

MICHIGAN DEPARTMENT OF PUBLIC HEALTH

CERTIFICATE OF NEED REVIEW STANDARDS FOR AIR AMBULANCE SERVICES

(By authority conferred on the Certificate of Need Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and Sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being Sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve air ambulance services.

(2) An air ambulance service is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use Sections 3, 4, 5, 6, 7, and 9, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 8, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5)(a) These standards shall apply to the review of all Certificate of Need applications for air ambulance services for which the Director of the Department of Public Health has not made a final decision under Section 22231(6) of the Code, being Section 333.22231(6) of the Michigan Compiled Laws, as of the effective date of these standards.

(b) In the case of an application which has been deemed submitted but which has not received a final decision by the Director on the effective date of these standards, the applicant may request and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(6) of the Code, being Section 333.22231(6) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.

(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8) of the Code, being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection, and shall consider the results of that hearing before a final decision is made.

Section 2. Definitions

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

(a) "Advanced life support services" means patient care that may include any care a paramedic is qualified to provide by paramedic education that meets the educational requirements established by the Department under Section 20912 of the Code, being Section 333.20912 of the Michigan Compiled Laws, or is authorized to provide by the protocols established by the local medical control authority under Section 20919 of the Code, being Section 333.20919 of the Michigan Compiled Laws, for a paramedic.

(b) "Advanced life support intercept," for purposes of these standards, means the use of an air ambulance to provide advanced life support services to a patient at the scene of an emergency that does not involve the transport of that patient by air.

(c) "Air ambulance," for purposes of these standards, means a rotary wing aircraft that is capable of providing treatment or transportation of a patient at or from the scene of an emergency. An air ambulance may also be used for the inter-facility transport of a patient requiring advanced life support, critical care

support or specialty care support services. The term does not include either a fixed wing aircraft; or an air ambulance licensed in a state other than Michigan that does not transport patients from the scene of an emergency in Michigan, except pursuant to mutual aid agreements, and which is not required to be licensed as an air ambulance under Part 209 of the Code, being Section 20901 et seq. of the Michigan Compiled Laws.

(d) "Air ambulance service" means the provision of emergency medical and air medical services by means of 1 or more air ambulances which operate in conjunction with a base of operations. The service shall be capable of providing at least advanced life support services but may include the provision of critical care or specialty care support services. Other functions of the service may include advanced life support intercepts, search and rescue, and emergency transportation of drugs, organs, medical supplies, equipment or personnel. An air ambulance service may operate an additional air ambulance for the purpose of a designated event with the prior notification and approval of the local medical control authority and the Department Division of Emergency Medical Services.

(e) "Air medical personnel" means the patient care staff involved in the provision of an air ambulance service and shall include at least 2 members, one of which shall be a paramedic licensed in Michigan.

(f) "Air medical service" means a service which provides air transportation to patients requiring medical care and has provisions for at least all of the following components:

(i) written policies and procedures specifying the mission statement and levels of patient care to be provided. The level of patient care provided shall be commensurate with the education and experience of the air medical team and the capabilities of the base of operations.

(ii) written patient care protocols including provisions for continuity of care;

(iii) written policies and procedures that define the roles and responsibilities of all air medical team members;

(iv) written operational policies and procedures addressing staff minimum licensure and/or certification requirements, work schedules and safety requirements;

(v) written policies and procedures addressing the appropriate use of air ambulance services;

(vi) a written communicable disease and infection control program;

(vii) a written plan for dealing with situations involving hazardous materials;

(viii) a planned and structured program for initial and continuing education and training, including didactic, clinical and in-flight, for all scheduled air medical team members appropriate for the respective duties and responsibilities;

(ix) written policies and procedures addressing the integration of the air medical service with public safety agencies governing the primary service area including but not limited to the federal aviation administration, medical control authorities, ground emergency vehicles and disaster planning;

(x) written policies and procedures governing the aircraft equipment and configuration, flight operations and communications;

(xi) a quality management program; and

(xii) a community education program.

(g) "Air medical team" means the personnel involved in the provision of an air ambulance service including the medical, aviation, maintenance, administrative and communication functions.

