

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 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 Part 222 of the Code.

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

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

- (k) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures are performed on patients under 18 years of age.
- (l) "Dental CT examinations" means use of a CT scanner specially designed to generate CT images to facilitate dental procedures.
- (m) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.
- (n) "Department" means the Michigan Department of Community Health (MDCH).
- (o) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.
- (p) "Existing CT scanner service" means the utilization of a CON-approved and operational CT scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.
- (q) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT scanner services.
- (r) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and transporting equipment operated by a central service coordinator serving two or more host sites.
- (s) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an existing CT scanner service.
- (t) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.
- (u) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.
- (v) "Hospital-based portable CT scanner" means a CT scanner capable of being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality imaging of critically ill patients.
- (w) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner services.
- (x) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or relocation of an existing CT scanner service or the renewal of a lease.
- (y) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.
- (z) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- (aa) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- (bb) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.
- (cc) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.
- (dd) "Pediatric patient" means any patient less than 18 years of age.
- (ee) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the existing site to a different site within the relocation zone.
- (ff) "Relocate an existing CT scanner service" means a change in the geographic location of an existing fixed CT scanner service from an existing site to a different site.
- (gg) "Relocation zone," means a site that is within a 10-mile radius of a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan

statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner service

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

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

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

(3) An applicant proposing to initiate a dental CT scanner service shall project an operating level of at least 200 dental CT examinations per year for the second 12-month period after beginning operation of the dental CT scanner.

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

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

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

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

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

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

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

Sec. 6. An applicant proposing to expand an existing fixed dental CT scanner service shall demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300 dental CT examinations per fixed dental CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number

of dental CT examinations performed by the applicant's total number of fixed dental CT scanners, including both operational and approved but not operational fixed dental CT scanners.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8. Requirements for approval for applicants proposing to replace an existing dental CT scanner

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

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

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

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

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

- (a) The existing fixed CT scanner service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
- (b) The proposed new site is in the relocation zone.
- (c) The requirements of sections 5 or 7, as applicable, have been met.
- (d) The CT scanner service to be relocated performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.
- (e) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.

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

- (a) The existing CT scanner service from which the CT scanner(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
- (b) The proposed new site is in the relocation zone.
- (c) The requirements of sections 5 or 7, as applicable, have been met.
- (d) Each existing CT scanner at the service from which a scanner is to be relocated performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.
- (e) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.

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

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

- (a) The existing fixed dental CT scanner service to be relocated has been in operation for at least 36 month as of the date an application is submitted to the Department.
- (b) The proposed new site is in the relocation zone.
- (c) The requirements of sections 6 or 8, as applicable, have been met.
- (d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.
- (e) The applicant agrees to operate the dental CT scanner service in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.

- (2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner service shall demonstrate that the proposed project meets all of the following:
- (a) The existing dental CT scanner service from which the dental CT scanner(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
 - (b) The proposed new site is in the relocation zone.
 - (c) The requirements of sections 6 or 8, as applicable have been met.
 - (d) Each existing dental CT scanner at the service from which a scanner is to be relocated performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.
 - (e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.

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

- Sec. 11. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service shall demonstrate that a proposed project meets all of the following:
- (a) The requirements of sections 5, 7, or 9, as applicable, have been met.
 - (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the applicable volume requirements set forth in Section 19 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.
 - (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.
- (2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or mobile CT scanner service shall demonstrate that the proposed project meets all of the following:
- (a) The requirements of sections 5, 7 or 9, as applicable, have been met.
 - (b) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate that the fixed or mobile CT scanner(s) to be acquired performed at least 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.

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

- Sec. 12. (1) An applicant proposing to acquire an existing fixed dental CT scanner service shall demonstrate that a proposed project meets all of the following:
- (a) The requirements of sections 6, 8, or 10, as applicable, have been met.
 - (b) For an application for the proposed first acquisition of an existing fixed dental CT scanner service, for which a final decision has not been issued after the effective date of these standards, an existing dental CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT scanner service shall be operating at the applicable volume requirements set forth in Section 19 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.
 - (c) For any application for proposed acquisition of an existing fixed dental CT scanner service, an applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least 200 dental CT examinations in the most recent 12-month period, for which the Department has verifiable data.

