

1 | MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

2
3 | CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
4 | PANCREAS TRANSPLANTATION 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.)
9

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~~
14 | ~~pancreas transplantation services. PURSUANT TO PART 222 OF THE CODE.~~

15
16 | ~~(2) Pancreas transplantation is a covered clinical service for purposes of Part 222 of the Code.~~

17
18 | ~~(3) The Department shall use sections 3 and 5, as applicable, THESE STANDARDS in applying~~
19 | ~~Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

20
21 | ~~(4) The Department shall use Section 4, as applicable, in applying AND Section 22225(2)(c)~~
22 | ~~of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

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24 | **Section 2. Definitions**

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

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

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

31 | (c) "Department" means the Michigan Department of Community Health (MDCH).

32 | ~~(d) "Implementation plan" means a plan that documents how a proposed pancreas transplantation~~
33 | ~~service will be initiated within the time period specified in these standards or the CON rules. At a~~
34 | ~~minimum, the implementation plan shall identify: (i) each component or activity necessary to begin~~
35 | ~~performing the proposed pancreas transplantation service including but not limited to the development of~~
36 | ~~physical plant requirements such as an intensive care unit capable of treating immune-suppressed~~
37 | ~~patients, equipment acquisition(s), and recruitment and employment of all physician and support staff; (ii)~~
38 | ~~the time table for completing each component or activity specified in subsection (i); and (iii) if the~~
39 | ~~applicant has previously been approved for a pancreas transplantation service where either the CON~~
40 | ~~expired or the service did not perform a transplant procedure during any consecutive 12-month period,~~
41 | ~~what changes have or will be made to ensure that the proposed service can be initiated and provided on~~
42 | ~~a regular basis.~~

43 | ~~(eD) "Initiate" or "implement" for purposes of these standards, means the performance of the first~~
44 | ~~transplant procedure. If the CON rules do not authorize a CON review standard to define the term of the~~
45 | ~~certificate, the term shall be as provided in Rule 325.9403(1) and (2). If the CON rules do authorize a~~
46 | ~~standard to define the term of a certificate, the term shall be 18 months or the extended period~~
47 | ~~established by Rule 325.9403(2), if authorized.~~

48 | ~~(fE) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility~~
49 | ~~authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital~~
50 | ~~with multiple sites, the location of each separate and distinct inpatient unit of the health facility as~~
51 | ~~authorized by license and listed on that licensee's certificate of licensure.~~

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

54 | (hG) "OPO" or "Organ Procurement Organization" means an organ procurement organization as
55 | defined by Title 42, Part 486.302.

56 | (iH) "OPTN" or "Organ Procurement and Transplantation Network" means the organization
57 | contracted by the federal Department of Health and Human Services to operate the organ procurement
58 | and transplantation network.

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

77

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

79

80 | **Section 3. Requirements for approval -- all applicants**

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82 | Sec. 3. (1) An applicant proposing to perform a pancreas transplantation service shall demonstrate
83 | that it offers all of the following services or programs on site:

84 | (a) operating rooms;

85 | (b) anesthesiology;

86 | (c) microbiology and virology laboratory;

87 | (d) continuous availability, either on-site or on-call, of diagnostic imaging services including: (i) CT
88 | scanning, (ii) magnetic resonance imaging, and (iii) nuclear medicine;

89 | (e) continuous availability, either on-site or on-call, of a broad range of sub-specialty consultants,
90 | adult and pediatric, as appropriate, in both medical and surgical specialties including but not limited to:
91 | pulmonary medicine with respiratory therapy support; cardiology; gastroenterology; pediatrics, as
92 | appropriate; nephrology; and immunology;

93 | (f) dialysis;

94 | (g) infectious disease;

95 | (h) inpatient-outpatient social work;

96 | (i) inpatient-outpatient psychiatry/psychology;

97 | (j) clinical research;

98 | (k) a histocompatibility laboratory that meets the standards of the American Society for
99 | Histocompatibility and Immunogenetics or an equivalent organization, either on-site or through written
100 | agreement;

101 | (l) other support services, as necessary, such as physical therapy and rehabilitation medicine;

102 | (m) continuous availability of anatomic and clinical pathology and laboratory services including
103 | clinical chemistry, immuno-suppressive drug monitoring, and tissue typing;

- 104 (n) continuous availability of red cells, platelets, and other blood components;
105 (o) an established organ donation protocol, with brain death protocol, consistent with applicable
106 Michigan law; and
107 (p) a written agreement with Michigan's federally designated organ procurement organization
108 (OPO) to promote organ donation at the applicant hospital(s).
109

110 (2) An applicant must provide, ~~at the time the CON application is submitted,~~ an implementation
111 plan for the proposed pancreas transplantation service. IMPLEMENTATION PLAN MEANS A PLAN
112 THAT DOCUMENTS HOW A PROPOSED PANCREAS TRANSPLANTATION SERVICE WILL BE
113 INITIATED WITHIN THE TIME PERIOD SPECIFIED IN THESE STANDARDS OR THE CON RULES.
114 AT A MINIMUM, THE IMPLEMENTATION PLAN SHALL IDENTIFY:

