MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR BONE MARROW TRANSPLANTATION (BMT) 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 to initiate or acquire BMT services under Part 222 of the Code. BMT services are a covered clinical service pursuant to Part 222 of the Code. 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(C) of the Code, being Section 333.22225(2)(C) of the Michigan Compiled Laws.

(2) A BMT service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic BMT procedures.

(3) An existing BMT service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing BMT service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Adult" means an individual age 18 or older.

(b) "Allogeneic" means transplantation between genetically non-identical individuals of the same species.

(c) "Autologous" means transplantation in which the donor and recipient are the same individual.

(d) "Bone marrow transplantation service" or "BMT service" means the transplantation of proliferating hematopoietic ~~stem~~ cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source. THE TERM INCLUDES THE FOLLOWING CELLULAR THERAPY PRODUCTS: CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELLS, NATURAL KILLER (NK) CELLS, DENDRITIC CELLS, MESENCHYMAL CELLS, AND GENE THERAPY PRODUCTS DERIVED FROM HEMATOPOIETIC STEM CELLS WHEN USED TO TREAT A HEMOTOLOGICAL MALIGNANCY.

(e) "Cancer hospital" means a hospital that is a Comprehensive Cancer Center designated by the National Cancer Institute or operates a Comprehensive Cancer Center as an affiliate of a Michigan university that is designated as a Comprehensive Cancer Center by the National Cancer Institute.

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

(g) "Comparative group" means the applications that have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

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

(i) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (~~MDCH~~MDHHS).

(j) "Department inventory of BMT services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former

Part 221; (ii) operating BMT services for which the operation of that service did not require a CON; and (iii) BMT services that are not yet operational but have a valid CON issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the BMT service is authorized.

(k) "Existing BMT service," for purposes of Section 3(5) AND 3(11) of these standards, means any of the following: (i) a BMT service listed on the Department inventory, (ii) a proposed BMT service under appeal from a final decision of the Department, or (iii) a proposed BMT service that is part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

(l) "Health service area" or "HSA" means the geographic area set forth in Appendix A.

(m) "Initiate" or "implement" means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2).

(n) "Institutional Review Board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

(o) "Licensed site" means the location of the hospital authorized by license and listed on that licensee's certificate of licensure.

(p) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

(q) "Pediatric" means any patient 20 years of age or less or any patient with congenital conditions or diseases for which BMT is a treatment.

(r) "Planning area" means:

(i) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

(ii) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

(s) "Qualifying project" means each application in a comparative group that has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(t) "Survival rate" means the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

(u) “Tumor registry” means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant’s facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

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

Section 3. Requirements to initiate a BMT service

Sec. 3. Initiate a BMT service means to begin operation of a BMT service at a site that does not provide either adult or pediatric BMT services and is not listed on the Department inventory as of the date an application is submitted to the Department. The term includes an adult service that is proposing to provide a pediatric BMT service, ~~and~~ a pediatric service that is proposing to provide an adult BMT service, AND AN EXISTING ADULT OR PEDIATRIC BMT SERVICE THAT IS PROPOSING TO PROVIDE ADDITIONAL CELLULAR THERAPY PRODUCTS NOT PREVIOUSLY APPROVED FOR UNDER THESE STANDARDS. The term does not include beginning operation of a BMT service by a cancer hospital which acquires an existing BMT service provided that all of the staff, services, and programs required under Section 3(3) are to be provided by the cancer hospital and/or by the hospital from which the BMT service is being acquired. An applicant proposing to initiate a BMT service shall demonstrate the following requirements, as applicable to the proposed project.

(1) An applicant shall specify in the application whether the proposed service will perform either or both adult and pediatric BMT procedures.

(2) An applicant shall specify the licensed site at which the BMT service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric BMT service shall demonstrate that the licensed site at which the transplants will be offered provides each of the following staff, services, and programs:

(a) operating rooms.

(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.

(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.

(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.

(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.

(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.

(m) continuous availability of red cells, platelets, and other blood components.

(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.
(x) oncology.
(xi) pathology, including blood banking experience.
(xii) pulmonary medicine.
(xiii) radiation oncology.
(xiv) radiology.
(xv) urology.

(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric BMT procedures, these specialists shall have specific experience in the care of pediatric patients.

