at the Positron Emission Tomography (PET) meetings held February 24, 2011 and March 14, 2011.

I. PET Discussion Meeting

The Department publicly held PET discussion meetings on February 24 and March 12, 2011 to receive feedback regarding PET issues and the proposed streamlined process to revise the CON Review Standards for PET Services as requested by the CON Commission at the January 26, 2011 meeting.

A. Public Attendees:

Arlene Elliott, Arbor Advisors	Kathy Lash, University of Michigan
Steven Szelag, University of Michigan	Karen Loren, Detroit Medical Center
Todd Faasse, Spectrum Health	Robert Meeker, Spectrum Health
Karen Kippen, Henry Ford Health System	Sarah Laya, Lakeland Regional
Patricia Woodcroft, Children's Hospital of MI	Gary S. Gustafson, MI Rad Society
Cheryl Martin, Henry Ford Health System	Eric Fischer, Detroit Medical
Dennis McCafferty, Economic Alliance of MI	Andy Bau, Kheder Davis & Assoc
Jim Madison, MMP	Brian Madison, MMP
Marc Himmelsbaugh, Alliance Imaging	David Kondes, Alliance Imaging
Carrie Linderoth, Kelley Cawthorne	Melissa Cupp, Wiener Associates
Nancy List, Covenant Healthcare	Alice Pichan, Trinity Health
Susan Wyman, St. Joseph Mercy	K.C. Karvelis, Henry Ford Health System

II. Departmental Topics

The Department, based on testimony received from the public hearing held October 13, 2010, recommended the following topics for the PET Standards discussion.

- A. Weighting Methodology – The Department recommended simplifying the methodology that would require conversion of thresholds for expansion.
- B. Replacement/Upgrade of PET Scanner(s) – The Department recommended no volume requirements for replacement and no CON review for upgrade of PET scanner(s).
- C. Pediatric PET Scanner Service – The Department recommended allowing applicants to initiate a PET scanner service with a dedicated Pediatric PET scanner.
- D. Conversion of Host Site – The Department recommended allowing fixed PET scanner providers that also have mobile PET service to aggregate volume of both the fixed and mobile services in order to add additional fixed PET scanner units when volume for expansion is met.
- E. Project Delivery Requirements – The Department recommended streamlining the project delivery requirements to assure each requirement can be objectively measured and achieves program goals (cost, quality and access) without overwhelming providers.
- F. PEM language – The Department recommended developing requirements for Positron Emission Mammography (PEM) scanner services.

III. Provider Topics

In addition to the Department's recommended topics, the external participants in the discussion meetings, including direct providers, payers, and consultants, brought up additional topics for consideration including, but not limited to, the need for a weighted methodology to account for variances in scan types, techniques and complexity (such as using broader categories based on CPT codes), the ability to use dedicated research scanners on a limited basis for non-research related scans, a review of changing the initiation requirements from PET data units to a scan-type methodology, and identified possible requirements for PEM scanner services.

IV. PET Discussion(s) Outcome

The Department recommends that it continue reviewing the standards, as there are two topics left to tackle; exploring weighted methodology and requirements for PEM scanner services, including accreditation requirements. Based on the positive discussions with external providers at the two meetings, the Department will continue its work drafting language with continued input from external providers and experts as it works through the remaining two topics listed above. It is the Department's intent to present the Commission with proposed PET language at the June 9, 2011 Commission meeting.

Introduction

The CON Commission approved MRI Standards on September 10, 2009; they became effective November 5, 2009. Those standards included language focusing specifically on an intraoperative magnetic resonance imaging (iMRI) pilot program (expiring December 31, 2010) to address this emerging neurotechnology. iMRI is mainly used to support delicate brain surgery.

iMRI has emerged as a technology that provides real-time assessment of the extent of tumor removal and enables the surgeon to plan a surgical approach avoiding critical structures and the problem of brain shift.

The types of brain surgery for which iMRI is most useful are:

- Tumors located close to areas of important brain function
- Pituitary tumors and other masses along the skull base
- Epilepsy surgery
- Functional neurosurgery targeting precise locations – e.g., placement of electrodes for deep brain stimulation to treat movement disorders

Currently, Henry Ford and Harper Hospital are the only facilities that have been approved to initiate a hospital based iMRI. In 2004, Harper Hospital was approved to operate, for dedicated research purposes, an iMRI within the Department of Neurological Surgery. Henry Ford's operating room was built in 2008 and was updated in 2010 with the iMRI. Although there is still a lack of Michigan specific data, a study conducted by the University of Minnesota showed that by using an iMRI, neurosurgeons are able to find and remove more of the tumor in 25 to 30 percent of cases, thus reducing the need for a second surgery in patients with brain tumors. (ref: Wallenta, Laura. "A Grand Surgical Benchmark Surpassed." Academic Health Center, University of Minnesota, 2011. <http://www.ahc.umn.edu/patients/i-mri/index.htm>.) Minnesota does not have a CON program, but iMRI services are available in the state.

