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. These standards are requirements for the approval of the initiation, expansion, replacement, or acquisition of CT services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, CT is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws 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 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) “Bundled body scan” means two or more body scans billed as one CT procedure.

(e) "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.

(f) "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.

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

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

(i) “CT-angio hybrid unit” means an integrated system comprised of both CT and angiography equipment sited in the same room that is designed specifically for interventional radiology or cardiac procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing a CT-angio hybrid procedure and is in need of a secondary diagnostic study.

(j) "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 22.

(k) "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.

(l) "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.

(m) “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.

(n) “Dental CT examinations” means use of a CT scanner specially designed to generate CT images to facilitate dental procedures.

(o) “Dental procedures” means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.

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

(q) "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.

(r) “Excess CT Equivalents” means the number of CT equivalents performed by an existing CT scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT equivalents shall include both existing and approved but not yet operational CT scanners. In the case of a CT scanner service that operates or has a valid CON to operate that has more than one fixed CT scanner at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the number of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a valid CON to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number that is in excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner service, the term means the sum of all CT equivalents performed by the same mobile CT scanner service at all of the host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service serves five host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five host sites combined that is in excess of 4,500 CT equivalents.

(s) “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.

(t) “Existing CT scanner” means a CON-approved and operational CT scanner used to provide CT scanner services.

(u) “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.

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

(w) "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.

(x) "Health Service Area" or "HSA" means the groups of counties listed in Appendix A.

(y) “HIPAA” means the Health Insurance Portability and Accountability Act of 1996.

(z) “Hospital-based portable CT scanner or 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.

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

(bb) "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 replacement of an existing CT scanner service at the existing site or to a different site or the renewal of a lease.

(cc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

(dd) "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.

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

(ff) “Pediatric patient” means any patient less than 18 years of age.

(gg) "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. The term also includes relocating an existing CT scanner or CT scanner service from an existing site to a different site.

(hh) "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).

(ii) "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) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service

Sec. 3. An applicant proposing to initiate a CT scanner service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate 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.

(4) An applicant proposing to initiate CT scanner services as an existing host site on a different mobile CT scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

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

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

(1) An applicant is proposing a dental 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, other than an applicant that is proposing a dental CT scanner service in HSA 8, 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.

(6) An applicant proposing to initiate mobile dental CT scanner services as an existing host site on a different mobile dental CT scanner service shall demonstrate the following:
(a) The applicant provides a proposed route schedule.
(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner service

Sec. 5. An applicant proposing to expand an existing CT scanner service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(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 6, 13, 14, and 18, 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 18 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 or mobile 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 or mobile 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 or mobile dental CT scanners, including both operational and approved but not operational fixed or mobile dental CT scanners.

Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner

Sec. 7. An applicant proposing to replace an existing CT scanner or service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner shall demonstrate all of the following:

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

(b) 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.

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

(a) The existing fixed CT scanner service to be replaced 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 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.

(c) The CT scanner service to be replaced 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, except for an applicant that meets all of the requirements of Section 3(1).

(d) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) An applicant proposing to replace a fixed CT scanner(s) of an existing CT scanner service to a different site 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 replaced 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 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..

(c) Each existing CT scanner at the service from which a scanner is to be replaced 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.

(d) 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 20 of these standards.

(e) For volume purposes, the new site shall remain associated with the existing CT service for a minimum of three years.

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 or service shall demonstrate the following, as applicable:

(1) An applicant proposing to replace an existing fixed or mobile dental CT scanner shall demonstrate all of the following:

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

(b) 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.

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

(a) The existing fixed dental CT scanner service to be replaced 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 within a 10-mile radius of a site at which an existing fixed dental CT scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a rural or micropolitan statistical area county.

(c) The dental CT scanner service to be replaced 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.

(d) The applicant agrees to operate the dental CT scanner service in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) An applicant proposing to replace a fixed dental CT scanner(s) of an existing dental CT scanner service to a different site 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 replaced has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) For volume purposes, the new site shall remain associated with the existing CT service for a minimum of three years.