115 (A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE
116 PROPOSED PANCREAS TRANSPLANTATION SERVICE INCLUDING BUT NOT LIMITED TO THE
117 DEVELOPMENT OF PHYSICAL PLANT REQUIREMENTS SUCH AS AN INTENSIVE CARE UNIT
118 CAPABLE OF TREATING IMMUNO-SUPPRESSED PATIENTS, EQUIPMENT ACQUISITION(S), AND
119 RECRUITMENT AND EMPLOYMENT OF ALL PHYSICIAN AND SUPPORT STAFF;

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

122 (C) IF THE APPLICANT HAS PREVIOUSLY BEEN APPROVED FOR A PANCREAS
123 TRANSPLANTATION SERVICE WHERE EITHER THE CON EXPIRED OR THE SERVICE DID NOT
124 PERFORM A TRANSPLANT PROCEDURE DURING ANY CONSECUTIVE 12-MONTH PERIOD, WHAT
125 CHANGES HAVE OR WILL BE MADE TO ENSURE THAT THE PROPOSED SERVICE CAN BE
126 INITIATED AND PROVIDED ON A REGULAR BASIS.
127

128 (3) An applicant for a pancreas transplantation service shall project a minimum of 42 pancreas
129 transplantation procedures annually in the second 12 months of operation following the date on which the
130 first pancreas transplant procedure is performed ~~and annually thereafter.~~
131

132 (4) An applicant proposing to provide a pancreas transplantation service shall demonstrate that it
133 offers all of the following services or programs:

- 134 (a) continuous availability, either on-site or on-call, of angiography;
135 (b) an intensive care unit with 24 hour per day on-site physician coverage;
136 (c) an on-site renal transplant service that has performed a minimum of 80 kidney transplants in
137 the 2 most recent 12 month periods for which verifiable data are available; and
138 (d) ophthalmology retinal eye service availability, either on site or on call.
139

140 (5) An applicant shall provide verification of Medicaid participation ~~at the time the application~~
141 ~~is submitted to the Department.~~ AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY
142 ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE
143 PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES
144 IF A CON IS APPROVED. ~~If the required documentation is not submitted with the application on the~~
145 ~~designated application date, the application will be deemed filed on the first applicable designated~~
146 ~~application date after all required documentation is received by the Department.~~
147

148 **Section 4. Project delivery requirements -- terms of approval for all applicants**

149

150 Sec. 4. (1) An applicant shall agree that, if approved, the services shall be delivered in compliance
151 with the following terms of CON approval:

152 (a) Compliance with these standards. An applicant shall immediately report to the Department any
153 changes in key staff or other aspects of the pancreas transplantation service that may affect its ability to
154 comply with these standards.

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

- 156 (c) Compliance with the following quality assurance standards, as applicable:
- 157 (i) The applicant shall perform A MINIMUM OF 2 PANCREAS TRANSPLANTATION
- 158 PROCEDURES ANNUALLY IN THE SECOND 12 MONTHS OF OPERATION FOLLOWING THE DATE
- 159 ON WHICH THE FIRST PANCREAS TRANSPLANT PROCEDURE IS PERFORMED~~the applicable~~
- 160 ~~required volumes within the time periods specified in these standards,~~ and annually thereafter.
- 161 (ii) THE APPLICANT SHALL PERFORM A MINIMUM OF 80 KIDNEY TRANSPLANTS AND/OR
- 162 PANCREAS TRANSPLANTATION PROCEDURES BY THE SECOND 12 MONTHS OF OPERATION
- 163 FOLLOWING THE DATE ON WHICH THE FIRST PANCREAS TRANSPLANT PROCEDURE IS
- 164 PERFORMED AND BIENNIALY (EVERY TWO YEARS) THEREAFTER.
- 165 (iii) The applicant shall comply with applicable OPTN and Medicare requirements.
- 166 (iiiV) The applicant shall have patient management plans and protocols that include the following: (A)
- 167 therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient
- 168 management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the
- 169 service; and (C) long-term management and evaluation, including education of the patient, liaison with the
- 170 patient's attending physician, and the maintenance of active patient records for at least five (5) years.
- 171 (iv) The applicant shall implement a program of education and training for nurses, technicians,
- 172 service personnel, and other hospital staff.
- 173 (v) An applicant shall actively participate in the education of the general public and the medical
- 174 community with regard to pancreas transplantation, and will make organ donation literature available in
- 175 public areas of the institution.
- 176 (vi) The applicant shall establish and maintain an active, formal multi-disciplinary research program
- 177 related to the proposed pancreas transplantation service.
- 178 (vii) The applicant's education and research program related to pancreas transplantation shall be
- 179 subject to external peer review.
- 180 (viiiX) The applicant shall maintain an organized institutional transplant registry for recording ongoing
- 181 information on its patients being evaluated for transplant and on its transplant recipients and shall
- 182 participate in state and national transplantation registries applicable to the pancreas transplantation
- 183 service.
- 184 (ix) The applicant shall participate in a data collection network established and administered by the
- 185 Department or its designee. The data may include, but is not limited to, annual budget and cost
- 186 information, operating schedules, through-put schedules, demographic and diagnostic information, patient
- 187 survival rates at both 12 and 24 months following the transplant procedure, primary and secondary
- 188 diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the
- 189 volume of care provided to patients from all payor sources, and other data requested by the Department
- 190 and approved by the CON Commission. The applicant shall provide the required data on an individual
- 191 basis for each designated licensed site, in a format established by the Department, and in a mutually
- 192 agreed upon media. The Department may elect to verify the data through on-site review of appropriate
- 193 records.
- 194 (x) The applicant, to assure that the pancreas transplantation service will be utilized by all
- 195 segments of the Michigan population, shall:
- 196 (A) not deny the services to any individual based on ability to pay or source of payment;
- 197 (B) provide the services to all individuals in accordance with the patient selection criteria developed
- 198 by appropriate medical professionals, and approved by the Department; and
- 199 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
- 200 source provided annually.
- 201 Compliance with selective contracting requirements shall not be construed as a violation of this term.
- 202 (xi) The applicant shall provide the Department with a notice stating the date on which the first
- 203 transplant procedure is performed and such notice shall be submitted to the Department consistent with
- 204 applicable statute and promulgated rules.
- 205 (xii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two
- 206 years of operation and continue to participate annually thereafter.
- 207 (d) An applicant shall agree to establish and maintain all of the following:

