

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 under Part
13 222 of the Code. Pursuant to Part 222 of the Code, BMT is a covered clinical service. The Department
14 shall use these standards in applying Section 22225(1) of the Code being Section 333.22225(1) of the
15 Michigan Compiled Laws and Section 22225(C) of the Code, being Section 333.22225(2)(C) of the
16 Michigan Compiled Laws.
17

18 (2) A BMT service listed on the Department inventory that is located at a hospital site and initially
19 does not perform both allogeneic and autologous procedures shall not be required to obtain separate
20 CON approval to begin performing both autologous and allogeneic BMT procedures.
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22 (3) An existing BMT service that performs only adult procedures shall require separate CON
23 approval in order to perform pediatric procedures. An existing BMT service that performs only pediatric
24 procedures shall require separate CON approval in order to perform adult procedures.
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26 **Section 2. Definitions**

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

29 (a) "Acquisition of a BMT service" means the acquisition (including purchase, lease, donation, or
30 other arrangement) of an existing BMT service.

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

32 (c) "Allogeneic" means transplantation between genetically nonidentical individuals of the same
33 species.

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

35 (e) "Bone marrow transplantation service" or "BMT service" means the transplantation of
36 proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow,
37 the peripheral circulation, cord blood, or any other source.

38 (f) "Cancer hospital" means a hospital that has been approved to participate in the Title XVIII
39 (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with Section
40 1886 (d)(1)(B)(v) of the Social Security Act, as amended.

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

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

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

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

49 (k) "Department inventory of BMT services" means the list maintained by the Department of: (i) the
50 bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former
51 Part 221; (ii) operating BMT services for which the operation of that service did not require a CON; and
52 (iii) BMT services that are not yet operational but have a valid CON issued under Part 222. The list shall

53 inventory adult and pediatric services separately and shall specify the site at which the BMT service is
54 authorized.

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

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

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

63 (o) "Initiate a BMT service" means to begin operation of a BMT service at a site that does not
64 provide either adult or pediatric BMT services and is not listed on the Department inventory as of the date
65 an application is submitted to the Department. The term includes an adult service that is proposing to
66 provide a pediatric BMT service, and a pediatric service that is proposing to provide an adult BMT
67 service. The term does not include beginning operation of a BMT service by a cancer hospital which
68 acquires an existing BMT service provided that all of the staff, services, and programs required under
69 section 3(3) are to be provided by the cancer hospital and/or by the hospital from which the BMT service
70 is being acquired.

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

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

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

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

79 (t) "Planning area" means:

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

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

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

90 (v) "Survival rate" means the rate calculated using the Kaplan-Meier technique and the following:

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

106 analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last
107 ascertained survival.

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

112
113 (2) The definitions of Part 222 shall apply to these standards.

114 115 **Section 3. Requirements to initiate a BMT service**

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117 Sec. 3. An applicant proposing to initiate a BMT service shall demonstrate the following
118 requirements:

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

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

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

128 (a) operating rooms.

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

131 (c) dialysis.

132 (d) inpatient-outpatient social work.

133 (e) inpatient-outpatient psychiatry/psychology.

134 (f) clinical research.

135 (g) a microbiology and virology laboratory.

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

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

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

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

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

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

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

149 (i) anesthesiology.

150 (ii) cardiology.

151 (iii) critical care medicine.

152 (iv) gastroenterology.

153 (v) general surgery.

154 (vi) hematology.

155 (vii) infectious diseases.

156 (viii) nephrology.

157 (ix) neurology.

158 (x) oncology.

- 159 (xi) pathology, including blood banking experience.
160 (xii) pulmonary medicine.
161 (xiii) radiation oncology.
162 (xiv) radiology.
163 (xv) urology.
164 (o) One or more consulting physicians who are board-certified or board-eligible in each of the
165 following specialties. For an applicant proposing to perform pediatric BMT procedures, these specialists
166 shall have specific experience in the care of pediatric patients.
167 (i) dermatology.
168 (ii) immunology.
169 (iii) neurosurgery.
170 (iv) orthopedic surgery.