(i) dermatology.
(ii) immunology.
(iii) neurosurgery.
(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed BMT service. "Implementation plan" means a plan that documents how a proposed BMT service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:

(a) each component or activity necessary to begin performing the proposed BMT service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;

(b) the time table for completing each component or activity specified in subsection (a); and

(c) if the applicant previously has been approved for a BMT service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.

(5)(a) An applicant shall demonstrate that the number of existing adult BMT services does not exceed three (3) adult BMT services in planning area one identified in Section 2(1)(t)(i) or one (1) adult BMT service in planning area two identified in Section 2(1)(t)(ii) and that approval of the proposed application will not result in the total number of adult BMT services exceeding the need for each specific planning area.

(b) An applicant shall demonstrate that the number of existing pediatric BMT services does not exceed two (2) pediatric BMT services in planning area one identified in Section 2(1)(t)(i) or one (1) pediatric BMT service in planning area two identified in Section 2(1)(t)(ii) and that approval of the proposed application will not result in the total number of pediatric BMT services exceeding the need for each specific planning area.

(6)(a) An applicant proposing to initiate an adult BMT service shall project that at least 30 transplants, of which at least 10 are allogeneic transplant procedures, will be performed in the third 12-months of operation.

(b) An applicant proposing to initiate a pediatric BMT service shall project that at least 10 transplants, of which 5 are allogeneic transplant procedures, will be performed in the third 12-months of operation.

(c) An applicant proposing to initiate both an adult and a pediatric BMT service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

(7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.

(8) An applicant shall demonstrate that the licensed site at which the proposed BMT service is proposed has an institutional review board.

(9) An applicant proposing to initiate a pediatric BMT service shall demonstrate that the licensed site at which the pediatric transplant procedures will be performed has each of the following:

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

(c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG).

(d) a pediatric tumor board that meets on a regularly scheduled basis.

(e) family support group services, provided either directly or through written agreements.

(f) a pediatric cancer program with the following staff:

(i) a director who is either a board-certified immunologist who has specific training and experience in BMT or a board-certified pediatric hematologist/oncologist.

(ii) nurses with training and experience in pediatric oncology.

(iii) social workers with training and experience in pediatric oncology.

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric BMT service shall submit, in its application, a written consulting agreement with an existing BMT service. The written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (FACT) accredited transplant unit that performs both allogenic and autologous transplants for either adult and/or pediatrics. The terms of the agreement and the roles and responsibilities of both the existing and proposed service shall include at least the following:

(i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform BMT procedures.

(ii) One or more representatives of the existing BMT service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.

(iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

(iv) Specify a schedule of site visits by staff of the existing BMT service that, at a minimum, includes:

(A) 3 visits during the first 12-months of operation of the proposed service.

(B) 3 visits during each the second 12-months and third 12-months of operation of the proposed service.

(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:

(A) a review of the number of patients transplanted.
(B) transplant outcomes.
(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
(D) all deaths occurring within 100 days from transplant.
(E) each of the requirements of subdivision (iii).
(vi) Specify that a written report and minutes of each site visit shall be completed by the existing BMT service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).
(vii) Specify that the existing BMT service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.
(viii) Specify that the existing BMT service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.
(b) For purposes of subsection (10), "existing BMT service" means a service that meets all of the following:
(i) currently is performing and is FACT accredited in, the types of transplants (allogeneic and autologous; adult or pediatric) proposed to be performed by the applicant;
(ii) currently is certified as a National Marrow Donor Program; and
(iii) is located in the United States.
(c) An applicant shall document that the existing BMT service meets the requirements of subsection (b).

(11) AN APPLICANT PROPOSING TO INITIATE A BMT SERVICE THAT IS TO PROVIDE ADDITIONAL CELLULAR THERAPY PRODUCTS NOT PREVIOUSLY APPROVED FOR UNDER THESE STANDARDS SHALL DEMONSTRATE THE FOLLOWING:
(a) THE APPLICANT IS AN EXISTING ADULT OR PEDIATRIC BMT SERVICE THAT IS MEETING VOLUME THE REQUIREMENTS IN SECTION 7(4).
(b) SUCH AN APPLICATION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW AND SHALL BE PROCESSED UNDER THE PROCEDURES FOR NON-SUBSTANTIVE REVIEW.
(c) AN APPLICANT AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

Section 4. Requirements for approval – acquisition of a BMT service by a cancer hospital

Sec 4. Acquisition of a BMT service means the acquisition (including purchase, lease, donation, or other arrangement) of an existing BMT service. An applicant proposing to acquire an existing BMT service shall demonstrate the following, as applicable to the proposed project.

