

1 | MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
2 |
3 | **CERTIFICATE OF NEED (CON) REVIEW STANDARDS**
4 | **FOR BONE MARROW TRANSPLANTATION (BMT) SERVICES**
5 |

6 | (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 | 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 | sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)
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10 | **Section 1. Applicability**

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12 | ~~Sec. 1. (1) These standards are requirements for the approval and delivery of services for all~~
13 | ~~projects approved and Certificates of Need issued under Part 222 of the Code which involve bone~~
14 | ~~marrow transplantation services. THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL~~
15 | ~~AND DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF~~
16 | ~~THE CODE, BONE MARROW TRANSPLANTATION IS A COVERED CLINICAL SERVICE. THE~~
17 | ~~DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE~~
18 | ~~BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION 22225(C) OF~~
19 | ~~THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.~~

20 |
21 | ~~(2) A bone marrow transplantation service is a covered clinical service for purposes of Part 222 of~~
22 | ~~the Code.~~

23 |
24 | ~~(3) A bone marrow transplantation BMT service listed on the Department inventory that is located~~
25 | ~~at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be~~
26 | ~~required to obtain separate CON approval to begin performing both autologous and allogeneic bone~~
27 | ~~marrow transplant BMT procedures.~~

28 |
29 | ~~(4) (3) An existing bone marrow transplantation BMT service that performs only adult procedures~~
30 | ~~shall require separate CON approval in order to perform pediatric procedures. An existing bone marrow~~
31 | ~~transplantation BMT service that performs only pediatric procedures shall require separate CON approval~~
32 | ~~in order to perform adult procedures.~~

33 |
34 | ~~(5) The Department shall use Sections 3, 7 & 8, as applicable, in applying Section 22225(1) of the~~
35 | ~~Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

36 |
37 | ~~(6) The Department shall use Sections 4, 5 & 6, as applicable, in applying Section 22225(2)(c) of~~
38 | ~~the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

39 |
40 | **Section 2. Definitions**

41 |
42 | Sec. 2. (1) As used in these standards:

43 | (a) "Acquisition of a bone marrow transplantation BMT service" means the acquisition (including
44 | purchase, lease, donation, or other arrangement) of an existing bone marrow transplantation BMT
45 | service.

46 | (b) "Adult," ~~for purposes of these standards,~~ means an individual age 18 or older.

47 | (c) "Allogeneic" means transplantation between genetically nonidentical individuals of the same
48 | species.

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

50 | (e) "Bone marrow transplantation service" **OR "BMT SERVICE"** means the transplantation of
51 | proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow,
52 | the peripheral circulation, cord blood, or any other source.

53 (f) "Cancer hospital" means a hospital that has been approved to participate in the Title XVIII
54 (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with Section
55 1886 (d)(1)(B)(v) of the Social Security Act, as amended.

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

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

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

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

64 (k) "Department inventory of bone marrow transplantation-BMT services" means the list
65 maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a
66 valid CON issued under Part 222 or former Part 221; (ii) operating bone marrow transplantation-BMT
67 services for which the operation of that service did not require a CON; and (iii) bone marrow
68 transplantation-BMT services that are not yet operational but have a valid CON issued under Part 222.
69 The list shall inventory adult and pediatric services separately and shall specify the site at which the bone
70 marrow transplantation-BMT service is authorized.

71 (l) "Existing bone marrow transplantation-BMT service," for purposes of Section 3(5) of these
72 standards, means any of the following: (i) a bone marrow transplantationBMT service listed on the
73 Department inventory, (ii) a proposed bone marrow transplantationBMT service under appeal from a final
74 decision of the Department, or (iii) a proposed bone marrow transplantationBMT service that is part of a
75 completed application under Part 222 (other than the application under review) for which a proposed
76 decision has been issued and which is pending final decision.

77 (m) "Health service area" or "HSA" means the geographic area set forth in Section 9.

78 ~~(n) "Implementation plan" means a plan that documents how a proposed bone marrow~~
79 ~~transplantation service will be initiated within the time period specified in these standards or the CON~~
80 ~~rules. At a minimum, the implementation plan shall identify:~~

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

85 ~~(ii) the time table for completing each component or activity specified in subsection (i); and~~

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

90 ~~(eN) "Initiate" or "implement" for purposes of these standards, means the performance of the first~~
91 ~~transplant procedure. The term of an approved CON shall be 18 months or the extended period~~
92 ~~established by Rule 325.9403(2), if authorized by the Department.~~

93 ~~(pO) "Initiate a bone marrow transplantationBMT service" means to begin operation of a bone~~
94 ~~marrow transplantationBMT service at a site that does not provide either adult or pediatric bone marrow~~
95 ~~transplantationBMT services and is not listed on the Department inventory as of the date an application is~~
96 ~~submitted to the Department. The term includes an adult service that is proposing to provide a pediatric~~
97 ~~bone marrow transplantationBMT service, and a pediatric service that is proposing to provide an adult~~
98 ~~bone marrow transplantationBMT service. The term does not include beginning operation of a bone~~
99 ~~transplantation-BMT service by a cancer hospital which acquires an existing bone marrow~~
100 ~~transplantationBMT service provided that all of the staff, services, and programs required under section~~
101 ~~3(3) are to be provided by the cancer hospital and/or by the hospital from which the bone marrow~~
102 ~~transplantationBMT service is being acquired.~~

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

105 ~~(rQ) "Licensed site" means either:~~

~~(i) in the case of a single site hospital, the location of the facility HOSPITAL authorized by license and listed on that licensee's certificate of licensure or~~

~~(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.~~

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

~~(tS)~~ "Pediatric" means, ~~for purposes of these standards,~~ any patient 20 years of age or less or any patient with congenital conditions or diseases for which ~~bone marrow transplantation BMT~~ is a treatment.

~~(uT)~~ "Planning area" means:

~~(i) for an adult bone marrow transplantation BMT service, the state of Michigan;~~

~~(ii) for a pediatric bone marrow transplantation BMT service, either:~~

~~(A)~~ 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

~~(B)~~ 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.

~~(vU)~~ "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.

~~(wV)~~ "Survival rate" means, ~~for purposes of these standards,~~ 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.