Survey of other states:

The Department conducted a survey of other states. Of the 16 responses received, Massachusetts, Mississippi, Tennessee, and Virginia are the four states that have and regulate iMRIs. Massachusetts has two (2) iMRIs located within academic centers, Mississippi has one (1) iMRI located within an academic center, Tennessee has two (2) iMRIs located within community hospitals, and Virginia has one (1) iMRI located within a community hospital. In all cases, the determination of need was made on a case by case basis. The states that responded to our survey were Arkansas, Florida, Louisiana, Massachusetts, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, Oregon, South Carolina, Tennessee, Virginia, Washington, West Virginia, and Wisconsin.

Costs:

The three applicants from the iMRI pilot show the following project costs as reported to the Department:

1. Henry Ford Health System \$743,875 - Philips Diamond Select Achieva 1.5 T fixed (currently operating)
2. Spectrum Health Hospitals \$6.893 million - IMRISneuro 3T-OR-DR (recently approved)
3. University of Michigan Health System \$5.6 million - IMRISneuro MR 1.5 Imaging System (recently approved)
4. Harper University \$896,000- PoleStar N-10 0.15 (research approved 2004)

The costs vary among health systems based on the type of equipment that is being purchased.

Benefits:

- Reduction in lengths of stay.
- Reduction of repeat resection rates.

- Reduction in hospital charges and costs.
- Reduction of complications.
- Improvements in surgical outcomes.
- Helps clinician confidence of all surgeries performed.

Drawbacks:

- iMRI systems can be very expensive, and there is no additional reimbursement for procedures under iMRI.
- iMRI can add up to 90 minutes to operating time depending on type of scans used.
- There is a lack of long-term data on iMRIs that raises questions about durability of clinical outcomes.
- The potential market demand for surgeries requiring iMRI assistance is limited.

Conclusion:

The intraoperative use of MRI in neurosurgery has matured, but applications and protocols for iMRI are still in development. Currently, in Michigan, there are two approved applications which were received prior to the December 31, 2010 expiration date of the pilot for hospital based iMRIs. Although iMRI is burdened by the necessity of specialized operating suites, instrumentation, and prolonged anaesthesia time which increases the overall cost of using this modality, the benefits outweigh the cost. iMRI applications are dominated by neurosurgery and suited for specialized neurosurgery facilities that focus on very complex adult cancers or large pediatric hospitals, reducing prospective overutilization. A recent scan of the Michigan Inpatient Data Base (2009) identifies at least two facilities that could qualify for this technology.

The next review for the MRI standards is in 2012. At the Commission's December 15, 2010 meeting, the Commission asked the Department to review and determine if anything needed to be done prior to 2012 related to the iMRI pilot. Since the application period for new iMRIs under the pilot has expired, no new applications can be filed. Based on the data and sources reviewed, the Department recommends that the requirements under the pilot language be made a permanent part of the standards at this time given that iMRI is a logical, progression in image-guided neurosurgery and that selected surgery and patient outcomes are improved by the use of this technology.

MEMORANDUM

Date: March 1, 2011
 To: Certificate of Need (CON) Commission
 From: Natalie Kellogg
 RE: March 24, 2011 Commission Meeting

This memo gives an overview of the highlights and the materials discussed at the Megavoltage Radiation Therapy (MRT) meeting held February 24, 2011.

I. MRT Discussion Meeting

The Department publicly held an MRT discussion meeting on February 24, 2011 to receive feedback regarding MRT issues and the proposed streamlined process to revise the MRT Standards as requested by the CON Commission at the January 26, 2011 meeting.