171
172 (4) An applicant must provide an implementation plan for the proposed BMT service.
173 "Implementation plan" means a plan that documents how a proposed BMT service will be initiated within
174 the time period specified in these standards or the CON rules. At a minimum, the implementation plan
175 shall identify:

- 176 (a) each component or activity necessary to begin performing the proposed BMT service including,
177 but not limited to, the development of physical plant requirements, such as an intensive care unit capable
178 of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all
179 physician and support staff;
180 (b) the time table for completing each component or activity specified in subsection (a); and
181 (c) if the applicant previously has been approved for a BMT service for which either the CON
182 expired or the service did not perform a transplant procedure during any consecutive 12-month period,
183 what changes have or will be made to ensure that the proposed service can be initiated and provided on
184 a regular basis.

185
186 (5)(a) An applicant shall demonstrate that the number of existing adult BMT services does not exceed
187 three (3) adult BMT services in planning area one identified in Section 2(1)(t)(i) or one (1) adult BMT
188 service in planning area two identified in Section 2(1)(t)(ii) and that approval of the proposed application
189 will not result in the total number of adult BMT services exceeding the need for each specific planning
190 area.

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

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

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

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

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

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213 (8) An applicant shall demonstrate that the licensed site at which the proposed BMT service is
214 proposed has an institutional review board.
215
216 (9) An applicant proposing to initiate a pediatric BMT service shall demonstrate that the licensed
217 site at which the pediatric transplant procedures will be performed has each of the following:
218 (a) a designated pediatric inpatient oncology unit.
219 (b) a pediatric inpatient intensive care unit.
220 (c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer
221 Group (CCG).
222 (d) a pediatric tumor board that meets on a regularly scheduled basis.
223 (e) family support group services, provided either directly or through written agreements.
224 (f) a pediatric cancer program with the following staff:
225 (i) a director who is either a board-certified immunologist who has specific training and experience
226 in BMT or a board-certified pediatric hematologist/oncologist.
227 (ii) nurses with training and experience in pediatric oncology.
228 (iii) social workers with training and experience in pediatric oncology.
229 (iv) pediatric psychologists.
230 (v) child life specialists.
231
232 (10)(a) An applicant proposing to initiate either a new adult or pediatric BMT service shall submit, in its
233 application, a written consulting agreement with an existing BMT service. The written consulting
234 agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular
235 Therapy (FACT) accredited transplant unit that performs both allogenic and autologous transplants for
236 either adult and/or pediatrics. The terms of the agreement and the roles and responsibilities of both the
237 existing and proposed service shall include at least the following:
238 (i) The term of the written consulting agreement is no less than 36 months after the proposed
239 service begins to perform BMT procedures.
240 (ii) One or more representatives of the existing BMT service have been designated as staff
241 responsible for carrying out the roles and responsibilities of the existing service.
242 (iii) The existing service shall evaluate and make recommendations to the proposed service on
243 policies and procedures, including time tables, for at least each of the following:
244 (A) nursing services.
245 (B) infection control.
246 (C) nutritional support.
247 (D) staff needs and training.
248 (E) inpatient and outpatient medical coverage.
249 (F) transfusion and blood bank policies.
250 (G) transplant treatment protocols.
251 (H) hematopoiesis laboratory services and personnel.
252 (I) data management.
253 (J) quality assurance program.
254 (iv) Specify a schedule of site visits by staff of the existing BMT service that, at a minimum,
255 includes:
256 (A) 3 visits during the first 12-months of operation of the proposed service.
257 (B) 3 visits during each the second 12-months and third 12-months of operation of the proposed
258 service.
259 (v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed
260 service and make recommendations related to quality assurance mechanisms of the proposed service,
261 including at least each of the following:
262 (A) a review of the number of patients transplanted.
263 (B) transplant outcomes.

- 264 (C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this
265 agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
266 (D) all deaths occurring within 100 days from transplant.
267 (E) each of the requirements of subdivision (iii).
268 (vi) Specify that a written report and minutes of each site visit shall be completed by the existing
269 BMT service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports
270 and minutes shall be available to the Department upon request. At a minimum, the written report shall
271 address each of the items in subdivision (v).
272 (vii) Specify that the existing BMT service shall notify the Department and the proposed service
273 immediately if it determines that the proposed service may not be in compliance with any applicable
274 quality assurance requirements, and develop jointly with the proposed service a plan for immediate
275 remedial actions.
276 (viii) Specify that the existing BMT service shall notify the Department immediately if the consulting
277 agreement required pursuant to these standards is terminated and that the notification shall include a
278 statement describing the reasons for the termination.
279 (b) For purposes of subsection (10), "existing BMT service" means a service that meets all of the
280 following:
281 (i) currently is performing and is FACT accredited in, the types of transplants (allogeneic and
282 autologous; adult or pediatric) proposed to be performed by the applicant;
283 (ii) currently is certified as a National Marrow Donor Program; and
284 (iii) is located in the United States.
285 (c) An applicant shall document that the existing BMT service meets the requirements of
286 subsection (b).
287