~~(W) "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 ~~for approval for applicants proposing to initiate a bone marrow transplantation BMT~~ service

Sec. 3. ~~(1)~~ An applicant proposing to initiate a ~~bone marrow transplantation BMT~~ service shall ~~demonstrate the following requirements:~~

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

160
161 | (2) An applicant shall specify the licensed hospital-site at which the bone marrow transplantation
162 | BMT service will be provided.
163
164 | (3) An applicant proposing to initiate either an adult or pediatric bone marrow transplantation-BMT
165 | service shall demonstrate that the licensed hospital-site at which the transplants will be offered provides
166 | each of the following staff, services, and programs:
167 | (a) operating rooms.
168 | (b) continuous availability, on-site or physically connected, either immediate or on-call, of CT
169 | scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.
170 | (c) dialysis.
171 | (d) inpatient-outpatient social work.
172 | (e) inpatient-outpatient psychiatry/psychology.
173 | (f) clinical research.
174 | (g) a microbiology and virology laboratory.
175 | (h) a histocompatibility laboratory that meets the standards of the American Society for
176 | Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written
177 | agreement.
178 | (i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.
179 | (j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels,
180 | available either on-site or through other arrangements that assure adequate availability.
181 | (k) other support services, as necessary, such as physical therapy and rehabilitation medicine.
182 | (l) continuous availability of anatomic and clinical pathology and laboratory services, including
183 | clinical chemistry, and immuno-suppressive drug monitoring.
184 | (m) continuous availability of red cells, platelets, and other blood components.
185 | (n) an active medical staff that includes, but is not limited to, the following board-certified or board-
186 | eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these
187 | specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.
188 | (i) anesthesiology.
189 | (ii) cardiology.
190 | (iii) critical care medicine.
191 | (iv) gastroenterology.
192 | (v) general surgery.
193 | (vi) hematology.
194 | (vii) infectious diseases.
195 | (viii) nephrology.
196 | (ix) neurology.
197 | (x) oncology.
198 | (xi) pathology, including blood banking experience.
199 | (xii) pulmonary medicine.
200 | (xiii) radiation oncology.
201 | (xiv) radiology.
202 | (xv) urology.
203 | (o) One or more consulting physicians who are board-certified or board-eligible in each of the
204 | following specialties. For an applicant proposing to perform pediatric bone marrow transplant-BMT
205 | procedures, these specialists shall have specific experience in the care of pediatric patients.
206 | (i) dermatology.
207 | (ii) immunology.
208 | (iii) neurosurgery.
209 | (iv) orthopedic surgery.
210
211 | (4) An applicant must provide an implementation plan for the proposed bone marrow
212 | transplantationBMT service. "IMPLEMENTATION PLAN" MEANS A PLAN THAT DOCUMENTS HOW A
213 | PROPOSED BMT SERVICE WILL BE INITIATED WITHIN THE TIME PERIOD SPECIFIED IN THESE

214 STANDARDS OR THE CON RULES. AT A MINIMUM, THE IMPLEMENTATION PLAN SHALL
215 IDENTIFY:

216 (A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE
217 PROPOSED BMT SERVICE INCLUDING, BUT NOT LIMITED TO, THE DEVELOPMENT OF PHYSICAL
218 PLANT REQUIREMENTS, SUCH AS AN INTENSIVE CARE UNIT CAPABLE OF TREATING IMMUNO-
219 SUPPRESSED PATIENTS, EQUIPMENT ACQUISITIONS, AND RECRUITMENT AND EMPLOYMENT
220 OF ALL PHYSICIAN AND SUPPORT STAFF;

221 (B) THE TIME TABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN
222 SUBSECTION (A); AND

223 (C) IF THE APPLICANT PREVIOUSLY HAS BEEN APPROVED FOR A BMT SERVICE FOR
224 WHICH EITHER THE CON EXPIRED OR THE SERVICE DID NOT PERFORM A TRANSPLANT
225 PROCEDURE DURING ANY CONSECUTIVE 12-MONTH PERIOD, WHAT CHANGES HAVE OR WILL
226 BE MADE TO ENSURE THAT THE PROPOSED SERVICE CAN BE INITIATED AND PROVIDED ON A
227 REGULAR BASIS.

228
229
230 (5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation
231 BMT services DOES NOT EXCEED THREE (3) ADULT BMT SERVICES IN PLANNING AREA ONE
232 IDENTIFIED IN in the planning area identified in Section 2(1)(uT)(i) OR ONE (1) ADULT BMT SERVICE
233 IN PLANNING AREA TWO IDENTIFIED IN SECTION 2(1)(T)(ii) AND THAT APPROVAL OF THE
234 PROPOSED APPLICATION WILL NOT RESULT IN THE TOTAL NUMBER OF ADULT BMT SERVICES
235 EXCEEDING THE NEED FOR EACH SPECIFIC PLANNING AREA. does not exceed three (3) adult bone
236 marrow transplantation BMT services and that approval of the proposed application will not result in the
237 total number of adult bone marrow transplantation BMT services exceeding three (3) in the planning area.

238 (b) An applicant shall demonstrate that the number of existing pediatric bone marrow
239 transplantationBMT services does not exceed two (2) pediatric bone marrow transplantationBMT services
240 in planning area one identified in Section 2(1)(uT)(iii)(A) or one (1) pediatric bone marrow
241 transplantationBMT service in planning area two identified in Section 2(1)(uT)(ii)(B) and that approval of
242 the proposed application will not result in the total number of pediatric bone marrow transplantationBMT
243 services exceeding the need for each specific pediatric planning area.

244
245 (6)(a) An applicant proposing to initiate an adult bone marrow transplantationBMT service that will
246 perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at
247 least 1030 TRANSPLANTS, OF WHICH AT LEAST 10 ARE allogeneic transplant procedures, will be
248 performed in the third 12-months of operation. An applicant proposing to initiate an adult bone marrow
249 transplantationBMT service that will perform only autologous procedures shall project that at least 10
250 autologous transplant procedures will be performed in the third 12-months of operation.

251 (b) An applicant proposing to initiate a pediatric bone marrow transplantationBMT service that will
252 perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at
253 least 10 TRANSPLANTS, OF WHICH 5 ARE allogeneic transplant procedures, will be performed in the
254 third 12-months of operation. An applicant proposing to initiate a pediatric bone marrow
255 transplantationBMT service that will perform only autologous procedures shall project that at least 10
256 autologous transplant procedures will be performed in the third 12-months of operation.

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

262
263 (7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically
264 connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body
265 irradiation.