(h) "Acquisition of an existing air ambulance service" means obtaining possession or control of an existing air ambulance service by contract, ownership, lease or other comparable arrangement.

(i) "Back-up air ambulance" means an air ambulance that is used to provide air ambulance services when the primary air ambulance is not available for patient transports. A back-up air ambulance shall not be operated at the same time as the primary aircraft for the provision of air ambulance services.

(j) "Base of operations" means the hospital or hospitals designated by the applicant in the Certificate of Need application as the location(s) to which the majority of patient transports will be completed.

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

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

(m) "Critical care support" means care provided directly by a Michigan licensed physician or registered nurse as part of the air medical personnel.

(n) "Department" means the state agency known as the Michigan Department of Public Health.

(o) "Department inventory of air ambulances" or "Department Inventory" means the list, maintained by the Department on a continuous basis, of:

(i) air ambulances operating pursuant to a valid Certificate of Need issued under Part 222 or former Part 221 of the Code;

(ii) air ambulances licensed and operating in Michigan for which the operation of the air ambulance did not require a Certificate of Need; and

(iii) air ambulances which are not yet operational but have a valid Certificate of Need issued under Part 222 or former Part 221 of the Code.

The inventory shall not include back-up air ambulances.

(p) "Designated event" means a temporary event, such as an air show, of no more than seven (7) days in duration that requires the full-time on-site availability of an air ambulance.

(q) "Emergency" means a condition or situation in which an individual declares a need for immediate medical attention for any individual, or where that need is declared by emergency medical services personnel or a public safety official.

(r) "Existing air ambulance service" means an air ambulance service listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department.

(s) "Expand an air ambulance service" means increasing the number of air ambulances operated by an existing air ambulance service from the same base of operations.

(t) "Fixed wing aircraft," for purposes of these standards, means an aircraft licensed under Part 209 of the Code, being Section 333.20901 *et seq.* of the Michigan Compiled Laws, that is not a rotary wing aircraft and is capable of providing patient care according to orders issued by a patient's physician.

(u) "Health facility" means a health facility or agency as defined in Section 20106 of the Code, being Section 333.20106 of the Michigan Compiled Laws.

(v) "Hospital" means a health facility licensed under Part 215 of the Code.

(w) "Implementation plan" means a plan which documents how an applicant will implement and operate a proposed air ambulance service or an existing air ambulance service that is proposed to be acquired. The plan shall include documentation of at least each of the components of an air medical service including how the air ambulance service will be integrated with local medical control authority(s).

(x) "Initiate an air ambulance service" means begin operation of an air ambulance service from a base of operations that does not offer air ambulance services in compliance with Part 222 of the Code and is not listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department. The term does not include the renewal of a lease.

(y) "Inter-facility transport," for purposes of these standards, means the transport of a patient between health facilities using an air ambulance.

(z) "Medical control authority" means an organization designated by the Department under Section 20910(1)(k) of the Code, being Section 333.20910(1)(k) of the Michigan Compiled Laws.

(aa) "Monitored bed" means a licensed hospital bed that has, at a minimum, the capability of electronically monitoring in real time a patient's cardiac activity.

(bb) "Mutual aid," for purposes of these standards, means a written agreement between 2 or more air ambulance services for the provision of emergency medical services when an air ambulance service is unable to respond to a request for a pre-hospital transport.

(cc) "Offer" means to make patient transports.

(dd) "Patient transport," for purposes of these standards, means the use of an air ambulance for the transport and treatment of a single patient for an inter-facility transport or a pre-hospital transport. The term does not include use of an air ambulance that does not involve the transport of a patient.

(ee) "Pre-hospital transport" means the use of an air ambulance to provide transportation and advanced life support services to a patient from the scene of an emergency to a hospital.

(ff) "Primary service area" means the geographic service area that is or will be authorized by an air ambulance service's license and encompasses the area(s) to which the air ambulance service will primarily make pre-hospital transports.

(gg) "Quality management program" means a planned and structured program to evaluate the appropriateness, necessity and effectiveness of an air ambulance service.