A. Public Attendees:

Arlene Elliott, Arbor Advisors	Kathy Lash, University of Michigan
Steven Szelag, University of Michigan	Karen Loren, Detroit Medical Center
Saraja Samuel, Detroit Medical Center	Robert Meeker, Spectrum Health
Karen Kippen, Henry Ford Health System	Walter M. Sahjidak, MSTRO
Jeffrey Forman, 21 st Century Oncology	Gary S. Gustafson, MI Rad Society
Paul Chuba, St. John's Health System Center/VG	Eric Fischer, Detroit Medical
Dennis McCafferty, Economic Alliance of MI	Andy Bau, Kheder Davis & Assoc
Dan Hollerud, Beaumont	Sal Jafar, St. Joseph Health System
Tewfik Bichay, Trinity Health	Walt Wheeler, WWA
Linda A. Filipczak, 21 st Century Oncology	Sarah Laya, Lakeland
Carrie Linderoth, Kelley Cawthorne	Melissa Cupp, Wiener Associates

II. Departmental Topics

The Department, based on testimony received from the public hearing held October 13, 2010, recommended the following topics for the MRT Standards discussion.

- A. Weighting Methodology - The Department recommended simplifying the methodology.
- B. Replacement/ Upgrade of MRT Units - The Department recommended no volume requirements for replacement and no CON review for upgrade of MRT units.
- C. Project Delivery Requirements - The Department recommended streamlining the project delivery requirements to assure each requirement can be objectively measured and achieves program goals (cost, quality and access) without overwhelming providers.

III. Provider Topics

In addition to the Department's recommended topics, the external participants in the discussion meeting, including direct providers, payers, and consultants, brought up the following topics for discussion.

- A. IGRT & IMRT Definition & Weighting Changes - The discussion centered on adding IGRT to the IMRT definition and create a weight distinction for this procedure, with a clinical emphasis that the two procedures should go hand-in-hand to treat a patient successfully. The counter argument is that some providers do not perform IGRT with IMRT sessions and that session times vary between clinicians.

The group's feedback deferred responsibility to the Department for further clarification of the definition and possible weighting revisions in consultation with expert clinicians.

- B. Gating Treatments - The discussion centered on the growing trend and prevalence of gating techniques during MRT treatments.

The group's feedback deferred review of respiratory gating to a later date as it needs further review. The Department was in agreement, to accept this recommendation of deferment, based on the testimony and discussion of the clinician(s) present.

- C. Smaller Proton-Beam Equipment - The discussion centered on the idea that this technology may become more common as equipment becomes cheaper. Currently within the MRT standards language already exists for initiation of units, such as Proton Beam Therapy (PBT) units, as well as weights for these units.

The group's feedback was that this is not an issue that needs to be addressed at this time. The current standards address high MRT (HMRT) equipment and weight values.

- D. A la Carte Language - The discussion centered on geographical expansion and relocation of an existing MRT service. Most find it difficult to initiate a new MRT service because of the methodology, while existing providers can relocate a unit to a new area under a simpler expansion methodology.

The group's feedback deferred responsibility to the Department for further evaluation of this provision, with regards to access to care. The Department will explore drafting a provision that limits use and focuses on improving access to care to under-served areas.

- E. Review of Stereotactic Radiosurgery and Radiotherapy Definition - The discussion centered on the assurance that the definition(s) of radiosurgery and radiotherapy accurately describe the treatment procedure(s) that is being performed, and if providers are improperly attaining added weights when performing one procedure or the other.

The group's feedback deferred responsibility to the Department for further clarification of the definition and possible weighting revisions.

- F. Clarify Cancer Data Commitments - The discussion centered on limiting cases to be committed to those only from hospitals with cancer programs.

The group's feedback deferred responsibility to the Department for further clarification to better define the sources for which projections can be calculated.

- G. Review current methodology in additional weighting for pediatrics and isocenters - The discussion centered on the appropriateness of the current weights as well as additional weighting due to the complexity of pediatric and other treatment procedures.

The group's feedback was that the current methodology and identified weights are appropriate, with some review of IMRT related to IGRT and stereotatic radio-surgery and radio-therapy (mostly how they are defined and counted in the current methodology).

IV. MRT Discussion Outcome

- A. Based on the discussion heard, the Department feels that the MRT Standards do not require formation of a workgroup or a Standard Advisory Committee to address the above referenced topics. The Department recommends that it continue with the review of the standards and holding MRT Standards presentation and Question/Answer Sessions as necessary as it works through the identified topics listed above. It is the Departments intent to present the Commission with proposed MRT language at the June 9, 2011 Commission meeting.