- 267 | (8) An applicant shall demonstrate that the licensed hospital site at which the proposed bone
268 | marrow transplantationBMT service is proposed has an institutional review board.
269 |
- 270 | (9) An applicant proposing to initiate a pediatric bone marrow transplantationBMT service shall
271 | demonstrate that the licensed hospital site at which the pediatric transplant procedures will be performed
272 | has each of the following:
- 273 | (a) a designated pediatric inpatient oncology unit.
 - 274 | (b) a pediatric inpatient intensive care unit.
 - 275 | (c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer
276 | Group (CCG).
 - 277 | (d) a pediatric tumor board that meets on a regularly scheduled basis.
 - 278 | (e) family support group services, provided either directly or through written agreements.
 - 279 | (f) a pediatric cancer program with the following staff:
 - 280 | (i) a director who is either a board-certified immunologist who has specific training and experience
281 | in bone marrow transplantationBMT or a board-certified pediatric hematologist/oncologist.
 - 282 | (ii) nurses with training and experience in pediatric oncology.
 - 283 | (iii) social workers with training and experience in pediatric oncology.
 - 284 | (iv) pediatric psychologists.
 - 285 | (v) child life specialists.
 - 286 |
- 287 | (10)(a) An applicant proposing to initiate either a new adult or pediatric bone marrow
288 | transplantationBMT service shall submit, in its application, a written consulting agreement with an existing
289 | bone marrow transplantationBMT service, ~~that meets each of the requirements in subsection (b).~~ **THE**
290 | **WRITTEN CONSULTING AGREEMENT MUST BE WITH AN EXISTING IN-STATE OR OUT-OF-STATE**
291 | **FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ACCREDITED**
292 | **TRANSPLANT UNIT THAT PERFORMS BOTH ALLOGENIC AND AUTOLOGOUS TRANSPLANTS**
293 | **FOR EITHER ADULT AND/OR PEDIATRICS. SHALL SPECIFY THE TERMS OF THE AGREEMENT**
294 | **AND THE ROLES AND RESPONSIBILITIES OF BOTH THE EXISTING AND PROPOSED SERVICE.**
295 | **SHALL INCLUDEING AT LEAST THE FOLLOWING:**
- 296 | ~~(b) The written consulting agreement required by subsection (a) shall specify the term of the~~
297 | ~~agreement and the roles and responsibilities of both the existing and proposed service, including at least~~
298 | ~~the following:~~
 - 299 | (i) The term of the written consulting agreement is no less than 36 months after the proposed
300 | service begins to perform bone marrow transplantBMT procedures.
 - 301 | (ii) One or more representatives of the existing bone marrow transplantationBMT service have
302 | been designated as staff responsible for carrying out the roles and responsibilities of the existing service.
 - 303 | (iii) The existing service shall evaluate and make recommendations to the proposed service on
304 | policies and procedures, including time tables, for at least each of the following:
 - 305 | (A) nursing services.
 - 306 | (B) infection control.
 - 307 | (C) nutritional support.
 - 308 | (D) staff needs and training.
 - 309 | (E) inpatient and outpatient medical coverage.
 - 310 | (F) transfusion and blood bank policies.
 - 311 | (G) transplant treatment protocols.
 - 312 | (H) hematopoiesis laboratory services and personnel.
 - 313 | (I) data management.
 - 314 | (J) quality assurance program.
 - 315 | (iv) Specify a schedule of site visits by staff of the existing bone marrow transplantationBMT
316 | service that, at a minimum, includes:
 - 317 | (A) **2** visits during the first 12-months of operation of the proposed service.
 - 318 | (B) **2** visits during each the second 12-months and third 12-months of operation of the proposed
319 | service.

- 320 (v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed
 321 service and make recommendations related to quality assurance mechanisms of the proposed service,
 322 including at least each of the following:
- 323 (A) a review of the number of patients transplanted.
 - 324 (B) transplant outcomes.
 - 325 (C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this
 326 agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
 - 327 (D) all deaths occurring within 100 days from transplant.
 - 328 (E) each of the requirements of subdivision (iii).
- 329 (vi) Specify that a written report and minutes of each site visit shall be completed by the existing
 330 bone marrow transplantationBMT service and sent to the proposed service within 2 weeks of each visit,
 331 and that copies of the reports and minutes shall be available to the Department upon request. At a
 332 minimum, the written report shall address each of the items in subdivision (v).
- 333 (vii) Specify that the existing bone marrow transplantationBMT service shall notify the Department
 334 and the proposed service immediately if it determines that the proposed service may not be in
 335 compliance with any applicable quality assurance requirements, and develop jointly with the proposed
 336 service a plan for immediate remedial actions.
- 337 (viii) Specify that the existing bone marrow transplantationBMT service shall notify the Department
 338 immediately if the consulting agreement required pursuant to these standards is terminated and that the
 339 notification shall include a statement describing the reasons for the termination.
- 340 (Be) For purposes of subsection (10), "existing bone marrow transplantationBMT service" means a
 341 service that meets all of the following:
- 342 (i) currently is performing and is Foundation for Accreditation of Cell Therapy (FACT) accredited
 343 in, the types of transplants (allogeneic ANDor autologous; adult or pediatric) proposed to be performed by
 344 the applicant;
 - 345 (ii) currently is certified as a National Marrow Donor Program; and
 - 346 (iii) is located in the United States.
- 347 (Ce) An applicant shall document that the existing bone marrow transplantationBMT service meets
 348 the requirements of subsection (eB).

349
 350 **SECTION 84. REQUIREMENTS FOR APPROVAL – ACQUISITION OF A BMT SERVICE BY A**
 351 **CANCER HOSPITAL**

352
 353 (1) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING BMT SERVICE SHALL
 354 DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND
 355 SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SECTION 3(5) AND THE
 356 DEPARTMENT INVENTORY.

357 (A) THE TOTAL NUMBER OF BMT SERVICES IS NOT INCREASED IN THE PLANNING
 358 AREA AS THE RESULT OF THE ACQUISITION.

359 (B) AS PART OF THE ACQUISITION OF THE BMT SERVICE, THE ACQUISITION OR
 360 REPLACEMENT OF THE CANCER HOSPITAL, OR FOR ANY OTHER REASONS, THE LOCATION
 361 OF THE BMT SERVICE SHALL BE LOCATED AT ITS PRIOR LOCATION OR IN SPACE WITHIN
 362 THE LICENSED CANCER HOSPITAL SITE.