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

- 289
290 (1) An applicant proposing to acquire an existing BMT service shall demonstrate that it meets
291 all of the requirements of this subsection and shall not be required to be in compliance with Section
292 3(5) and the department inventory.
293 (a) The total number of BMT services is not increased in the planning area as the result of the
294 acquisition.
295 (b) As part of the acquisition of the BMT service, the acquisition or replacement of the cancer
296 hospital, or for any other reasons, the location of the BMT service shall be located at its prior location
297 or in space within the licensed cancer hospital site.
298 (c) The applicant is a cancer hospital as defined by these standards. The applicant shall, to the
299 satisfaction of the Department, provide verification of PPS-exemption at the time of application, or
300 shall demonstrate compliance with the following to the satisfaction of the Department:
301 (i) The applicant, or an affiliate of the applicant, operates a comprehensive cancer center
302 recognized by the National Cancer Institute in conjunction with a Michigan university that is
303 designated as a comprehensive cancer center, or the applicant is the Michigan university that is
304 designated as a comprehensive cancer center.
305 (ii) The applicant commits to provide evidence, satisfactory to the Department, of approval as a
306 PPS-exempt hospital within the time limits specified in subsection (g).
307 (d) The applicant demonstrates that it meets, directly or through arrangements with the hospital
308 from which it acquires the BMT service, the requirements set forth under Section 3(3), (6), (7), and (8),
309 as applicable.
310 (e) The applicant agrees to either have a written consulting agreement as required by Section
311 3(10) or obtain a determination by the Department that such an agreement is not required because
312 the existing BMT staff, services, and program substantially will continue to be in place after the
313 acquisition.
314 (f) The applicant agrees and assures to comply, either directly or through arrangements with
315 the hospital from which it acquires the BMT service, with all applicable project delivery requirements.

316 (g) If the applicant described in this subsection, **OR AN APPLICANT PREVIOUSLY**
 317 **APPROVED UNDER THIS SUBSECTION**, does not meet the Title XVIII requirements of the Social
 318 Security Act for exemption from PPS within 24 months after receiving CON approval under this
 319 section **OR SUCH LATER DATE AS THE DEPARTMENT MAY HAVE PREVIOUSLY APPROVED**,
 320 the Department may extend the 24-month deadline to no later than the last session day permitted by
 321 the **United States Constitution for the 113TH United States Congress**. Extension of the deadline
 322 **UNTIL THE END OF THE 113TH CONGRESS** shall require **THE FILING OF A CON APPLICATION**
 323 **UNDER THIS SECTION THAT PROVIDES** demonstration by the applicant, to the satisfaction of the
 324 Department, that **THE APPLICANT IS CONTINUING TO PURSUE** the PPS exemption. If the
 325 applicant fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or
 326 its possible extension^S, then the Department may expire the CON granted pursuant to this
 327 **SUBSECTION**. However, prior to the **DEPARTMENT EXPIRING** the CON, the **ORIGINAL** holder of the
 328 **CON** to provide the BMT service may apply for acquisition of the service, pursuant to all the provisions
 329 of this section, except for **subsectionS (c) AND (G)**.

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

333 **Section 5. Review standards for comparative reviews**

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

339
 340 (2) Each application in a comparative group shall be individually reviewed to determine whether
 341 the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225
 342 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these
 343 standards. If the Department determines that two or more competing applications satisfy all of the
 344 requirements for approval, these projects shall be considered qualifying projects. The Department shall
 345 approve those qualifying projects which, when taken together, do not exceed the need, as defined in
 346 Section 22225(1) being Section 333. 22225(1) of the Michigan Compiled Laws, and which have the
 347 highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects
 348 are determined to have an identical number of points, then the Department shall approve those qualifying
 349 projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the Code,
 350 being Section 333. 22225(1) of the Michigan Compiled Laws, in the order in which the applications were
 351 received by the Department, based on the date and time stamp placed on the applications by the CON
 352 administrative unit of the Department responsible for administering the CON program when an application
 353 is submitted.

354
 355 (3)(a) A qualifying project will have points awarded based on the straight-line distance to the nearest
 356 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

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

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

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

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

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

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

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

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

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

395 (IV) therapeutic drug monitoring.