(1) The applicant meets all of the requirements of this subsection and shall not be required to be in compliance with Section 3(5) and the department inventory.
(a) The total number of BMT services is not increased in the planning area as the result of the acquisition.
(b) As part of the acquisition of the BMT service, the acquisition or replacement of the cancer hospital, or for any other reasons, the location of the BMT service shall be located at its prior location or in space within the licensed cancer hospital site.
(c) The applicant is a cancer hospital as defined by these standards.
(d) The applicant demonstrates that it meets, directly or through arrangements with the hospital from which it acquires the BMT service, the requirements set forth under Section 3(3), (6), (7), and (8), as applicable.

(e) The applicant agrees to either have a written consulting agreement as required by Section 3(10) or obtain a determination by the Department that such an agreement is not required because the existing BMT staff, services, and program substantially will continue to be in place after the acquisition.

(f) The applicant agrees and assures to comply, either directly or through arrangements with the hospital from which it acquires the BMT service, with all applicable project delivery requirements.

(2) An applicant approved for and holding a CON for BMT services under this section prior to the effective date of this revision of the BMT standards, September 29, 2014, shall apply to reacquire the BMT service, and the acquired BMT service shall be accountable under these revised standards.

(3) Applicants proposing to acquire an existing BMT service under this section shall not be subject to comparative review.

Section 5. Review standards for comparative reviews

Sec. 5. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules applicable.

(2) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) being Section 333. 22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333. 22225(1) of the Michigan Compiled Laws, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the CON administrative unit of the Department responsible for administering the CON program when an application is submitted.

(3)(a) A qualifying project will have points awarded based on the straight-line distance to the nearest existing BMT service of the type applied for (adult or pediatric), as shown in the following schedule:

Straight-line Distance to Nearest BMT Service	Points Awarded
<75 miles	0
75 – 150 miles	1
>150 miles	2

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed site at which the proposed BMT service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume. Determine the licensed site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed site by 4.0. The result is the indigent volume factor rounded to the nearest whole number.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the nearest whole number, is the number of points that will be awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total hospital charges expressed as a percentage, rounded to the nearest whole number, as determined by the Michigan Department of Community Health Medical Services Administration. The indigent volume data being used in this subsection is the data in the most current DCH-MSA Disproportionate Share Hospital (DSH) Report at the time the application(s) is deemed submitted by the Department.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the BMT procedures will be performed and were referred for and received a BMT at an existing BMT service, and submits documentation from the existing BMT service(s) of these referrals.

(d) A qualifying project will have points awarded based on the number of necessary support services/personnel as identified in Section 7 that the applicant has available on-site on the date the application is submitted to the Department, as follows:

(i) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(ii) a processing and cryopreservation laboratory that meets the standards of the fact or an equivalent organization.

(iii) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease and other opportunistic infections in immuno-compromised hosts.

(iv) therapeutic drug monitoring.

(v) one or more attending physicians with fellowship training, and/or at least 2 years of experience, in pediatric and/or adult BMT, as appropriate.

(vi) board-certified or board-eligible consulting physicians in all of the following areas: anatomic pathology with competence in graft versus host disease and other opportunistic diseases, infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.

(vii) a transplant team coordinator, with experience in evaluating pre and post BMT patients.

(viii) nurses with specialized training in pediatric and/or adult, as appropriate, BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(ix) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(x) an active, formal multi-disciplinary research program related to BMT.

(xi) a protective environmental inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

The applicant shall receive points, up to a maximum of three (3), for this criterion according to the following schedule:

Number of BMT Support Personnel/Services Available	Points
zero or one	0
two to five	1
six to nine	2
ten or eleven	3

(4) Submission of conflicting information in this section may result in a lower point award. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from the conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section 6. Requirements for Medicaid participation

Sec. 6. 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 7. Project delivery requirements terms of approval for all applicants

Sec. 7. An applicant shall agree that, if approved, the BMT service shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the BMT service that may affect its ability to comply with these standards.

(2) Compliance with the following quality assurance requirements, as applicable, no later than the date the first BMT procedure, allogeneic or autologous, is performed:

(a) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(i) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(ii) a cytogenetics and/or molecular genetic laboratory.

(iii) a processing and cryopreservation laboratory that meets the standards of the FACT or an equivalent organization.