363 (C) THE APPLICANT IS A CANCER HOSPITAL AS DEFINED BY THESE STANDARDS. THE
 364 APPLICANT SHALL, TO THE SATISFACTION OF THE DEPARTMENT, PROVIDE VERIFICATION
 365 OF PPS-EXEMPTION AT THE TIME OF APPLICATION, OR SHALL DEMONSTRATE COMPLIANCE
 366 WITH THE FOLLOWING TO THE SATISFACTION OF THE DEPARTMENT:

367 (I) THE APPLICANT, OR AN AFFILIATE OF THE APPLICANT, OPERATES A
 368 COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE IN
 369 CONJUNCTION WITH A MICHIGAN UNIVERSITY THAT IS DESIGNATED AS A COMPREHENSIVE
 370 CANCER CENTER, OR THE APPLICANT IS THE MICHIGAN UNIVERSITY THAT IS DESIGNATED
 371 AS A COMPREHENSIVE CANCER CENTER.

372 (II) THE APPLICANT COMMITS TO PROVIDE EVIDENCE, SATISFACTORY TO THE
373 DEPARTMENT, OF APPROVAL AS A PPS-EXEMPT HOSPITAL WITHIN THE TIME LIMITS
374 SPECIFIED IN SUBSECTION (G).

375 (D) THE APPLICANT DEMONSTRATES THAT IT MEETS, DIRECTLY OR THROUGH
376 ARRANGEMENTS WITH THE HOSPITAL FROM WHICH IT ACQUIRES THE BMT SERVICE, THE
377 REQUIREMENTS SET FORTH UNDER SECTION 3(3), (6), (7), AND (8), AS APPLICABLE.

378 (E) THE APPLICANT AGREES TO EITHER HAVE A WRITTEN CONSULTING AGREEMENT
379 AS REQUIRED BY SECTION 3(10) OR OBTAIN A DETERMINATION BY THE DEPARTMENT THAT
380 SUCH AN AGREEMENT IS NOT REQUIRED BECAUSE THE EXISTING BMT STAFF, SERVICES,
381 AND PROGRAM SUBSTANTIALLY WILL CONTINUE TO BE IN PLACE AFTER THE ACQUISITION.

382 (F) THE APPLICANT AGREES AND ASSURES TO COMPLY, EITHER DIRECTLY OR
383 THROUGH ARRANGEMENTS WITH THE HOSPITAL FROM WHICH IT ACQUIRES THE BMT
384 SERVICE, WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

385 (G) IF THE APPLICANT DESCRIBED IN THIS SUBSECTION DOES NOT MEET THE TITLE
386 XVIII REQUIREMENTS OF THE SOCIAL SECURITY ACT FOR EXEMPTION FROM PPS WITHIN 24
387 MONTHS AFTER RECEIVING CON APPROVAL UNDER THIS SECTION, THE DEPARTMENT MAY
388 EXTEND THE 24-MONTH DEADLINE TO NO LATER THAN THE LAST SESSION DAY PERMITTED
389 BY THE UNITED STATES CONSTITUTION FOR THE NEXT UNITED STATES CONGRESS IN
390 SESSION AFTER THE EFFECTIVE DATE OF THESE STANDARDS. EXTENSION OF THE
391 DEADLINE SHALL REQUIRE DEMONSTRATION BY THE APPLICANT, TO THE SATISFACTION
392 OF THE DEPARTMENT, THAT THERE HAS BEEN PROGRESS TOWARD ACHIEVING THE
393 CHANGES IN FEDERAL LAW AND REGULATIONS THAT ARE REQUIRED TO SECURE THE PPS
394 EXEMPTION. IF THE APPLICANT FAILS TO MEET THE TITLE XVIII REQUIREMENTS FOR PPS
395 EXEMPTION WITHIN THE 24-MONTH PERIOD, OR ITS POSSIBLE EXTENSION, THEN THE
396 DEPARTMENT MAY EXPIRE THE CON GRANTED PURSUANT TO THIS SECTION SHALL
397 EXPIRE AUTOMATICALLY AND WILL NOT BE SUBJECT TO FURTHER APPLICATIONS FOR
398 ACQUISITION. HOWEVER, PRIOR TO THE FINAL DEADLINE FOR THE EXPIRATION OF THE
399 CON, THE PRIOR HOLDER OF THE (CON/AUTHORIZATION) TO PROVIDE THE BMT SERVICE
400 MAY APPLY FOR ACQUISITION OF THE SERVICE, PURSUANT TO ALL THE PROVISIONS OF
401 THIS SECTION, EXCEPT FOR SUBSECTION (C).

402
403 2. APPLICANTS PROPOSING TO ACQUIRE AN EXISTING BMT SERVICE UNDER THIS
404 SECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

405
406
407 **Section 54. REVIEW STANDARDS FOR Additional requirements for applications included in**
408 **comparative reviews**

409
410 Sec. 45. (1) Any application subject to comparative review under Section 22229 of the Code, being
411 Section 333.22229 of the Michigan Compiled Laws, or UNDER these standards, shall be grouped and
412 reviewed COMPARATIVELY with other applications in accordance with the CON rules applicable, ~~to~~
413 ~~comparative reviews.~~

414
415 (32) EACH APPLICATION IN A COMPARATIVE GROUP SHALL BE INDIVIDUALLY REVIEWED
416 TO DETERMINE WHETHER THE APPLICATION HAS SATISFIED ALL THE REQUIREMENTS OF
417 SECTION 22225 OF THE CODE BEING SECTION 333.22225 OF THE MICHIGAN COMPILED LAWS
418 AND ALL OTHER APPLICABLE REQUIREMENTS FOR APPROVAL IN THE CODE AND THESE
419 STANDARDS. IF THE DEPARTMENT DETERMINES THAT TWO OR MORE COMPETING
420 APPLICATIONS SATISFY ALL OF THE REQUIREMENTS FOR APPROVAL, THESE PROJECTS
421 SHALL BE CONSIDERED QUALIFYING PROJECTS. THE DEPARTMENT SHALL APPROVE THOSE
422 QUALIFYING PROJECTS WHICH, WHEN TAKEN TOGETHER, DO NOT EXCEED THE NEED, AS
423 DEFINED IN SECTION 22225(1) BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED
424 LAWS, AND WHICH HAVE THE HIGHEST NUMBER OF POINTS WHEN THE RESULTS OF
425 SUBSECTION (2) ARE TOTALED. IF TWO OR MORE QUALIFYING PROJECTS ARE DETERMINED