(hh) "Receiving hospital" means a hospital to which an air ambulance will transport patients.

(ii) "Renewal of a lease" means extending the effective period of a lease for a helicopter for an existing air ambulance service which does not involve either the replacement of a helicopter or a change in the parties to the lease.

(jj) "Replace an air ambulance" means either: an equipment change which results in an air ambulance service operating an air ambulance, other than a back-up air ambulance, with a different aircraft manufacturer's serial number, and an applicant operating the same number of air ambulances before and after project completion at the same base of operations; or the renewal of a lease.

(kk) "Rotary wing aircraft" means a helicopter.

(ll) "Secondary service area" means an area in which an air ambulance service will make inter-facility transports or pre-hospital transports, or may operate pursuant to mutual aid agreements.

(mm) "Specialty care support" means care provided by one or more professionals who can be added to or substituted for one of the regularly scheduled air medical personnel for the provision of specialty services.

(2) The definitions of Part 209 and 222 shall apply to these standards.

Section 3. Requirements for approval for applicants proposing to initiate an air ambulance service

Sec. 3. (1) An applicant proposing to initiate an air ambulance service shall submit an implementation plan in a Certificate of Need application when it is submitted to the Department.

(2) An applicant proposing to initiate an air ambulance service shall demonstrate all of the following:

(a) An applicant shall project, in accordance with the methodology set forth in Section 9, that at least 275 patient transports will be made in months 7 through 18 after beginning operation, and annually thereafter.

(b) At least 80% of the projected total number of patient transports will result in an admission to a monitored bed in a hospital or involve the transport of a patient who expires prior to admission to a hospital.

(c) An application proposes to operate only 1 rotary wing aircraft.

(d) An applicant shall demonstrate, in its application on the date it is submitted to the Department, that all existing air ambulance services with a base of operations within a 75-mile radius of the base of operations of the proposed air ambulance service have been notified of an applicant's intent to initiate an air ambulance service. An applicant shall demonstrate, by means of the date on a certified mail return receipt, that such notice was given to each service at least 45 days prior to the date an application is submitted to the Department.

Section 4. Requirements for approval for applicants proposing to expand an air ambulance service

Sec. 4. An applicant proposing to expand an air ambulance service shall demonstrate each of the following:

(a) An average of at least 600 patient transports for each existing air ambulance was made during the most recent 12 month period for which verifiable data are available to the Department.

(b) An applicant shall project, in accordance with the methodology set forth in Section 9, that the number of patient transports to be made in the months 7 through 18 after beginning operation of an additional air ambulance, and annually thereafter, is equal to or greater than 600 multiplied by the existing number of air ambulances plus 200. For example, an air ambulance service with 1 air ambulance shall project that at least 800 patients transports ($600 \times 1 + 200 = 800$) will be made in months 7 through 18 after beginning operation of the additional air ambulance.

(c) An applicant proposes the addition of 1 air ambulance.

(d) An applicant, approved under these standards, shall demonstrate that, at the time an application is submitted to the Department to expand an air ambulance service, an applicant is in compliance with each of the project delivery requirements set forth in Section 8 of these standards, if such application is filed subsequent to 24 months after the date a Certificate of Need is approved pursuant to these standards.

Section 5. Requirements for approval for applicants proposing to replace an air ambulance

Sec. 5. An applicant proposing to replace an existing air ambulance shall demonstrate either of the following, as applicable:

(a) An air ambulance service that operates 1 air ambulance shall demonstrate that at least 275 patient transports were made in the most recent 12 month period for which verifiable data are available to the Department.

(b) An air ambulance service that operates 2 or more air ambulances shall demonstrate that the number of patient transports made in the most recent 12 month period for which verifiable data are available to the Department was equal to or greater than the number of patient transports required in Section 4(b) applicable to the number of air ambulances operated by an applicant.

(c) An applicant proposing to replace an air ambulance that does not involve a renewal of a lease shall demonstrate that the existing helicopter to be replaced is fully depreciated according to generally accepted accounting principles, or that the replacement helicopter offers significant technological improvements which enhance safety or quality of care, increases efficiency, or reduces operating costs.