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

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

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

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

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

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

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

413 The applicant shall receive points, up to a maximum of three (3), for this criterion according to the
414 following schedule:
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Number of BMT Support Personnel/Services Available	Points
zero or one	0

two to five	1
six to nine	2
ten or eleven	3

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(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 approval -- all applicants

Sec. 6. An applicant shall provide verification of Medicaid participation. An applicant that is initiating a new service or 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

Sec. 7. (1) An applicant shall agree that, if approved, the BMT service shall be delivered in compliance with the following terms of CON approval:

- (a) 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.
 - (b) Compliance with applicable safety and operating standards.
 - (c) Compliance with the following quality assurance standards, as applicable, no later than the date the first BMT procedure, allogeneic or autologous, is performed:
 - (i) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:
 - (A) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.
 - (B) a cytogenetics and/or molecular genetic laboratory.
 - (C) a processing and cryopreservation laboratory that meets the standards of the FACT or an equivalent organization.
 - (D) 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.
 - (E) 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).
 - (F) therapeutic drug monitoring.
 - (ii) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:
 - (A) 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.
 - (B) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

467 (iii) An applicant shall establish and maintain written policies related to outpatient care for BMT
468 patients, including at least the following:
469 (A) the ability to evaluate and provide treatment on a 24-hour basis.
470 (B) nurses experienced in the care of BMT patients.
471 (C) a designated outpatient area for patients requiring long-duration infusions or the administration
472 of multiple medications or blood product transfusions.
473 (iv) A BMT service shall establish and maintain a dedicated transplant team that includes at least
474 the following staff:
475 (A) a transplant team leader, who is a physician that is board-certified in at least one of the
476 following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as
477 appropriate, and has had either at least one year of specific clinical training or two years of experience,
478 both inpatient and outpatient, as an attending physician principally responsible for the clinical
479 management of patients treated with hematopoietic transplantation. The team leader's experience shall
480 include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the
481 transplant team leader shall include overseeing the medical care provided by attending physicians,
482 reporting required data to the Department, and responsibility for ensuring compliance with the all
483 applicable project delivery requirements.
484 (B) one or more attending physicians with specialized training in pediatric and/or adult BMT, as
485 appropriate. At least one attending physician shall have specialized training in allogeneic transplantation,
486 adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in
487 hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.
488 (C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric,
489 as appropriate, in at least the following specialties: cardiology, gastroenterology nephrology, psychiatry,
490 pulmonary medicine, and critical care medicine.
491 (D) on-site availability of board-certified or board-eligible consulting physicians in the following areas:
492 anatomic pathology with competence in graft versus host disease (services performing allogeneic
493 transplants) and other opportunistic diseases (services performing allogeneic and autologous transplants),
494 infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience
495 in total body irradiation.
496 (E) a transplant team coordinator, who shall be responsible for providing pre-transplant patient
497 evaluation and coordinating treatment and post-transplant follow-up and care.
498 (F) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical
499 status.
500 (G) nurses with specialized training in pediatric and/or adult, as appropriate, BMT,
501 hematology/oncology patient care, administration of cytotoxic therapies, management of infectious
502 complications associated with compromised host-defense mechanisms, administration of blood components,
503 the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.
504 (H) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the
505 hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.
506 (I) dietary staff capable of providing dietary consultations regarding a patient's nutritional status,
507 including total parenteral nutrition.
508 (J) designated social services staff.
509 (K) designated physical therapy staff.
510 (L) data management personnel designated to the BMT service.
511 (M) for an applicant performing pediatric BMT, a child-life specialist.
512 (v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall
513 include a patient ombudsman, who is familiar with the BMT service, but who is not a member of the
514 transplant team.
515 (vi) An applicant shall develop and maintain patient management plans and protocols that include the
516 following:
517 (A) therapeutic and evaluative procedures for the acute and long-term management of a patient.
518 (B) patient management and evaluation during the waiting, in-hospital and immediate post-
519 discharge phases of the service.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

567 (A) disease type.

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

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

570 (D) patient age, i.e., adult or pediatric as defined by these standards.

571 (E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.

572 (F) relapse rates at 6-months, 1-year, and 5-years post-transplant.