426 TO HAVE AN IDENTICAL NUMBER OF POINTS, THEN THE DEPARTMENT SHALL APPROVE
 427 THOSE QUALIFYING PROJECTS WHICH, TAKEN TOGETHER, DO NOT EXCEED THE NEED, AS
 428 DEFINED IN SECTION 22225(1) OF THE CODE, BEING SECTION 333. 22225(1) OF THE MICHIGAN
 429 COMPILED LAWS, IN THE ORDER IN WHICH THE APPLICATIONS WERE RECEIVED BY THE
 430 DEPARTMENT, BASED ON THE DATE AND TIME STAMP PLACED ON THE APPLICATIONS BY THE
 431 CON ADMINISTRATIVE UNIT OF THE DEPARTMENT RESPONSIBLE FOR ADMINISTERING THE
 432 CON PROGRAM WHEN AN APPLICATION IS SUBMITTED.

433
 434
 435 ~~(23)(a) A qualifying project will have points awarded based on the number of bone marrow~~
 436 ~~transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health~~
 437 ~~service area in which the proposed service will be located, on the date the application is submitted to the~~
 438 ~~Department, as shown in the following schedule.~~

Number of BMT Transplant Services (adult or pediatric, as applicable) in HSA	Points Awarded
Two or more services	0
One service	2
No services	4

449
 450 ~~(2)(A) A QUALIFYING PROJECT WILL HAVE POINTS AWARDED BASED ON THE STRAIGHT-LINE~~
 451 ~~DISTANCE TO THE NEAREST EXISTING BMT SERVICE OF THE TYPE APPLIED FOR (ADULT OR~~
 452 ~~PEDIATRIC), AS SHOW IN THE FOLLOWING SCHEDULE.~~

STRAIGHT-LINE DISTANCE TO NEAREST BMT SERVICE	Points Awarded
<75 MILES	0
75 – 150 MILES	1
>150 MILES	2

460
 461 (b) A qualifying project will have up to 4 points awarded based on the percentage of the
 462 medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow
 463 transplantationBMT service will be provided in accordance with the following:

464 (i) For each applicant in the same comparative group, determine the medical/surgical indigent
 465 volume, ~~rounded to the nearest whole number, for each licensed hospital site at which a bone marrow~~
 466 ~~transplantationBMT service is proposed to be provided.~~ Determine the licensed hospital site that has the
 467 highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for
 468 that licensed hospital site by 4.0. The result is the indigent volume factor ROUNDED TO THE NEAREST
 469 WHOLE NUMBER.

470 (ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume
 471 by the indigent volume factor determined in subdivision (i). The result, to the NEAREST WHOLE
 472 NUMBERfirst decimal place, is the number of points that will be awarded to each applicant pursuant to
 473 this subsection.

474 For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to
 475 its total HOSPITAL charges expressed as a percentage, ROUNDED TO THE NEAREST WHOLE
 476 NUMBER, as determined by the Michigan Department of Community Health Medical Services
 477 Administration ~~pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual.~~ The
 478 indigent volume data being used IN THIS SUBSECTIONfor rates IS THE DATA IN THE MOST
 479 CURRENT DCH-MSA DISPROPORTIONATE SHARE HOSPITAL (DSH) REPORT in effect at the time

480 the application(S) is deemed submitted will be used by the Department in determining the number of
481 points awarded to each qualifying project.

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

488 (D) A QUALIFYING PROJECT WILL HAVE POINTS AWARDED BASED ON THE NUMBER OF
489 NECESSARY SUPPORT SERVICES/PERSONNEL AS IDENTIFIED IN SECTION 7 THAT THE
490 APPLICANT HAS AVAILABLE ON-SITE ON THE DATE THE APPLICATION IS SUBMITTED TO THE
491 DEPARTMENT. THE APPLICANT SHALL EARN ONE (1) POINT EACH, UP TO A MAXIMUM OF
492 ELEVEN (11) POINTS, FOR THE FOLLOWING.

493 (I) 24-HOUR BLOOD BANK SUPPORT, INCLUDING PHERESIS CAPABILITY, IRRADIATED
494 BLOOD PRODUCTS SUITABLE FOR CYTOMEGALOVIRUS-NEGATIVE TRANSPLANTS, AND
495 BLOOD COMPONENT THERAPY.

496 (II) A PROCESSING AND CRYOPRESERVATION LABORATORY THAT MEETS THE
497 STANDARDS OF THE FACT OR AN EQUIVALENT ORGANIZATION.

498 (III) ANATOMIC AND CLINICAL PATHOLOGY WITH COMPETENCY IN INTERPRETING
499 PATHOLOGIC FINDINGS RELATED TO GRAFT-V-HOST DISEASE AND OTHER OPPORTUNISTIC
500 INFECTIONS IN IMMUNO-COMPROMISED HOSTS.

501 (IV) THERAPEUTIC DRUG MONITORING.

502 (V) ONE OR MORE ATTENDING PHYSICIANS WITH FELLOWSHIP TRAINING, AND/OR AT
503 LEAST 2 YEARS OF EXPERIENCE, IN PEDIATRIC AND/OR ADULT BMT, AS APPROPRIATE.

504 (VI) BOARD-CERTIFIED OR BOARD-ELIGIBLE CONSULTING PHYSICIANS IN ALL OF THE
505 FOLLOWING AREAS: ANATOMIC PATHOLOGY WITH COMPETENCE IN GRAFT VERSUS HOST
506 DISEASE AND OTHER OPPORTUNISTIC DISEASES, INFECTIOUS DISEASES WITH EXPERIENCE IN
507 IMMUNO-COMPROMISED HOSTS, AND RADIATION ONCOLOGY WITH EXPERIENCE IN TOTAL BODY
508 IRRADIATION.

509 (VII) A TRANSPLANT TEAM COORDINATOR, WITH EXPERIENCE IN EVALUATING PRE AND
510 POST BMT PATIENTS.

511 (VIII) NURSES WITH SPECIALIZED TRAINING IN PEDIATRIC AND/OR ADULT, AS APPROPRIATE,
512 BMT, HEMATOLOGY/ONCOLOGY PATIENT CARE, ADMINISTRATION OF CYTOTOXIC THERAPIES,
513 MANAGEMENT OF INFECTIOUS COMPLICATIONS ASSOCIATED WITH HOST-DEFENSE
514 MECHANISMS, ADMINISTRATION OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF
515 THE TRANSPLANT PATIENT, AND MANAGING IMMUNO-SUPPRESSED PATIENTS.