CERTIFICATE OF NEED
1st Quarter Program Activity Report to the CON Commission
 October 1, 2010 through September 30, 2011 (FY 2011)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	112	N/A	112	N/A
Letters of Intent Processed within 15 days	112	100%	112	100%
Letters of Intent Processed Online	111	99%	111	99%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	78	N/A	78	N/A
Applications Processed within 15 Days	77	99%	77	99%
Applications Incomplete/More Information Needed	15	19%	15	19%
Applications Filed Online*	71	97%	71	97%
Application Fees Received Online*	31	40%	31	40%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	52	100%	52	100%
Substantive Applications	28	100%	28	100%
Comparative Applications	9	100%	9	100%

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	1	N/A	1	N/A
Decisions Issued within 10 workings Days	1	100%	1	100%

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	22	100%	22	100%

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	22	N/A	22	N/A
FOIA Requests Processed on Time	22	100%	22	100%
Number of Applications Viewed Onsite	3	N/A	3	N/A

FOIA – Freedom of Information Act.

CERTIFICATE OF NEED
1st Quarter Compliance Report to the CON Commission
 October 1, 2010 through September 30, 2011 (FY 2011)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

- (a) Revoke or suspend the certificate of need.*
- (b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.*
- (c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.*
- (d) Request enforcement action under section 22253.*
- (e) Take any other enforcement action authorized by this code.*
- (f) Publicize or report the violation or enforcement action, or both, to any person.*
- (g) Take any other action as determined appropriate by the department.*

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	1 st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	58	58
Approved projects contacted on or before anniversary date	36	36
Approved projects completed on or before 1-year follow up	62%	62%
CON approvals expired due to noncompliance with Part 222	12	12
Total follow up correspondence sent	142	142
Total approved projects still ongoing	298	

Compliance: The Evaluation Section has resolved all four (4) non-compliance investigations related to open heart surgical, surgical, and CT scanner services. Three (3) of the four investigations have been resolved with compliance agreements and monetary penalties.

CERTIFICATE OF NEED LEGAL ACTION
(03.17.11)

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<p><i>Livingston County - Compare Group # 95-0206</i></p> <p><u>INCLUDES:</u> Howell Health Campus CON App# 10-0148</p> <p>Medilodge of Howell CON App# 10-0147</p>	<p>01/07/11</p>	<p>Livingston County – Comparative Review of nursing home beds – Administrative Appeal. The two applicants are: (1) Howell Health Campus (Petitioner) and (2) Medilodge of Howell.</p>	<p>Medilodge of Howell filed a Motion to Dismiss. On March 8, 2011, the ALJ held a preliminary hearing. The ALJ will rule on the Motion following briefing.</p>

CON Leg Action; report 03.17.11

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2010												2011											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Cardiac Catheterization Services**			•	•	•	•	•	•	•	PH	■	■	■	■	■	■	■	•R—	•	•P	•▲F			
Computed Tomography (CT) Scanner Services**	•R	•	•	•			■	■	■	■	■	■	■	•	—	•	•P	•▲F						
Hospital Beds and Addendum for HIV Infected Individuals										PH•	•	•	•R	•S	•	•	■	■	■	■	■	■	■	—
Magnetic Resonance Imaging (MRI) Services									•R—	P•	•	•▲F	•	•	•R	•	•	•R—	•	•P	•▲F			
Megavoltage Radiation Therapy (MRT) Services/Units										PH	•	•	•R	•	•R									
Open Heart Surgery Services										PH	•	•	•R	Pending CCSAC										
Positron Emission Tomography (PET) Scanner Services										PH	•	•	•R	•	•R	•	•	•R—	•	•P	•▲F			
Surgical Services										PH	•	•	•R	•	•	•	•	•	•	•R—	•P	•	•▲F	
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																								
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

- KEY**
- - Receipt of proposed standards/documents, proposed Commission action
 - * - Commission meeting
 - - Staff work/Standard advisory committee meetings
 - ▲ - Consider Public/Legislative comment
 - ** - Current in-process standard advisory committee or Informal Workgroup
 - - Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
 - A - Commission Action
 - C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
 - D - Discussion
 - F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
 - M - Monitor service or new technology for changes
 - P - Commission public hearing/Legislative comment period
 - PH - Public Hearing for initial comments on review standards
 - R - Receipt of report
 - S - Solicit nominations for standard advisory committee or standing committee membership

For Approval March 24, 2011

Updated March 16, 2011

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy & Regulation Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	August 12, 2010	2013
Bone Marrow Transplantation Services	December 3, 2010	2012
Cardiac Catheterization Services	February 25, 2008	2014
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2014
Magnetic Resonance Imaging (MRI) Services	March 11, 2011	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	2014
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2013
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2013
Open Heart Surgery Services	February 25, 2008	2014
Pancreas Transplantation Services	November 5, 2009	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2014
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	2014
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2013

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.