(c) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a rural or micropolitan statistical area county.

(d) Each existing dental CT scanner at the service from which a scanner is to be replaced 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 20 of these standards.

Section 9. Requirements for approval for applicants proposing to acquire an existing CT scanner service or an existing CT scanner(s)

Sec. 9. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(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) 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 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(b) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following, as applicable:

(i) The fixed CT scanner service to be acquired performed at least 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the Department has verifiable data, unless an applicant meets all of the requirements of Section 3(1).

(ii) The mobile CT scanner service to be acquired performed at least 3,500 CT equivalents per mobile CT scanner 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 the following:

(a) 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 the following, as applicable:

(i) The fixed CT scanner(s) to be acquired performed at least 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the department has verifiable data.

(ii) The mobile CT scanner(s) to be acquired performed at least 3,500 CT equivalents per mobile CT scanner in the most recent 12-month period for which the Department has verifiable data.

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

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

(a) For an application for the proposed first acquisition of an existing fixed or mobile 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 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(b) For any application for proposed acquisition of an existing fixed or mobile 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 per dental CT scanner 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 or mobile dental CT scanner service shall demonstrate that the proposed project meets the following:

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

Section 11. Requirements for a dedicated research fixed CT scanner

Sec. 11. An applicant proposing to add a fixed CT scanner to an existing CT scanner service for exclusive research use shall demonstrate the following:

(1) The applicant agrees that the dedicated research CT scanner will be used primarily (70% or more of the scans) for research purposes.

(2) The dedicated research CT scanner shall operate under a protocol approved by the applicant's Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

(3) The proposed site can have no more than three dedicated research fixed CT scanners approved under this section.

(4) The dedicated research scanner approved under this section may not utilize CT procedures performed on the dedicated CT scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 12. Requirements for approval of an applicant proposing a CT scanner used for the sole purpose of performing dental CT examinations exclusively for research

Sec. 12. (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 20(6).

(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 13. Requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition

Sec. 13. 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, or has performed >100 craniotomies in the most recent 12- month period verifiable by the Department.

(4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all applicable project delivery requirements set forth in Section 20 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.

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 20 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. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition

Sec. 15. An applicant proposing to initiate, replace, or acquire a hospital-based CT-angio hybrid unit shall demonstrate each of the following, as applicable to the proposed project:

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

(2) The proposed site has an existing fixed CT scanner service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site offers the following services:
(a) diagnostic cardiac catheterization; or
(b) interventional radiology; or
(c) surgical services

(4) The proposed CT-angio hybrid unit must be located in one of the following rooms:
(a) cardiac catheterization lab; or
(b) interventional radiology suite; or
(c) licensed operating room

(5) Diagnostic CT studies shall not be performed on a CT-angio hybrid unit approved under this section unless the patient is currently undergoing a CT-angio hybrid interventional procedure and is in need of a secondary diagnostic CT study.

(6) The approved CT-angio hybrid shall not be subject to CT volume requirements.

(7) The applicant shall not utilize the procedures performed on the CT-angio hybrid unit to demonstrate need or to satisfy CT CON review standards requirements.

Section 16. Additional requirements for approval of a mobile CT scanner service

Sec. 16. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:

(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.

(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 additional requirements:

(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.

Section 17. Additional requirements for approval of a mobile dental CT scanner service

Sec. 17. (1) An applicant proposing to initiate a mobile dental CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:

(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 dental CT scanner service shall be included in the CON application submitted by the central service coordinator.

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

(a) Approval of the application will not result in an increase in the number of operating mobile dental CT scanners for the mobile dental CT scanner network unless the requirements of Section 6 have been met.

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

Section 18. Requirements for approval of an applicant proposing to establish dedicated pediatric CT Scanner

Sec. 18. (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 19. Requirements for Medicaid participation

Sec. 19. 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 20. Project delivery requirements and terms of approval for all applicants

Sec. 20. An applicant shall agree that, if approved, the CT scanner(s) services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

(i) 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

(ii) 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 (a)(i), 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 (a)(i) 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.