516 (IX) A PHARMACIST EXPERIENCED WITH THE USE OF CYTOTOXIC THERAPIES, USE OF
517 BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT, AND THE
518 MANAGEMENT OF IMMUNO-SUPPRESSED PATIENTS.

519 (X) AN ACTIVE, FORMAL MULTI-DISCIPLINARY RESEARCH PROGRAM RELATED TO BMT.

520 (XI) A PROTECTIVE ENVIRONMENTAL INPATIENT UNIT FOR IMMUNO-SUPPRESSED PATIENTS
521 THAT HAS AN ISOLATION POLICY, AN INFECTION CONTROL PLAN SPECIFIC TO THAT UNIT, AND
522 AIR HANDLING SYSTEM CAPABLE OF PREVENTING NOSOCOMIAL INFECTIONS DISSEMINATED
523 FROM CENTRAL HEATING AND COOLING SYSTEMS AND AMBIENT AIR.

524
525
526 (3) Each application in a comparative group shall be individually reviewed to determine whether
527 the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225
528 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these
529 standards. If the Department determines that two or more competing applications satisfy all of the
530 requirements for approval, these projects shall be considered qualifying projects. The Department shall
531 approve those qualifying projects which, when taken together, do not exceed the need, as defined in
532 Section 22225(1) BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWS of the Code,
533 and which have the highest number of points when the results of subsection (2) are totaled. If two or

534 ~~more qualifying projects are determined to have an identical number of points, then the Department shall~~
535 ~~approve those qualifying projects which, when taken together, do not exceed the need, AS DEFINED IN~~
536 ~~SECTION 22225(1) OF THE CODE, BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED~~
537 ~~LAWS, in the order in which the applications were received by the Department, based on the date and~~
538 ~~time stamp placed on the applications by the CON ADMINISTRATIVE UNIT OF THE DEPARTMENT~~
539 ~~RESPONSIBLE FOR ADMINISTERING THE CON PROGRAM WHEN AN APPLICATION IS~~
540 ~~SUBMITTED. Department in accordance with Rule 325.9123.~~

541
542 (4) ~~SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A~~
543 ~~LOWER POINT AWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH~~
544 ~~COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE~~
545 ~~DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE~~
546 ~~AWARDED FROM THE CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED~~
547 ~~INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING~~
548 ~~INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE~~
549 ~~AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE~~
550 ~~DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED~~
551 ~~INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING~~
552 ~~INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE~~
553 ~~AWARDED. No points will be awarded to an applicant under specific subsections of Section 4 if~~
554 ~~information presented is inconsistent with related information provided in other portions of the CON~~
555 ~~application.~~

556 **Section 56. Requirements for approval -- all applicants**

557
558
559 Sec. 56. An applicant shall provide verification of Medicaid participation ~~at the time the application is~~
560 ~~submitted to the Department.~~ An applicant that is initiating a new service or is a new provider not
561 currently enrolled in Medicaid shall ~~provide a signed affidavit stating- CERTIFY~~ that proof of Medicaid
562 participation will be provided to the Department within six (6) months from the offering of services if a
563 CON is approved. ~~If the required documentation is not submitted with the application on the designated~~
564 ~~application date, the application will be deemed filed on the first applicable designated application date~~
565 ~~after all required documentation is received by the Department.~~

566 **Section 67. Project delivery requirements -- terms of approval ~~for all applicants~~**

567
568
569 Sec. 67. (1) An applicant shall agree that, if approved, the ~~bone marrow transplantation~~BMT service
570 shall be delivered in compliance with the following terms of CON approval:

571 (a) Compliance with these standards. An applicant shall immediately report to the Department any
572 changes in key staff or other aspects of the ~~bone marrow transplantation~~BMT service that may affect its
573 ability to comply with these standards.

574 (b) Compliance with applicable safety and operating standards.

575 (c) Compliance with the following quality assurance standards, as applicable, no later than the
576 date the first ~~bone marrow transplant~~BMT procedure, allogeneic or autologous, is performed:

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

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

581 (B) a cytogenetics and/or molecular genetic laboratory.

582 (C) a processing and cryopreservation laboratory that meets the standards of the ~~Foundation for~~
583 ~~Accreditation of Cell Therapy (FACT)~~ or an equivalent organization.

584 (D) ~~for a program that performs allogeneic transplants,~~ a histocompatibility laboratory that has the
585 capability of DNA-based HLA-typing and meets the standards of the American Society for
586 Histocompatibility and Immunogenetics or an equivalent organization.

587 (E) anatomic and clinical pathology with competency in interpreting pathologic findings related to
588 graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in
589 immuno-compromised hosts (programs performing allogeneic ~~AND/or~~ autologous transplants).

590 (F) therapeutic drug monitoring.

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

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

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

598 (iii) An applicant shall establish and maintain written policies related to outpatient care for ~~bone~~
599 ~~marrow transplantation~~BMT patients, including at least the following:

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

601 (B) nurses experienced in the care of ~~bone marrow transplantation~~BMT patients.

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

604 (iv) A ~~bone marrow transplantation~~BMT service shall establish and maintain a dedicated transplant
605 team that includes at least the following staff:

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

616 (B) one or more attending physicians with specialized training in pediatric and/or adult ~~BMT~~, as
617 appropriate, ~~bone marrow transplantation~~. ~~If a service performs allogeneic transplants, a~~ at least one
618 attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as
619 appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical
620 oncology, immunology, or pediatric hematology/oncology, as appropriate.