(iv) a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(v) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic and autologous transplants).

(vi) therapeutic drug monitoring.

(b) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(i) a protective environmental BMT inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(ii) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(c) An applicant shall establish and maintain written policies related to outpatient care for BMT patients, including at least the following:

(i) the ability to evaluate and provide treatment on a 24-hour basis.

(ii) nurses experienced in the care of BMT patients.

(iii) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

(d) A BMT service shall establish and maintain a dedicated transplant team that includes at least the following staff:

(i) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. The team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(ii) one or more attending physicians with specialized training in pediatric and/or adult BMT, as appropriate. At least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(iii) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: cardiology, gastroenterology nephrology, psychiatry, pulmonary medicine, and critical care medicine.

(iv) on-site availability of board-certified or board-eligible consulting physicians in the following areas: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic and autologous transplants), infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.

(v) a transplant team coordinator, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.

(vi) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.

(vii) nurses with specialized training in pediatric and/or adult, as appropriate, BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(viii) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(ix) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.

(x) designated social services staff.

(xi) designated physical therapy staff.

(xii) data management personnel designated to the BMT service.

(xiii) for an applicant performing pediatric BMT, a child-life specialist.

(e) In addition to the dedicated transplant team required in subsection (d), an applicant's staff shall include a patient ombudsman, who is familiar with the BMT service, but who is not a member of the transplant team.

(f) An applicant shall develop and maintain patient management plans and protocols that include the following:

(i) therapeutic and evaluative procedures for the acute and long-term management of a patient.

(ii) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service.

(iii) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(iv) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative

regimen, post-transplantation care, prevention and treatment of graft-versus-host disease, and follow-up care.

(g) An applicant shall establish and maintain a written quality assurance plan.

(h) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(i) An applicant shall participate actively in the education of the general public and the medical community with regard to BMT, and make donation literature available in public areas of the institution.

(j) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed BMT service.

(k) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating BMT patients.

(l) A pediatric BMT service shall maintain membership status in the Children's Oncology Group (COG).

(m) For purposes of evaluating subsection (2), except subdivision (k), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant documents that the BMT service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

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

(a) The BMT service shall accept referrals for BMT services from all appropriately licensed health care practitioners.

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

(c) The BMT service shall not deny BMT services to any individual based on ability to pay or source of payment.

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

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

(a) An adult BMT service shall perform at least 30 transplants, of which at least 10 are allogeneic transplants, in the third 12-months of operation and annually thereafter.

(b) A pediatric BMT service shall perform at least 10 transplants, of which at least 5 are allogeneic transplants, in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(c) A BMT service that performs both adult and pediatric BMT shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(d) 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, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; 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. In addition, an applicant shall report at least the following data for each patient:

(i) disease type.

(ii) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.

(iii) source of hematopoietic ~~stem~~ cell, i.e., bone marrow, peripheral circulation, cord blood, etc.

(iv) patient age, i.e., adult or pediatric as defined by these standards.
(v) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.
(vi) relapse rates at 6-months, 1-year, and 5-years post-transplant.
(vii) median follow-up, and patients lost-to-follow-up.
(viii) cause(s) of death, if applicable.
(ix) additional summary information, as applicable.

An applicant annually shall report for its BMT service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic ~~stem~~ cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from BMT.

(e) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the BMT service.

(f) The BMT service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules. A BMT service that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform autologous procedures.

(g) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the BMT service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(h) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

(5) 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 8. Documentation of projections

Sec. 8. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. The applicant shall use relevant and unduplicated data for patients in the same planning area as the proposed BMT service, which are verifiable from the most recent statewide tumor registry. The applicant shall only include new cancer cases that are appropriate for referral for BMT services and from the age grouping of patients based on the type of service to be offered. This specification of projections shall include an assessment of the accuracy of projections, and of the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 9. Department Inventory of BMT Services

Sec. 9. The Department shall maintain, and provide on request, a listing of the Department Inventory of BMT services.

Section 10. Effect on prior CON Review Standards; comparative reviews

Sec. 10. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Organ Transplantation Services pertaining to BMT services approved by the CON Commission on ~~December 13, 2012~~JUNE 12, 2014 and effective on ~~March 22, 2013~~SEPTEMBER 29, 2014.

(2) Projects reviewed under these standards shall be subject to comparative review except for Section 4.

APPENDIX A

Counties assigned to each health service area 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