

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR AIR AMBULANCE SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, expansion, or acquisition of Air Ambulance Services, and the delivery of these services under Part 222 of the Code. Pursuant to part 222 of the Code, Air ambulance is a covered clinical service. The Department shall use these Standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

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" 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" 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 at minimum advanced life support. The term does not include 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 providing at least advanced life support services utilizing an air ambulance(s) that operates in conjunction with a base hospital(s). Other functions of the service may include searches, emergency transportation of drugs, organs, medical supplies, equipment or personnel. An air ambulance service may operate a back-up air ambulance when the primary air ambulance(s) is not available or for a designated event with prior notification and approval from the local medical control authority.

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

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

(g) "Base of operations" means the site or sites at which the air ambulance(s) and crew are located for the air ambulance service.

(h) "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.

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

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

(k) "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.

(l) "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, pursuant to MCL 333.20904.

(m) "Existing air ambulance" means an operational air ambulance on the date which an application is submitted to the Department.

(n) "Existing air ambulance service" means an operational air ambulance service or an air ambulance service approved, but not yet operational on the date which an application is submitted to the Department.

(o) "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.

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

(q) "Inter-facility transport" means the transport of a patient between health facilities using an air ambulance.

(r) "Medical control authority" means an organization designated by the Department under Section 20910(1)(g) to provide medical control, pursuant to MCL 333.20906.

(s) "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.

(t) "Mutual aid" 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.

(u) "Organ transport" means the use of an air ambulance to transport an organ(s) and surgical transplant team between hospitals for transplantation purposes occurring in Michigan.

(v) "Patient transport" means the use of an air ambulance to provide an advanced life support intercept, a pre-hospital transport or an inter-facility transport occurring in Michigan.

(w) "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.

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

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

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

Sec. 3. "Initiate an air ambulance service" means begin operation of an air ambulance service from a base of operations that does not provide 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. An applicant proposing to initiate an air ambulance service shall:

(1) Operate only one (1) air ambulance.

(2) Identify the base hospital(s) of the proposed air ambulance service.

(3) Identify the base of operations of the proposed air ambulance service.

(4) Provide a letter of support from the medical control authority for the base of operations indicating that the applicant's proposed protocols comply with the requirements of the medical control authority.

(5) Demonstrate 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 the applicant's intent to initiate an air ambulance service, by means of certified mail return receipt, dated before the deemed complete date of the application.

Section 4. Requirements for approval to replace an air ambulance service

Sec. 4. "Replace an air ambulance" means an equipment change which results in an air ambulance service operating an air ambulance, with a different aircraft manufacturer's serial number, other than a back-up air ambulance. An applicant proposing to replace an existing air ambulance shall:

(1) Demonstrate that the existing air ambulance to be replaced is fully depreciated according to generally accepted accounting principles, or that the replacement air ambulance offers significant technological improvements which enhance safety or quality of care, increases efficiency, or reduces operating costs.

(2) Identify the existing base of operations of the air ambulance service.

(3) Identify the existing base hospital(s) of the air ambulance service.

(4) Assert that the air ambulance to be replaced shall be removed from operation at the applicant's air ambulance service or designated as a back-up air ambulance.

(5) Provide a letter of support from the medical control authority for the base of operations indicating that the applicant's proposed protocols comply with the requirements of the medical control authority.

Section 5. Requirements for approval to expand an air ambulance

Sec. 5. "Expand an air ambulance service" means increasing the number of air ambulances operated by an existing air ambulance service. An applicant proposing to expand an existing air ambulance shall:

(1) Identify the existing base of operations of the air ambulance service.

(2) Identify any proposed base of operations and demonstrate that the proposed base of operations is within the same medical control authority as the existing base of operations.

(3) Identify the existing and proposed base hospital(s) of the air ambulance service.

(4) Provide a letter of support from the medical control authority for the base of operations indicating that the applicant's proposed protocols comply with the requirements of the medical control authority.

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

Sec. 6. "Acquisition of an existing air ambulance service" means obtaining possession and control of an existing air ambulance service by contract, ownership, lease or other comparable arrangement. An applicant proposing to acquire an existing air ambulance service shall:

(1) Identify the existing base of operations of the air ambulance service.

(2) Identify any proposed base of operations and demonstrate that the proposed base of operations is within the same medical control authority as the existing base of operations.

(3) Identify the existing and proposed base hospital(s) of the air ambulance service.

(4) Provide a letter of support from the medical control authority for the base of operations indicating that the applicant's proposed protocols comply with the requirements of the medical control authority.

Section 7. Requirements for Medicaid participation

Sec. 7. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services, if a CON is approved.

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

Sec. 8. An applicant shall agree that, if approved, the Air Ambulance services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance requirements:

(a) Compliance with applicable state and federal safety, operating, and licensure standards.

(b) Compliance with applicable local medical control authority protocols for scene responses by air ambulances.

(c) Compliance with either of the following quality assurance standards:

(i) The applicant shall be accredited as an air ambulance service by the Commission on the Accreditation of Medical Transport Systems (CAMTS) within 2 years of beginning operation; or

(ii) the applicant shall maintain the following:

(A) written policies and procedures specifying the levels of patient care to be provided. The level of patient care provided shall be commensurate with the education and experience of the staff and the capabilities of the base hospitals.

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

(C) written policies and procedures that define the roles and responsibilities of all staff members;

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

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

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

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

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

(I) a quality management program;

(J) a clinical data base for utilization review and quality assurance purposes; and

(K) procedures to screen patients to assure appropriate utilization of the air ambulance service.

(d) Compliance with staffing and essential equipment as required by Part 209 of the Code, being Section 20901 et seq. of the Michigan Compiled Laws.

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

(a) Compliance with all appropriate requests for services for pre-hospital transports.

(b) Assurance that an air ambulance service will be utilized by all segments of the Michigan population, shall:

- (i) not deny air ambulance services to any individual based on ability to pay or source of payment;
- (ii) provide air ambulance services to any individual based on clinical necessity ; and
- (iii) Participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

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

(a) Participation in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to: annual budget and cost information; 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.

(b) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

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

Section 9. Effect on Prior CON Review Standards; Comparative reviews

Sec. 9. (1) These CON review standards supersede and replace the CON Review Standards for Air Ambulance Services approved by the CON Commission on June 10, 2010 and effective on August 12, 2010.

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