621 (C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric,
622 as appropriate, in at least the following specialties: ~~anatomic pathology with competence in graft-versus-host~~
623 ~~disease (services performing allogeneic transplants) and other opportunistic diseases (services performing~~
624 ~~allogeneic or autologous transplants), cardiology, gastroenterology, infectious diseases with experience in~~
625 ~~immuno-compromised hosts, nephrology, psychiatry, pulmonary medicine, and CRITICAL CARE~~
626 ~~MEDICINE, radiation oncology with experience in total body irradiation, and an intensivist who is board-~~
627 ~~certified in critical care.~~

628 ~~(D) ON-SITE AVAILABILITY OF BOARD-CERTIFIED OR BOARD-ELIGIBLE CONSULTING~~
629 ~~PHYSICIANS IN THE FOLLOWING AREAS. ANATOMIC PATHOLOGY WITH COMPETENCE IN GRAFT~~
630 ~~VERSUS HOST DISEASE (SERVICES PERFORMING ALLOGENEIC TRANSPLANTS) AND OTHER~~
631 ~~OPPORTUNISTIC DISEASES (SERVICES PERFORMING ALLOGENEIC OR AND AUTOLOGOUS~~
632 ~~TRANSPLANTS), INFECTIOUS DISEASES WITH EXPERIENCE IN IMMUNO-COMPROMISED HOSTS,~~
633 ~~AND RADIATION ONCOLOGY WITH EXPERIENCE IN TOTAL BODY IRRADIATION.~~

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

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

638 ~~(FG)~~ nurses with specialized training in pediatric and/or adult, as appropriate, ~~bone marrow~~
639 ~~transplantation~~BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of
640 infectious complications associated with compromised host-defense mechanisms, administration of blood

641 components, the hemodynamic support of the transplant patient, and managing immuno-suppressed
642 patients.

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

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

647 | (J) designated social services staff.

648 | (JK) designated physical therapy staff.

649 | (KL) data management personnel designated to the bone marrow transplantationBMT service.
650 | (LM) for an applicant performing pediatric bone marrow transplantsBMT, a child-life specialist.

651 (v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall
652 | include a patient ombudsman, who is familiar with the bone marrow transplantationBMT service, but who is
653 not a member of the transplant team.

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

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

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

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

661 (D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-
662 approved clinical research protocol, written policies and procedures that include at least the following:
663 donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative
664 regimen, post-transplantation care, prevention and treatment of graft-versus-host disease allogeneic
665 transplants, and follow-up care.

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

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

669 (ix) An applicant shall participate actively in the education of the general public and the medical
670 | community with regard to bone marrow transplantationBMT, and make donation literature available in
671 public areas of the institution.

672 (x) An applicant shall establish and maintain an active, formal multi-disciplinary research program
673 | related to the proposed bone marrow transplantationBMT service.

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

677 | (xii) A pediatric bone marrow transplantBMT service shall maintain membership status in the
678 Children's Oncology Group (COG).

679 (xiii) For purposes of evaluating subsection (c), except subdivision (xii), the Department shall
680 consider it prima facie evidence as to compliance with the applicable requirements if an applicant
681 | documents that the bone marrow transplantationBMT service is accredited by the National Marrow Donor
682 Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

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

685 (d) Compliance with the following terms of approval:

686 (i) An applicant shall perform the applicable required volumes as follow:

687 | (A) An adult bone marrow transplantationBMT service ~~that performs only allogeneic transplants, or~~
688 both allogeneic and autologous transplants, shall perform at least 1030 TRANSPLANTS, OF WHICH AT
689 LEAST 10 ARE allogeneic transplants, in the third 12-months of operation AND ANNUALLY
690 THEREAFTER. If an adult service performs only autologous transplants, the service shall perform at
691 least 10 autologous transplants in the third 12-months of operation. After the third 12-months of
692 operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period,
693 with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation,
694 and thereafter.

695 (B) A pediatric bone marrow transplantationBMT service that performs only allogeneic transplants,
696 or both allogeneic and autologous transplants, shall perform at least 10 TRANSPLANTS, OF WHICH AT
697 LEAST 5 ARE allogeneic transplants, in the third 12-months of operation. If a pediatric service performs
698 only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-
699 months of operation. After the third 12-months of operation, an applicant shall perform at least 30
700 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in
701 any 12-month period, beginning with the third 12-months of operation, and thereafter.

702 (C) A bone marrow transplantationBMT service that performs both adult and pediatric bone marrow
703 transplantsBMT shall specify whether each patient age 18-20 is included in the category of adult
704 procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-
705 20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each
706 patient age 18-20 in only 1 category.

707 (ii) The applicant shall participate in a data collection network established and administered by the
708 Department or its designee. The data may include, but is not limited to, annual budget and cost information,
709 demographic and diagnostic information, primary and secondary diagnoses, whether the transplant
710 procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients
711 from all payor sources, and other data requested by the Department and approved by the CON Commission.
712 The applicant shall provide the required data on an individual basis for each designated licensed site; in a
713 format established by the Department; and in a mutually-agreed upon media. The Department may elect to
714 verify the data through on-site review of appropriate records. In addition, an applicant shall report at least
715 the following data for each patient:

- 716 (A) disease type.
- 717 (B) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.
- 718 (C) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.
- 719 (D) patient age, i.e., adult or pediatric as defined by these standards.
- 720 (E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.
- 721 (F) relapse rates at 6-months, 1-year, and 5-years post-transplant.
- 722 (G) median follow-up, and patients lost-to-followup.
- 723 (H) cause(s) of death, if applicable.
- 724 (I) additional summary information, as applicable.

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

731 (iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing
732 information on its patients being evaluated for transplant and on its transplant recipients and shall participate
733 in the national and international registries applicable to the bone marrow transplantationBMT service.

734 (iv) An applicant, to assure that the bone marrow transplantationBMT service(s) will be utilized by all
735 segments of the Michigan population, shall:

- 736 (A) not deny the services to any individual based on ability to pay or source of payment;
- 737 (B) provide the services to all individuals in accordance with the patient selection criteria developed
738 by appropriate medical professionals, and approved by the Department; and
- 739 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
740 source provided annually.

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

743 (v) The applicant shall provide the Department with a notice stating the date on which the first
744 transplant procedure is performed and such notice shall be submitted to the Department consistent with
745 applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and
746 autologous procedures also shall notify the Department when it begins to perform either allogeneic or
747 autologous procedures, whichever was not performed initially by the applicant.