(d) An applicant, approved under these standards, shall demonstrate that, at the time an application to replace an air ambulance is submitted to the Department, an applicant is in compliance with each of the project delivery requirements set forth in Section 8 of these standards, if such application is filed subsequent to 24 months after the date a Certificate of Need is approved pursuant to these standards.

Section 6. Requirements for approval for applicants proposing to acquire an existing air ambulance service

Sec. 6. An applicant proposing to acquire an existing air ambulance service shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing air ambulance service.

(b) The project will not result in an increase in the number of air ambulances listed on the Department inventory of air ambulances at the base of operations of the air ambulance service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4, as applicable.

(c) The project will not result in the replacement of the air ambulance(s) operated by the air ambulance service to be acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 5, as applicable.

(d) All air ambulances at the base of operations to be acquired are listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department and the acquisition shall not result in a change in the base of operations.

(e) An applicant agrees to operate the air ambulance service in accordance with all applicable project delivery requirements set forth in Section 8 of these standards.

(f) An applicant shall submit an implementation plan in the Certificate of Need application on the date on which it is submitted to the Department.

Section 7. Requirements for approval -- all applicants

Sec. 7. (a) An applicant shall identify the primary and secondary service areas in which the existing or proposed air ambulance service will or does operate.

(b) An applicant shall identify the base of operations of the existing or proposed air ambulance service in its application.

Section 8. Project delivery requirements--terms of approval for all applicants

Sec. 8. (1) An applicant shall agree that, if approved, the services provided by the air ambulance service shall be delivered in compliance with the following terms of Certificate of Need approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable state and federal safety, operating and licensure standards.
- (c) An approved air ambulance service shall operate in accordance with applicable local medical control authority protocols for scene responses by air ambulances.
- (d) Compliance with the following quality assurance standards:
 - (i) An approved air ambulance shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.
 - (ii) An applicant shall operate an air medical service. For purposes of evaluating this subsection, the Department shall consider it *prima facie* evidence of meeting this requirement if an applicant submits evidence that an air ambulance service is accredited as an air medical service by the Commission on the Accreditation of Air Medical Services within 2 years of beginning operation of an air ambulance service approved under these standards. However, an applicant may submit and the Department may accept other evidence that an applicant operates an air medical service.
 - (iii) An applicant shall:
 - (A) establish an air medical team;
 - (B) develop a clinical data base for utilization review and quality assurance purposes; and
 - (C) screen patients to assure appropriate utilization of the air ambulance service.
 - (iv) At a minimum, an air medical team shall include the following personnel, employed directly by the applicant or on a contractual basis, who shall be appropriately trained and licensed:
 - (A) an air medical service director whose responsibilities shall include assuring that all patients receive services appropriate for their needs;
 - (B) a medical director of the air medical service who shall be a physician licensed in Michigan and shall have appropriate training and familiarity with the appropriate use of air ambulance services;
 - (C) communication personnel;
 - (D) appropriately trained patient care personnel including but not limited to: physicians, registered nurses, emergency medical technicians, and paramedics;
 - (E) a clinical care supervisor;
 - (F) flight operations and aviation personnel;
 - (G) maintenance personnel; and
 - (H) on all pre-hospital transports, a paramedic licensed in Michigan.
 - (v) An applicant shall maintain an individual record of service maintenance on each air ambulance operated by the approved service.
 - (vi) All approved air ambulances shall be equipped, at a minimum, with the essential equipment as required by Part 209 of the Code, being Section 20901 *et seq.* of the Michigan Compiled Laws.
 - (e) Compliance with the following requirements:
 - (i) An applicant shall respond, or ensure a response, to all appropriate requests for services for all pre-hospital transports within its primary service area.
 - (ii) An applicant, to assure that an air ambulance service will be utilized by all segments of the Michigan population, shall:
 - (A) not deny air ambulance services to any individual based on ability to pay or source of payment;
 - (B) provide air ambulance services to any individual based on the clinical indications of need for the service; and
 - (C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

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

 - (iii) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to: annual budget and cost information; operating schedules; through-put schedules; demographic and diagnostic information; the volume of care provided to patients from all payor sources; and other data requested by the Department. The applicant shall

provide the required data on a separate basis for each separate and distinct site, as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) An air ambulance to be replaced shall be removed from service.