- 208 (i) a written agreement with the federally approved organ procurement organization whose
- 209 designated service area includes the location of the proposed pancreas transplantation service;
- 210 (ii) organ preservation capability;
- 211 (iii) an organized 24-hour transport system for transportation of organs, donors, and blood serum;
- 212 (iv) an organized 24-hour communication service capable of serving the transplant team and
- 213 others, as appropriate;
- 214 (v) a laboratory with immunosuppression assay results available on the same day, as appropriate;
- 215 (vi) an immunologic monitoring laboratory;
- 216 (vii) a specialized inpatient pancreas transplantation unit or a combined inpatient renal and
- 217 extrarenal transplantation unit;
- 218 (viii) a medical staff and governing board policy that provides for the selection of candidates for
- 219 organ transplantation procedures in accordance with the patient selection criteria approved by the
- 220 Department;
- 221 (ix) an ethics committee or human use committee to review and approve the institution's protocols
- 222 related to organ transplantation, including protocols involving the selection of donors and recipients;
- 223 (x) a multi-disciplinary transplant recipient evaluation committee;
- 224 (xi) a histocompatibility laboratory that meets the standards of the American Society for
- 225 Histocompatibility and Immunogenetics or an equivalent organization, either operated on-site or through
- 226 written agreement;
- 227 (xii) insulin, C-peptide, glycosylated hemoglobin assays;
- 228 (xiii) glucometer glucose assay availability; and
- 229 (xiv) electromyography.
- 230 (e) An applicant shall agree that the pancreas transplantation service shall be staffed and provided
- 231 by at least the following:
- 232 (i) a transplant team leader and coordinator;
- 233 (ii) transplant surgeons and physicians experienced with renal transplantation in diabetics;
- 234 (iii) surgeons with demonstrated proficiency in major pancreatic surgery;
- 235 (iv) both adult and pediatric surgeons, as appropriate;
- 236 (v) qualified adult and pediatric, as appropriate, transplant surgeon(s) and transplant physician(s).
- 237 For purposes of evaluating subsection (v), the Department shall consider it prima facie evidence as to the
- 238 qualifications of the surgeon(s) and physician(s) if both the kidney and pancreas transplantation programs
- 239 are approved by and a member in good standing of the OPTN;
- 240 (vi) a pathologist capable of diagnosing pancreatic rejection; and
- 241 (vii) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used
- 242 in conjunction with the transplantation service, trained in the hemodynamic support of transplant patients,
- 243 and managing immuno-suppressed patients.

244 (f) Compliance with the REVISED Uniform Anatomical Gift Law, Act No. 186 of the Public Acts of

245 1986, being pursuant to MCL Section 333.10101 et seq. of the Michigan Compiled Laws.

246

247 (2) An applicant must demonstrate pancreatic graft survival rates at one year and two years after

248 transplantation of no less than the national average survival rate for the most recent year for which data is

249 published by the OPTN.

250

251 (3) The agreements and assurances required by this section, ~~as applicable,~~ shall be in the form of

252 a certification authorized by the governing body of AGREED TO BY the applicant or its authorized agent.

253

254 **Section 5. Documentation of projections**

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256 Sec. 5. An applicant required to project volumes of service under Section 3 shall specify how the

257 volume projections were developed. This specification of projections shall include a description of the

258 data source(s) used, assessments of the accuracy of these data, and the statistical method used to make

259 the projections. Based on this documentation, the Department shall determine if the projections are
260 reasonable.

261

262 **Section 6. Effect on prior CON review standards; comparative reviews**

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264 Sec. 6. (1) These CON review standards supersede and replace the CON Review Standards for
265 Pancreas Transplantation Services approved by the CON Commission on ~~September 26, 2002~~MARCH 9,
266 2004 and effective on ~~December 23, 2002~~JUNE 4, 2004.

267

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