- 573 (G) median follow-up, and patients lost-to-followup.
574 (H) cause(s) of death, if applicable.
575 (I) additional summary information, as applicable.
576 An applicant annually shall report for its BMT service annual and cumulative survival rates by type of
577 transplant performed reported in actual number of transplants by disease category, transplant type, i.e.,
578 related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e.,
579 adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and
580 five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death
581 occurring within 100 days from BMT.
582 (iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing
583 information on its patients being evaluated for transplant and on its transplant recipients and shall participate
584 in the national and international registries applicable to the BMT service.
585 (iv) An applicant, to assure that the BMT service(s) will be utilized by all segments of the Michigan
586 population, shall:
587 (A) not deny the services to any individual based on ability to pay or source of payment;
588 (B) provide the services to all individuals in accordance with the patient selection criteria developed
589 by appropriate medical professionals, and approved by the Department; and
590 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
591 source provided annually.
592 Compliance with selective contracting requirements shall not be construed as a violation of this
593 term.
594 (v) The applicant shall provide the Department with a notice stating the date on which the first
595 transplant procedure is performed and such notice shall be submitted to the Department consistent with
596 applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and
597 autologous procedures also shall notify the Department when it begins to perform autologous
598 procedures.
599 (vi) An applicant shall notify the Department immediately if the consulting agreement required
600 pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of
601 operation of the BMT service. The notification shall include a statement describing the reasons for the
602 termination. An applicant shall have 30 days following termination of that agreement to enter into a
603 written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide
604 the Department with a copy of that written consulting agreement.
605 (vii) The Department may use the information provided pursuant to Section 3(10) of these
606 standards in evaluating compliance with the requirements of this section.
607
608 (2) The agreements and assurances required by this section shall be in the form of a certification
609 agreed to by the applicant or its authorized agent.
610

611 **Section 8. Documentation of projections**

612
613 Sec. 8. An applicant required to project volumes of service under Section 3 shall specify how the
614 volume projections were developed. The applicant shall use relevant and unduplicated data for
615 patients in the same planning area as the proposed BMT service, which are verifiable from the most
616 recent statewide tumor registry. The applicant shall only include new cancer cases that are
617 appropriate for referral for BMT services and from the age grouping of patients based on the type of
618 service to be offered. This specification of projections shall include an assessment of the accuracy of
619 projections, and of the statistical method used to make the projections. Based on this documentation,
620 the Department shall determine if the projections are reasonable.
621

622 **Section 9. Health Service Areas**

623
624 Sec. 9. Counties assigned to each health service area are as follows:
625

	HSA		COUNTIES	
626				
627				
628	1	Livingston	Monroe	St. Clair
629		Macomb	Oakland	Washtenaw
630		Wayne		
631				

632	2	Clinton	Hillsdale	Jackson
633		Eaton	Ingham	Lenawee
634				
635	3	Barry	Calhoun	St. Joseph
636		Berrien	Cass	Van Buren
637		Branch	Kalamazoo	
638				
639	4	Allegan	Mason	Newaygo
640		Ionia	Mecosta	Oceana
641		Kent	Montcalm	Osceola
642		Lake	Muskegon	Ottawa
643				
644	5	Genesee	Lapeer	Shiawassee
645				
646	6	Arenac	Huron	Roscommon
647		Bay	Iosco	Saginaw
648		Clare	Isabella	Sanilac
649		Gladwin	Midland	Tuscola
650		Gratiot	Ogemaw	
651				
652	7	Alcona	Crawford	Missaukee
653		Alpena	Emmet	Montmorency
654		Antrim	Gd Traverse	Oscoda
655		Benzie	Kalkaska	Otsego
656		Charlevoix	Leelanau	Presque Isle
657		Cheboygan	Manistee	Wexford
658				
659				
660	8	Alger	Gogebic	Mackinac
661		Baraga	Houghton	Marquette
662		Chippewa	Iron	Menominee
663		Delta	Keweenaw	Ontonagon
664		Dickinson	Luce	Schoolcraft

665
666 **Section 10. Department Inventory of BMT Services**

667
668 Sec 10. The Department shall maintain, and provide on request, a listing of the Department
669 Inventory of BMT services.

670
671 **Section 11. Effect on prior CON Review Standards; comparative reviews**

672
673 Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for
674 Extrarenal ORGAN Transplantation Services pertaining to BMT services approved by the CON
675 Commission on MARCH 25, 2010 and effective on MAY 28, 2010.

676
677 (2) Projects reviewed under these standards shall be subject to comparative review **EXCEPT FOR**
678 **SECTION 4.**

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