(v) Within 30 days after beginning operation of a new, additional or replacement air ambulance, an applicant shall provide the Department with a notice stating the first date on which the air ambulance began operating on a regular basis.

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

(3) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 9. Methodology for computing projected patient transports

Sec. 9. An applicant required to project patient transports shall compute projected patient transports in accordance with subsection (1) or (2), as applicable. In computing projected patient transports, an applicant shall consider weather and maintenance and training requirements on the ability to transport patients by air ambulance.

(1) An applicant proposing to initiate an air ambulance service shall:

(a) Identify the receiving hospital or hospitals to which patient transports will be completed by the proposed air ambulance service.

(b) For each hospital in the proposed primary and secondary service areas from which patients will be transported to the receiving hospital(s) identified in subsection (a), document each of the following:

(i) The number of patients that were transferred to each receiving hospital and either admitted to a monitored bed or expired prior to admission during the most recent 12 month period preceding the date on which an application is submitted to the Department. In order to include data from any hospital, an applicant shall document in the application each hospital's intent to utilize the proposed air ambulance service.

(ii) The number of patients identified in subdivision (i) that were transferred by ground transportation.

(iii) The number of patients identified in subdivision (ii) for which air transport would have been appropriate.

(c) An applicant shall document the number of patients transferred from the scene of an emergency by ground transport to the receiving hospital(s) during the most recent 12 month period preceding the date on which an application is submitted to the Department for which air transport would have been appropriate.

(d) The projected number of patient transports shall be the sum of the results of subsections (b)(iii) and (c).

(2) An applicant proposing to expand an existing air ambulance service shall:

(a) Document the actual number of patient transports made during the most recent 12 month period preceding the date on which an application is submitted to the Department.

(b) If the actual number of patient transports identified in subsection (a) is less than the number required to be projected pursuant to Section 4 of these standards, document the number of requests for patient transport that were denied during the most recent 12 month period preceding the date on which an application is submitted to the Department due to the unavailability of an existing air ambulance(s) for reasons other than weather.

(c) If the sum of the results of subsections (a) and (b) is less than the number of patient transports required to be projected pursuant to Section 4 of these standards, the additional number of projected patient transports necessary to demonstrate compliance with the minimum volume required by Section 4 of these standards shall be computed in accordance with subsection (1).

(d) The projected number of patient transports shall be the sum of the results of subsections (a), (b) and (c), as applicable.

Section 10. Department Inventory of Air Ambulances

Sec. 10. Appendix A sets forth the air ambulances listed on the Department Inventory of Air Ambulances as of the effective date of these standards. Modification to Appendix A shall be made by the Department pursuant to decisions on Certificate of Need applications and Certificates of Need.

Section 11. Comparative reviews

Sec. 11. Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

DEPARTMENT INVENTORY OF AIR AMBULANCES

<u>Air Ambulance Service City (County)</u>	<u>Number of Air Ambulances*</u>	<u>Base of Operations</u>
Butterworth AeroMed Grand Rapids (Kent)	1	Butterworth Hospital
Flight Care Saginaw (Saginaw)	1	St. Mary's Med Ctr
Midwest MEDFLIGHT Ypsilanti (Washtenaw)	1	St. Jos. Mercy Hosp--Ann Arbor Children's Hosp of MI Detroit Receiving Hospital and University Health Center Hutzel Hospital Harper Hospital
North Flight Traverse City (Gr. Traverse)	1	Munson Med Ctr
St. Vincent Med Ctr Toledo, OH	2	St. Vincent Med Ctr
Survival Flight Ann Arbor (Washtenaw)	2	University of Michigan Hospitals
West Michigan Air Care Kalamazoo (Kalamazoo)	1	Borgess Med Ctr Bronson Meth Hosp

*Does not include back-up air ambulances