- (2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed dental CT scanner service shall demonstrate that the proposed project meets all of the following:
- (a) The requirements of sections 6, 8, or 10, as applicable, have been met.
 - (b) For any application for proposed acquisition of an existing fixed dental CT scanner(s) of an existing fixed dental CT scanner service, an applicant shall be required to demonstrate that the fixed dental CT scanner(s) to be acquired performed at least 200 dental CT examinations in the most recent 12-month period for which the Department has verifiable data.

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

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

- (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two hospital-based portable CT scanners.
- (2) The proposed site is a hospital licensed under Part 215 of the Code.
- (3) The hospital has been certified as a level I or level II trauma facility by the American College of Surgeons.
- (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.
- (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.
- (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner to demonstrate need or to satisfy CT CON review standards requirements.
- (7) The provisions of Section 13 are part of a pilot program approved by the CON Commission and shall expire and be of no further force and effect, and shall not be applicable to any application which has not been submitted by October 1, 2008.

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

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

- (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.
- (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.
- (3) The approved PET/CT hybrid will not be subject to CT volume requirements.
- (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid scanner to demonstrate need or to satisfy CT CON review standards requirements.

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

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

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

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

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

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

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

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

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

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

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

(a) The applicant operates a dental radiology program in a certified dental school.

(b) The research dental CT scanner shall operate under a protocol approved by the applicant's institutional review board.

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

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

Section 17. Requirements for approval of an applicant proposing to establish dedicated pediatric CT

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

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

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

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

(i) pediatric radiology (at least two)

(ii) pediatric anesthesiology

(iii) pediatric cardiology

(iv) pediatric critical care

(v) pediatric gastroenterology

(vi) pediatric hematology/oncology

- (vii) pediatric neurology
- (viii) pediatric neurosurgery
- (ix) pediatric orthopedic surgery
- (x) pediatric pathology
- (xi) pediatric pulmonology
- (xii) pediatric surgery
- (xiii) neonatology
- (d) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:
 - (i) pediatric bone marrow transplant program
 - (ii) established pediatric sedation program
 - (iii) pediatric open heart program

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

Section 18. Requirements for approval -- all applicants

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

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

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

- (a) Compliance with these standards
- (b) Compliance with applicable safety and operating standards
- (c) Compliance with the following quality assurance standards:
 - (i) The approved CT scanners shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.
 - (ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified

dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The applicant agrees to provide quarterly reports to the Department within one month following the end of each calendar quarter, starting with the quarter the applicant initiates use of the hospital-based portable CT scanner.

(b) The Department will develop a questionnaire to be used by the applicant for the quarterly report. This questionnaire, at a minimum, will include information regarding the utilization, cost, and benefit for patient care as compared to the use of full-body CT scanners.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 21. Determination of CT Equivalents

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

- (a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.
- (b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.
- (c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.
- (d) The conversion factor for pediatric/special needs patients does not apply to procedures performed on a dedicated pediatric CT scanner.

Table 1 Category	Number of Billable CT Procedures		Conversion Factor	=	CT Equivalents
Head Scans w/o Contrast (includes dental CT examinations)	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
Pediatric/Special Needs Patient Head scans w/o Contrast (includes dental CT examinations)	_____	x	1.25	=	_____
Pediatric/Special Needs Patient Head Scans with Contrast	_____	x	1.50	=	_____
Pediatric/Special Needs Patient Head Scans w/o & with Contrast	_____	x	2.00	=	_____
Pediatric/Special Needs Patient Body Scans w/o Contrast	_____	x	1.75	=	_____
Pediatric/Special Needs Patient Body Scans with Contrast	_____	x	2.00	=	_____
Pediatric/Special Needs Patient Body Scans w/o & with Contrast	_____	x	3.00	=	_____
TOTAL CT EQUIVALENTS					_____

Section 22. Documentation of projections

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

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

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

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

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

(4) An applicant shall demonstrate that the projected number of referrals to be performed at the proposed site under subsections (1) and (2) are from an existing CT scanner service that is in compliance with the volume requirements applicable to that service, and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner service by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

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

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

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

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

Sec. 23. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on March 11, 2008 and effective May 5, 2008.

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

**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