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

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

756
757 ~~(2) The agreements and assurances required by this section, as applicable, shall be in the shall be~~
758 ~~in the form of a certification agreed to by the applicant or its authorized agent, authorized by the~~
759 ~~governing body of the applicant or its authorized agent.~~

761 **Section 78. Documentation of projections**

762
763 Sec. 78. An applicant required to project volumes of service under Section 3 shall specify how
764 the volume projections were developed. THE APPLICANT SHALL USE RELEVANT AND
765 UNDUPLICATED DATA FOR PATIENTS IN THE SAME PLANNING AREA AS THE PROPOSED
766 BMT SERVICE, WHICH IS VERIFIABLE FROM THE MOST RECENT STATEWIDE TUMOR
767 REGISTRY. THE APPLICANT SHALL COUNT ONLY NEW CANCER CASES THAT ARE
768 APPROPRIATE FOR REFERRAL FOR BONE MARROW TRANSPLANTATION SERVICES AND
769 FROM THE AGE GROUPING OF PATIENTS BASED ON THE TYPE OF SERVICE TO BE
770 OFFERED. This specification of projections shall include a N description of the data source(s) used,
771 assessments of the accuracy of these data PROJECTIONS, and OF the statistical method used to
772 make the projections. Based on this documentation, the Department shall determine if the projections
773 are reasonable.

774 **Section 8. Requirements for approval – acquisition of a bone marrow transplantation service** 775 **by a cancer hospital**

776
777
778 ~~(1) An applicant proposing to acquire an existing bone marrow transplantation service shall~~
779 ~~demonstrate that it meets all of the requirements of this subsection and shall not be required to be in~~
780 ~~compliance with section 3(5) and the department inventory.~~

781 ~~(a) The total number of bone marrow transplantation services is not increased in the planning~~
782 ~~area as the result of the acquisition.~~

783 ~~(b) As part of the acquisition of the bone marrow transplantation service, the acquisition or~~
784 ~~replacement of the cancer hospital, or for any other reasons, the location of the bone marrow~~
785 ~~transplantation service shall be located at its prior location or in space within the licensed cancer~~
786 ~~hospital site.~~

787 ~~(c) The applicant is a cancer hospital as defined by these standards. The applicant shall, to the~~
788 ~~satisfaction of the Department, provide verification of PPS exemption at the time of application, or~~
789 ~~shall demonstrate compliance with the following to the satisfaction of the Department:~~

790 ~~(i) The applicant, or an affiliate of the applicant, operates a comprehensive cancer center~~
791 ~~recognized by the National Cancer Institute in conjunction with a Michigan university that is~~
792 ~~designated as a comprehensive cancer center, or the applicant is the Michigan university that is~~
793 ~~designated as a comprehensive cancer center.~~

794 ~~(ii) The applicant commits to provide evidence, satisfactory to the Department, of approval as a~~
795 ~~PPS-exempt hospital within the time limits specified in subsection (g).~~

796 ~~(d) The applicant demonstrates that it meets, directly or through arrangements with the hospital~~
797 ~~from which it acquires the bone marrow transplantation service, the requirements set forth under~~
798 ~~section 3(3), (6), (7), and (8), as applicable.~~

799 ~~(e) The applicant agrees to either have a written consulting agreement as required by Section~~
800 ~~3(10) or obtain a determination by the Department that such an agreement is not required because~~

801 ~~the existing bone marrow transplantation staff, services, and program substantially will continue to be~~
802 ~~in place after the acquisition.~~

803 ~~_____ (f) The applicant agrees and assures to comply, either directly or through arrangements with~~
804 ~~the hospital from which it acquires the bone marrow transplantation service, with all applicable project~~
805 ~~delivery requirements.~~

806 ~~_____ (g) If the applicant described in this subsection does not meet the Title XVIII requirements of~~
807 ~~the Social Security Act for exemption from PPS within 24 months after receiving CON approval under~~
808 ~~this section, the Department may extend the 24-month deadline to no later than the last session day~~
809 ~~permitted by the United States Constitution for the next United States Congress in session after the~~
810 ~~effective date of these standards. Extension of the deadline shall require demonstration by the~~
811 ~~applicant, to the satisfaction of the Department, that there has been progress toward achieving the~~
812 ~~changes in federal law and regulations that are required to secure the PPS exemption. If the applicant~~
813 ~~fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or its possible~~
814 ~~extension, then the CON granted pursuant to this section shall expire automatically and will not be~~
815 ~~subject to further applications for acquisition. However, prior to the final deadline for the expiration of~~
816 ~~the CON, the prior holder of the (CON/authorization) to provide the bone marrow transplantation~~
817 ~~service may apply for acquisition of the service, pursuant to all the provisions of this section, except~~
818 ~~for subsection (c).~~

819 ~~_____~~
820 ~~_____ 2. Applicants proposing to acquire an existing bone marrow transplantation service under this~~
821 ~~section shall not be subject to comparative review.~~

822
823 **Section 9. Health Service Areas**

824
825 Sec. 9. Counties assigned to each health service area are as follows:

826
827

HSA	COUNTIES		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw

828
829
830
831
832

833	2	Clinton	Hillsdale	Jackson
834		Eaton	Ingham	Lenawee
835				
836	3	Barry	Calhoun	St. Joseph
837		Berrien	Cass	Van Buren
838		Branch	Kalamazoo	
839				
840	4	Allegan	Mason	Newaygo
841		Ionia	Mecosta	Oceana
842		Kent	Montcalm	Osceola
843		Lake	Muskegon	Ottawa
844				
845	5	Genesee	Lapeer	Shiawassee
846				
847	6	Arenac	Huron	Roscommon
848		Bay	Iosco	Saginaw
849		Clare	Isabella	Sanilac
850		Gladwin	Midland	Tuscola
851		Gratiot	Ogemaw	
852				
853	7	Alcona	Crawford	Missaukee
854		Alpena	Emmet	Montmorency
855		Antrim	Gd Traverse	Oscoda
856		Benzie	Kalkaska	Otsego
857		Charlevoix	Leelanau	Presque Isle
858		Cheboygan	Manistee	Wexford
859				
860				
861	8	Alger	Gogebic	Mackinac
862		Baraga	Houghton	Marquette
863		Chippewa	Iron	Menominee
864		Delta	Keweenaw	Ontonagon
865		Dickinson	Luce	Schoolcraft
866				

867 | **Section 10. Department Inventory of Bone Marrow TransplantationBMT Services**

868
869 Sec 10. The Department shall maintain, and provide on request, a listing of the Department
870 | Inventory of bone marrow transplantationBMT services.

871
872 | **Section 11. Effect on prior CON Review Standards; comparative reviews**

873
874 Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for
875 | Extrarenal Transplantation Services pertaining to bone marrow transplantationBMT services approved by
876 | the CON Commission on December 12, 2006SEPTEMBER 16, 2008 and effective on March 8,
877 | 2007NOVEMBER 13, 2008.

878
879 (2) Projects reviewed under these standards shall be subject to comparative review.