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

(c) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (a)(i) 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.

(d) 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 (a)(i) within 24 hours.

(e) 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.

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

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

(h) 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.

(i) An applicant approved under Section 18 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.

(3) Compliance with the following access to care requirements:

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

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

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

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

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

(c) 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).

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

(4) Compliance with the following monitoring and reporting requirements:

(a) The approved CT scanners shall be operating at an average of 7,500 CT equivalents scanner per fixed scanner and 3,500 CT equivalents per mobile scanner per year for the second 12-month period after beginning operation of the CT scanner, and annually thereafter, except for those scanners exempt under applicable sections.

(b) 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.

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

(d) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(e) An applicant approved under Section 4 shall not be required to be in compliance with subsection (2).

(5) Compliance with the following dental CT scanner (fixed or mobile) requirements, if applicable:

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

(b) 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.

(c) 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.

(d) 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.

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

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

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

(iii) 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.

(f) 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.

(g) 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.

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

(i) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

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

(6) An applicant for a CT scanner used for dental research under Section 12(1) shall agree that the services provided by the CT scanner approved pursuant to Section 12(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 12(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 12(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 12.

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

(a) Portable CT scanner can only be used by a qualifying program for the following purposes:

(i) Brain scanning of patients being treated in an adult or pediatric Intensive Care Unit (ICU).

(ii) Non-diagnostic, intraoperative guidance in an operating room.

(b) The approved applicant must provide annual reports to the Department by January 31st of each year for the preceding calendar year. This requirement applies to all applicants approved under Section 13.

(c) The following data must be reported to the Department:

(i) Number of adult studies (age>=18)

(ii) Number of pediatric studies (age<18)

(iii) Number of studies performed using a portable CT on the same patient while that patient is in an ICU

(8) An applicant approved under Section 15 shall be in compliance with the following:

(a) The proposed site offers the following services:

(i) diagnostic cardiac catheterization; or

(ii) interventional radiology; or

(iii) surgical services

(b) The proposed CT-Angio hybrid unit must be located in one of the following rooms:

(i) cardiac catheterization lab; or

(ii) interventional radiology suite; or

(iii) licensed operating room

(9) 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. Project delivery requirements and additional terms of approval for applicants involving mobile CT scanners

Sec. 21. (1) In addition to the provisions of Section 20, 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 20(2)(i).

(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 22. Determination of CT Equivalents

Sec. 22. 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
<u>Adult Patient</u>					
Head Scans w/o Contrast	_____	X	1.00	=	_____
(includes dental CT examinations)					
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	=	_____
Bundled body Scan	_____	X	3.50	=	_____
<u>Pediatric/Special Needs Patient</u>					
Head scans w/o Contrast	_____	x	1.25	=	_____
(includes dental CT examinations)					
Head Scans with Contrast	_____	x	1.50	=	_____
Head Scans w/o & with Contrast	_____	x	2.00	=	_____
Body Scans w/o Contrast	_____	x	1.75	=	_____
Body Scans with Contrast	_____	x	2.00	=	_____
Body Scans w/o & with Contrast	_____	x	3.00	=	_____
Bundled body Scan	_____	X	4.00	=	_____
Total CT Equivalents					_____

Section 23. Documentation of projections

Sec. 23. An applicant required to project volumes under sections 3 and 4 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 shall demonstrate that the projected number of referrals to be performed at the proposed site under subsection (1) 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. This does not include dental CT scanners. Only excess CT equivalents equal to or greater than what is being committed pursuant to this subsection may be used to document projections under subsection (1). 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 24. Effect on prior CON review standards; comparative reviews

Sec. 24. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~December 15, 2011~~MARCH 18, 2014 and effective on ~~February 27, 2012~~JUNE 2, 2014.

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

APPENDIX A

Counties assigned to each of the health service areas are as follows:

HEALTH SERVICE AREA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

APPENDIX B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget