(b) N.J.A.C. 8:41–1 through 9 and 12 shall apply to mobile intensive care programs.

(c) N.J.A.C. 8:41–1 through 8, 10 and 12 shall apply to specialty care transport services.

(d) N.J.A.C. 8:41–1 through 8, 11 and 12 shall apply to air medical services.

8:41–1.3 Definitions

The following words and terms, as utilized in this chapter, shall have the following meanings, unless the context in which they are utilized clearly indicates otherwise:

"ACLS certification" or "certification in ACLS" means valid certification in Advanced Cardiac Life Support as issued by the American Heart Association.

"Acute care hospital" means any hospital, validly licensed by the Department, which maintains and operates organized facilities and services for the diagnosis, treatment or care of persons suffering from acute illness, injury or deformity and in which all diagnoses, treatment and care are administered by or performed under the direction of persons who, in accordance with N.J.S.A. 45:9–6, are validly licensed to practice medicine and surgery by the New Jersey State Board of Medical Examiners.

"Advanced life support" or "ALS" means an advanced level of pre-hospital, inter-facility or emergency medical care that includes basic life support functions, cardiac monitoring, cardiac defibrillation, telemetered electrocardiography, administration of anti-arrhythmic agents, intravenous (IV) therapy, administration of specific medications, drugs and solutions, utilization of adjunctive ventilation devices, trauma care and other techniques and procedures authorized in writing by the Commissioner.

"Advanced practice nurse" means a person who is validly licensed by the New Jersey Board of Nursing in accordance with the standards set forth at N.J.S.A. 45:11–45 et seq.

"Advertising" means any information directly or indirectly issued, distributed, hand-delivered or implied through any medium and utilized for the purpose of promoting the service of a provider.

"AHA CPR Guidelines" means the "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" as published by the American Heart Association, National Center, 7272 Greenville Avenue, Dallas, TX 75231–4596, incorporated herein by reference, as amended and supplemented. A copy of the guidelines is on file and available for inspection at the Office of Emergency Medical Services.

"Aircraft" means a device that is utilized, or intended to be utilized, for flight in the air, and shall include both airplanes and helicopters.

"Air medical service" means an entity that is validly licensed by the Department to provide pre-hospital advanced life support care to accident or trauma victims or ALS inter-facility transfers of acutely ill or injured patients requiring specialty medical care by way of a specially equipped and specially staffed air medical unit.

"Air medical unit" or "AMU" means a specially equipped helicopter or airplane that is validly licensed by the Department and operated in accordance with the standards set forth in this chapter.

"Airplane" means, as defined at 14 C.F.R. 1.1, an engine-driven fixed-wing aircraft heavier than air, which is supported in flight by the dynamic reaction of the air against its wings.

"ALS crewmember" means:

1. A registered nurse who meets the requirements set forth at N.J.A.C. 8:41–9.9 or 10.8(d)1 through (d)5vii; and/or

2. An EMT–Paramedic, who staffs a mobile intensive care unit, specialty care transport unit or air medical unit.

"ALS inter-facility transfer" means the transportation of a patient in need of advanced life support care or medical monitoring that is beyond the capabilities of BLS ambulances and their crewmembers from one health care facility to another (such as a nursing home, rehabilitation facility or other facility as provided for at N.J.S.A. 26:2H–2a) via a specialty care transport unit or air medical unit.

"AMD Standard" means the ambulance design and construction specifications (KKK–A–1822E) published by the Ambulance Manufacturers Division of the Truck Body and Equipment Association. Copies of the standards may be obtained from the Truck Body and Equipment Association, Suite 1220, 5530 Wisconsin Avenue, Washington, D.C. 20015.

"APLS certification" or "certified in APLS" means valid certification in Advanced Pediatric Life Support as issued by the American College of Emergency Physicians and the American Academy of Pediatrics.

"Automated external defibrillator or AED" means a device that can be attached to a patient in cardiopulmonary arrest, analyze an electrocardiogram for the presence of potentially lethal dysrhythmias (specifically, ventricular fibrillation and fast ventricular tachycardia), deliver an electrical defibrillation to the patient in accordance with the requirements of standard treatment protocols, and produce an event summary that documents significant events in the utilization of the device, specifically events prior to and after an electrical defibrillation.

"Available" means ready for immediate utilization (pertaining to equipment, vehicles and personnel) or immediately accessible (pertaining to records).

"Base station" means the actual communications console that permits the receiving of voice communications as well as telemetered electrocardiograms. Such base station shall be readily accessible to the medical command physician.

"Basic life support" or "BLS" means a basic level of pre-hospital care that includes patient stabilization, airway clearance and maintenance, cardiopulmonary resuscitation (CPR) (to the level of the Professional Rescuer or Health Care Provider as issued by either the American Heart Association, the American Red Cross, the National Safety Council or other entity determined by the Department to comply with AHA CPR Guidelines), hemorrhage control, initial wound care, fracture stabilization, victim extrication and other techniques and procedures as defined in the United States Department of Transportation (U.S.D.O.T.) EMT–Basic National Standards Curriculum (obtainable from The National Highway Traffic Safety Administration, 400 7th Street S.W., Washington, D.C. 20590, by accessing their website at www.nhtsa.dot. gov/people/injury/ems or by calling (888) 327–4236).

"Basic life support ambulance" or "BLS ambulance" means an emergency medical services vehicle that is validly licensed by the Department and operated in accordance with the standards set forth at N.J.A.C. 8:40.

"Basic life support ambulance service" or "BLS ambulance service" means an entity that is validly licensed by the Department to provide pre-hospital basic life support care; and/or BLS inter-facility transfers.

"BLS inter-facility transfer" means the transportation of a patient not in need of advanced life support care from one health care facility to another via a basic life support ambulance.

"BTLS certification" or "certification in BTLS" means valid certification in Basic Trauma Life Support as issued by the American College of Emergency Physicians.

"Cardiac defibrillation" means the discharge of electrical current through the fibrillating myocardium for the purpose of restoring a perfusing cardiac rhythm.

"Certificate of need" means the formal written approval of the New Jersey Department of Health and Senior Services to construct or expand a health care facility or to institute a new health care service, in accordance with requirements set forth at N.J.A.C. 8:33.

"Certified" or "certification" means official documentation that a person has completed all the requirements of an approved training program and has demonstrated competence in the subject matter to the satisfaction of the certifying agency.

"Commissioner" means the Commissioner of the New Jersey Department of Health and Senior Services.

"Communicable disease" means an illness due to a specific infectious agent or its toxic products, specifically including, but not limited to, those pathogens defined in the Federal bloodborne pathogen standards found at 29 C.F.R. 1910.1030(b), and which occurs through transmission of that agent or its toxic products from a reservoir to a susceptible host.

"Communications failure," when applied to medical command, means circumstances that prevent ALS crewmembers from engaging in two-way communications with the medical command physician due to technical difficulties.

"Communications failure protocols" means the specific course of treatment to be followed by ALS crewmembers in the event that two-way communications with the medical command physician cannot be made. Communications failure protocols shall first be approved by the Department, in accordance with N.J.A.C. 8:41–3.21.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

"Contaminated sharps" means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes and exposed ends of dental wires.

"Controlled dangerous substance" means a drug, substance or immediate precursor identified in Schedules I through V of the New Jersey Controlled Dangerous Substances Act (N.J.S.A. 24:21–5 through 24:21–8.1). The term shall not include distilled spirits, wine or malt beverages, as those terms are defined or utilized in N.J.S.A. 33:1–1 et seq., or tobacco and tobacco products.

"Convicted" or "conviction" means a finding of guilt by a judge or jury, a guilty plea, a plea of nolo contendere or non-vult or entry into a pre-trial intervention program, or other diversionary program authorized under the statutes of the State of New Jersey or under any other state's statutes.

"CPR certification" means valid certification in cardiopulmonary resuscitation to the level of the Professional Rescuer or Health Care Provider as issued by either the American Heart Association, the American Red Cross, the National Safety Council or other entity determined by the Department to comply with AHA CPR Guidelines.

"Crashworthy" means that all supplies, equipment, oxygen systems and patient litters carried on the vehicle shall remain firmly in place and shall not present a hazard to any vehicle occupant in the event of an accident or sudden change in vehicle speed or direction. Crashworthy retention systems shall not incorporate rubber straps, "shock cords" or Velcro® type closures. Crashworthy retention systems for some items are covered by specific Federal standards. The Department's test for crashworthiness of other retention systems is whether the item can be removed from place without unlatching or unbuckling the retention system.

"Crewmember" means any person (including, but not limited to, an EMT–Basic, EMT–Paramedic or registered nurse, excluding pilots) who staffs a mobile intensive care unit, specialty care transport unit or air medical unit.

"Crime" means, in accordance with the New Jersey Code of Criminal Justice, specifically N.J.S.A. 2C:1–4, any offense for which a sentence of imprisonment in excess of six months is authorized.

"Department" means the New Jersey Department of Health and Senior Services.

"Department–Initiated–Out–of–Service" or "DIOOS" means the immediate removal from service of a vehicle by Department staff, such that the vehicle may not be utilized for the provision of any basic and/or advanced life support care. Vehicles removed from service in this manner shall be identified by the placement of an official Department "Out-of-Service" sticker on at least one of the vehicle's windows.

"Director" means the person responsible for all activities of a mobile intensive care program or air medical service. The criteria for directors differ for mobile intensive care programs and air medical services. The specific criteria for each is set forth at N.J.A.C. 8:41–9.3 and 11.3, respectively.

"Disorderly persons offense" or "petty disorderly persons offense" shall have the same meaning as the definition provided by the New Jersey Code of Criminal Justice at N.J.S.A. 2C:1–4, incorporated herein by reference, as amended and supplemented. Generally, such offenses are under the jurisdiction of municipal courts, carry out a maximum jail term of six months or less, and are characterized by being minor in nature, not giving rise to the rights of trial by jury or indictment by grand jury. Examples of these offenses include harassment, obstructing a public passage, and fighting in a public place.

"Emergency" means a person's perceived need for immediate medical care in order to prevent death or aggravation of physiological or psychological illness or injury.

"Emergency medical services" or "EMS" means a system for the provision of emergency care and transportation of persons who are sick or injured and in need of immediate medical care.

"Emergency Medical Technician–Basic" or "EMT–Basic" means a person trained in basic life support care and validly certified or recognized by the Commissioner in accordance with the standards for Emergency Medical Technician–Basic certification as set forth at N.J.A.C. 8:40A.

"Emergency Medical Technician–Paramedic" or "EMT–Paramedic" means a person trained in advanced life support care and validly certified or recognized by the Commissioner in accordance with the standards for Emergency Medical Technician–Paramedic certification as set forth at N.J.A.C. 8:41A.

"Emergency response" means the provision of pre-hospital basic life support care by crewmembers staffing a basic life support ambulance, and includes those services that are provided after a call has been received by a 9–1–1 dispatcher requiring an immediate response (for example, automobile accidents, mass gatherings, special events and stadium/arena EMS services) as well as emergent responses to long-term care facilities that may or may not be routed through a 9–1–1 dispatcher.

"EMS educator" means the person responsible for coordinating all activities associated with the clinical portion of an EMT–Paramedic training program. The specific responsibilities required of an EMS educator are set forth at N.J.A.C. 8:41A–2.4(c)1 through 8.

"EMT–Paramedic student" means a person enrolled in an approved EMT–Paramedic training program, as provided for at N.J.A.C. 8:41A. An EMT–Paramedic student shall not be utilized to meet the minimum staffing requirements set forth at N.J.A.C. 8:41–9.8, 10.7 or 11.7.

"EMT–Paramedic training program" means a course of study, as provided for at N.J.A.C. 8:41A, consisting of both didactic and clinical instruction, designed for the purpose of preparing a person to sit for the National Registry of Emergency Medical Technicians–Paramedic Certification Examination.

"Federal Specification, KKK–A–1822" means the Federal Specification for the Star-of-Life Ambulance KKK–A–1822E, Edition E, June 1, 2002, incorporated herein by reference, as amended and supplemented. Copies of the standards may be obtained from the General Services Administration, Centralized Mailing List Service (TCAFL) P.O. Box 6477, Fort Worth, Texas 76115.

"Flight nurse" means a registered nurse who meets the criteria set forth at N.J.A.C. 8:41–9.9 and who has successfully completed specialized training in air medical care. Flight nurses are given a unique identification number.

"Flight paramedic" means an individual certified by the Department as an Emergency Medical Technician–Paramedic in accordance with the standard set forth in N.J.A.C. 8:41A and who has successfully completed specialized training in air medical care. Flight paramedics are given a unique identification number.

"FMVSS" means Federal Motor Vehicle Safety Standards, as set forth at 49 C.F.R. 571, incorporated herein by reference. Copies of the standards may be obtained from the Superintendent of Documents, Washington, D.C.

"Health care facility" means a facility so defined in the Health Care Facilities Planning Act, N.J.S.A. 26:2H–1.1 et seq.

"Helicopter" means a heavier-than-air aircraft that depends principally for its support in flight on the lift generated by one or more rotors.

"Impervious" means not allowing liquids or dirt to penetrate the surface of the material. For the purposes of this chapter, impervious surfaces do not include coverings made of or containing carpet, velour or cloth.

"In-service" means the presence of a mobile intensive care unit, specialty care transport unit or air medical unit at a sending or receiving health care facility; the picking up, transporting or discharging of any patient; or any instance where the mobile intensive care unit, specialty care transport unit or air medical unit is ready to accept patients and perform advanced life support care.

"JEMS (Jersey Emergency Medical Services) Communications Plan" means the authorized communications plan for emergency medical services, as issued by the Department. Copies of the plan are available, for a fee, from the Office of Emergency Medical Services.

"License" or "licensed" means validly licensed by the Commissioner in accordance with the standards for licensure as set forth in this chapter.

"Medical command" means the medical direction provided to ALS crewmembers by a medical command physician. The criteria for medical command differ for mobile intensive care units, specialty care transport units and air medical units. The specific criteria for each is set forth at N.J.A.C. 8:41–9.6, 10.6 and 11.6, respectively.

"Medical command physician" means a physician validly licensed by the New Jersey Board of Medical Examiners or another state's board of medical examiners (or equivalent licensing agency) who provides medical direction to ALS crewmembers via radio, telephone or other direct means of communications. The criteria for medical command physicians differ for mobile intensive care units, specialty care transport units and air medical units. The specific criteria for each is set forth at N.J.A.C. 8:41–9.5, 10.5 and 11.5, respectively.

"Medical control" means the general medical oversight provided to the operations of a mobile intensive care program, specialty care transport service or air medical service, including written protocols, quality assurance and other medical supervision of the service's operations.

"Medical director" means the physician responsible for the medical oversight of the operations of a mobile intensive care program, specialty care transport service or air medical service. The specific criteria required of a medical director are set forth at N.J.A.C. 8:41–9.4, 10.4 and 11.4, respectively.

"Medical record" means any information and/or reports (including, but not limited to, patient care reports) that describe a person's physical condition and/or medical history.

"MICU Advisory Council" means the advisory council charged with advising the Commissioner on matters regarding the provision of pre-hospital advanced life support care, as defined at N.J.S.A. 26:2K–16.

"Mobile intensive care hospital" means an acute care hospital authorized by the Commissioner, by way of a certificate of need, to develop and maintain a mobile intensive care program for the purpose of providing advanced life support care to a specific population, geographic region or political subdivision.

"Mobile intensive care nurse" or "MICN" means a registered nurse who meets all of the criteria set forth at N.J.A.C. 8:41–9.9.

"Mobile intensive care program" means a program, operated by a mobile intensive care hospital, which is validly licensed by the Department to provide pre-hospital advanced life support care by way of a specially equipped and staffed mobile intensive care unit. The mobile intensive care hospital shall be vested with the ultimate responsibility for the delivery of services and shall be held accountable for the actions of all of its crewmembers in the event that there are violations of any State or Federal licensing standards.

"Mobile intensive care unit" or "MICU" means a specialized emergency medical services vehicle that is validly licensed by the Department and operated in accordance with the standards set forth in this chapter.

"Mobility assistance vehicle" or "MAV" means a specialized transport vehicle that is validly licensed by the Department and operated in accordance with the standards set forth at N.J.A.C. 8:40.

"Neonatal" means the period of time from the moment of birth up to and including the 28th day following birth.

"Office of Emergency Medical Services" or "OEMS" means the Office of Emergency Medical Services in the New Jersey Department of Health and Senior Services, PO Box 360, Trenton, New Jersey 08625–0360. The telephone number for OEMS is (609) 633–7777.

"PALS certification" or "certification in PALS" means valid certification in Pediatric Advanced Life Support as issued by the American Heart Association.

"Patient" means any person who is ill or injured, living or deceased and with whom a crewmember has established physical or verbal contact.

"Patient care report" means the written documentation completed each time a crewmember makes physical or verbal contact with a patient.

"Pediatric" means the period of time beginning with the 29th day following birth up to, but not including, a person's thirteenth birthday.

"Petty disorderly persons offense" shall have the same meaning as the definition provided by the New Jersey Code of Criminal Justice at N.J.S.A. 2C:1–4, incorporated herein by reference, as amended and supplemented. Generally, such offenses are under the jurisdiction of municipal courts, carry a maximum jail term of six months or less, and are characterized by being minor in nature, not giving rise to the rights of trial by jury or indictment by grand jury. Examples of these offenses include harassment, obstructing a public passage, and fighting in a public place.

"Physician" means a person who is validly licensed by the New Jersey State Board of Medical Examiners in accordance with the standards set forth at N.J.S.A. 45:9–6.

"Physician assistant" means a person who is validly licensed by the New Jersey State Board of Medical Examiners in accordance with the standards set forth at N.J.S.A. 45:9–27.13.

"PHTLS certification" or "certification in PHTLS" means valid certification in Pre–Hospital Trauma Life Support as issued by the National Association of EMTs.

"Positive latching mechanism" means a latching mechanism that requires the manual release of the latching device. This does not include magnetic or friction-type latches.

"Pre-hospital" means the period of time prior to the delivery of a patient to a physician or registered nurse at an acute care hospital or satellite emergency department.

"Provider" means a mobile intensive care program, specialty care transport service or air medical service. By virtue of such status, the provider shall assume full legal responsibility for the delivery of services and shall be held accountable for the actions of its crewmembers in the event that there are violations of any State or Federal licensing standards.

"Provider–Initiated–Out–of–Service" or "PIOOS" means the temporary removal from service of a vehicle by the provider. A provider may choose to remove a vehicle from service for various reasons including, but not limited to, when the vehicle is in transit for repairs, when being utilized for official administrative duties or when being utilized in a parade or similar ceremony. Vehicles removed from service in this manner shall be identified by the placement of a placard in one of the vehicle's windows.

"Receiving health care facility" means a licensed health care facility, such as a nursing home, rehabilitation facility or other facility as provided for at N.J.S.A. 26:2H–2a, to which a patient is transferred following evaluation and/or treatment.

"Regional dispatch center" means a facility that provides coordinated dispatching of emergency services for a given area.

"Regional trauma center" means a State designated Level One hospital-based trauma center equipped and staffed to provide emergency medical services to accident or trauma victims.

"Registered nurse" means a person who is validly licensed by the New Jersey State Board of Nursing in accordance with the standards set forth at N.J.S.A. 45:11–26.

"Regulated medical waste" means, as defined at N.J.A.C. 7:26–3A.5, those medical wastes that have been listed or meet the waste characteristic classification criteria described at N.J.A.C. 7:26–3A.6 and that must be managed in accordance with the requirements of N.J.A.C. 7:26–3A.

"Respiratory care practitioner" means a person who is validly licensed by the New Jersey State Board of Respiratory Care in accordance with the standards set forth at N.J.S.A. 45:14E–10.

"Revocation" or "revoked" means the permanent voiding, withdrawal and/or cancellation of a license or certification.

"Satellite emergency department" means a facility that is owned and operated by an acute care hospital, which provides emergency care and treatment.

"Sending health care facility" means a licensed health care facility such as a nursing home, rehabilitation facility or other facility as provided for at N.J.S.A. 26:2H–2(a), incorporated herein by reference as amended and supplemented, from which a patient is transferred by the patient's attending physician for treatment or services not available at the sending licensed health care facility.

"Specialty care coordinator" means the person responsible for the general operation of a specialty care transport service. The criteria for a specialty care coordinator is set forth at N.J.A.C. 8:41–10.3.

"Specialty care transport service" means an entity that is validly licensed by the Department to provide ALS interfacility transfers, by way of a specially equipped and staffed specialty care transport unit, between a sending health care facility and a receiving health care facility (such as a nursing home, rehabilitation facility or other facility as provided for at N.J.S.A. 26:2H–2a) of patients requiring specialized medical intervention or medical monitoring that is beyond the capabilities of BLS ambulances and their crewmembers.

"Specialty care transport unit" or "SCTU" means a specialized transport medical service vehicle that is validly licensed by the Department and operated in accordance with the standards set forth in this chapter.

"Specialty staff" means validly licensed or certified persons such as physicians, specially trained nurses or respiratory care practitioners that may accompany the required crewmembers on a mobile intensive care unit, specialty care transport unit or air medical unit.

"Specific order" means an order by a medical command physician with regard to the treatment of a patient, whether directly transmitted by the physician or relayed through a registered nurse.

"Standing orders" means specific treatment protocols, authorized by the Commissioner, that occur prior to any communications with the medical command physician.

"Star of Life" means the symbol described in certification of registration number 1,058,022, which the United States Commissioner of Patents and Trademarks has issued to the National Highway Traffic Safety Administration.

"Therapeutic agent" means any drug or agent which is utilized in the treatment of the sick or injured, including those authorized in accordance with N.J.A.C. 8:41–6.1.

"Untreated regulated medical waste" means regulated medical waste, as defined in this subchapter, which has not been treated to substantially reduce or eliminate its potential for causing disease.

"Valid" or "validly" means original (not a photo copy), current, up-to-date, not expired, in effect and/or not past the renewal date required by the issuer.

"Vehicle" means a mobile intensive care unit, specialty care transport unit or air medical unit, as defined in this subchapter.

8:41–1.4 Waivers

(a) The Commissioner or his or her designee may grant a waiver of any part of this chapter if, in his or her opinion, such a waiver would not:

1. Endanger the life of any person;

2. Endanger the public health, safety or welfare; or

3. Adversely affect the provision of advanced life support care.

(b) A provider or applicant, as applicable, seeking a waiver shall apply, in writing, to OEMS.

(c) An application for waiver shall include the following:

1. The nature of the waiver requested;

2. The specific standards for which a waiver is requested;

3. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would occur if the waiver is not granted;

4. An alternative proposal that would ensure public safety; and

5. Documentation to support the waiver application.

(d) The Department reserves the right to request additional information before processing an application for waiver.

SUBCHAPTER 2. LICENSURE, INSPECTIONS AND AUDITS

8:41–2.1 Application for licensure

(a) Any person, public or private institution, agency, entity, corporation, acute care hospital or business concern seeking to be licensed to operate a mobile intensive care program, specialty care transport service or air medical service shall:

1. Fully complete an OEMS application for licensure, listing the name(s), home addresses and telephone numbers of all persons with an ownership interest in the proposed service. However, applicants that are publicly held corporations need only list the person, corporation and/or entity with the controlling interest and those persons, corporations and/or entities holding five percent or more of the available shares of the corporation;

i. Incomplete applications shall not be processed and shall be returned to the applicant with no action taken. Incomplete applications may be completed and returned to the Department within six months from the date on which the application was returned to the applicant without the requirement of a second application fee. Once an applicant has been notified that the application is complete, the applicant shall have six months within which to request an initial provider audit and vehicle inspections. Failure to comply with these time frames shall require submission of a new application and fee;

ii. No application shall be processed if the proposed trade name of the service duplicates or is essentially similar to a licensed service's trade name or the proposed trade name of an applicant that has an application pending before the Department;

2. Provide the Department with the specific street address of the principal place of business of the proposed service. The principal place of business shall be located on an actual piece of real property and shall not be a post office box or mail drop. Applications listing a post office box or mail drop as the principal place of business shall be rejected;

3. Make available to the Department upon request a copy of the standard operating procedures (SOP) manual, which addresses all of the areas identified at N.J.A.C. 8:41–3.12. No provider shall develop policies that are contrary to any applicable law, rule and/or regulation;

4. Demonstrate that it maintains crewmember personnel files that meet the standards set forth at N.J.A.C. 8:41–3.13;

8:41–3.12 Standard operating procedures manual

(a) Each provider shall develop and maintain a written standard operating procedures (SOP) manual. The SOP manual shall reflect the methods of daily operation, and shall be consistent with the provisions of this chapter. A copy of the SOP manual shall be available at each location where a vehicle is garaged, shall be readily accessible to all crewmembers and shall be made available to Department staff upon demand.

(b) The SOP manual shall contain, but is not limited to, policies addressing the following:

1. Crewmember functions in the emergency department of an acute care hospital;

2. Narcotic control, storage and procurement;

3. Medication control (both vehicle and station);

4. Pronouncement of death;

5. Air medical service utilization;

6. Triage to regional trauma centers, including trauma triage policies;

7. Hospital diversions;

8. State HAZ–MAT Annex and local policies for responding to HAZ–MAT incidents;

9. Mass casualty incidents, which shall include a copy of the Emergency Operating Plan (EMS Annex);

10. Physician and nurse orientation to the base station curriculum;

11. A current copy of N.J.A.C. 8:41;

12. The quality assurance plan;

13. Vehicle sanitation and maintenance, including the provider's procedures for both DIOOS and PIOOS status;

14. The required reporting of certain events as set forth at N.J.A.C. 8:41–3.10;

15. Communicable disease guidelines;

16. Patient rights;

17. Abuse reporting, such as child, elder and domestic;

18. A nondiscrimination statement, outlining the provider's willingness to transport and treat patients regardless of a person's race, sex, creed, national origin, sexual preference, age, disability, medical condition (including, but not limited to, patients with AIDS/HIV,TB, Hepatitis B or other communicable diseases) or ability to pay;

19. Procedures for handling patients with physician issued "Do not resuscitate" orders and/or a living will; and

20. Employees' responsibilities including, but not limited to, cooperating with Department staff during inspections, the possibility of incurring monetary penalties in case of licensure violations, the importance of having all required credentials available for inspection by Department staff, approved scope of practice and the performance of duties in a professional manner.

(c) Each provider shall develop a policy to ensure that all patient information, including patient identifiable data, remains confidential and private. This policy shall be part of the SOP manual, and shall be provided to each of the provider's employees. Patient information shall only be disclosed or released:

1. If the patient, guardian, executor or other legally authorized person has requested in writing that the information be released to a specific person, entity or company;

2. In compliance with a subpoena, judicial order or applicable law, rule and/or regulation;

3. To process a claim for insurance, including Medicare or Medicaid;

4. To Department staff in the performance of their duties and/or while conducting inspection, audit and/or investigation; and

5. To effect the transfer of the patient to another health care professional receiving the patient.

8:41–3.13 Personnel files

(a) A provider shall maintain a personnel file for each crewmember. Each file shall contain, at a minimum:

1. The name and home address of the crewmember;

2. A copy of the crewmember's valid driver's license;

3. A copy of the crewmember's photo I.D. (a valid photo driver's license may be utilized);

4. A copy of the crewmember's EMT–Basic certification card, EMT–Paramedic certification card or in the case of a registered nurse, a provider shall have written documentation that the registered nurse's license was physically presented to the provider;

5. Copies of the crewmember's certification cards in CPR, ACLS, PALS and either PHTLS or BTLS, as applicable;

6. With respect to EMTs–Paramedic, documentation of continuing education hours and skills for the previous recertification period if applicable; and

7. With respect to MICNs, official correspondence from the mobile intensive care program with regard to the person's endorsement status. The MIC program must submit an endorsement letter, endorsing the registered nurse for every certification period as an MICN.

(b) All personnel files shall be maintained at the provider's principal place of business, shall be maintained in a

readily accessible manner and shall be made available to Department staff upon demand.

(c) A provider shall not knowingly verify or accept a record or document that is falsified, fraudulent or untrue. The knowing verification of such false records or documents shall be sufficient cause for refusal to issue or renew a license and/or revocation of any existing provider and/or vehicle licenses.

8:41–3.14 Quarterly reports

(a) Each provider shall file a report with the Department outlining all activities for that quarter. The reports shall be made on a form and in the manner specified by the Department (Appendices A, B and C, incorporated herein by reference) and shall be delivered to OEMS on or before the due date. The reporting periods and due dates are as follows:

Period	Due
January 1 through March 31	April 30
April 1 through June 30	July 31
July 1 through September 30	October 31
October 1 through December 31	January 31

(b) The Department shall keep the data on file and shall generate a yearly report reflecting the activities of the providers. Yearly reports shall be available at OEMS for public inspection.

8:41–3.15 Quality assurance

(a) A continuous quality improvement structural organization shall be made a part of a provider's organizational structure.

1. The governing authority of the hospital (such as the board of trustees) or provider shall have ultimate responsibility for the continuous quality improvement program.

2. The provider shall have a continuous quality improvement program based on a written continuous quality improvement plan that is implemented and that monitors the quality of patient care.

3. Each provider shall have continuous quality improvement activities that are part of the overall quality assurance plan.

(b) A continuous quality improvement program shall contain the following policies and procedures:

1. The continuous quality improvement plan shall be reviewed at least annually and revised as necessary. Responsibility for reviewing and revising the plan shall be designated in the plan itself.

2. The continuous quality improvement plan shall delineate lines of communication between the continuous quality improvement program and the medical staff, chief executive officer or administrator, and governing authority.

3. The provider's continuous quality improvement plan shall specify procedures for the development, implementation, and coordination of quality reviews. The plan shall also establish a mechanism for the evaluation of the continuous quality improvement program.

4. The provider shall disseminate its findings and results of continuous quality improvement activities internally, as defined in the continuous quality improvement plan.

(c) A continuous quality improvement program shall be coordinated by a designated staff member.

1. There shall be an individual responsible for coordinating all aspects of the continuous quality improvement program.

(d) A continuous quality improvement program shall evaluate the following patient services:

1. There shall be an ongoing process of monitoring patient care. Evaluation of patient care is criteria-based, so that certain review actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

2. The continuous quality improvement coordinator shall be available to provide ongoing consultation to employees including assistance with the development of specific indicators used to evaluate service outcome.

3. The program shall follow up on its findings to assure that effective corrective actions have been taken, including at least policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.

4. The continuous quality improvement program shall provide information that is utilized in the evaluation of the clinical competence of all clinical practitioners.

(e) Each provider shall develop and maintain a quality assurance plan that is consistent with the standards set forth at N.J.A.C. 8:43G–27.1 through 27.5.

(f) The provider's medical director (or his or her physician designee meeting the requirements for medical command physicians found at N.J.A.C. 8:41–9.5, 10.5 and 11.5) shall be responsible for the coordination of all aspects of the quality assurance program and shall be available to provide ongoing consultation to the provider, including assistance with the development of specific indicators utilized to evaluate service outcomes on the MICU, SCTU or AMU.

(e) In the instance where a physician arrives on the scene after the arrival of the crewmembers, the crewmembers shall advise the physician that they are operating under the direct supervision of a medical command physician. If the on-scene physician feels that he or she may be helpful in the patient's medical treatment, he or she should speak to the medical command physician to relay information and discuss care. The medical command physician may then, as he or she deems appropriate, either retain medical command or turn over medical command to the on-scene physician. If the on-scene physician assumes medical command, he or she must be physically present with the crewmembers throughout the transport to the receiving health care facility and shall sign off on the patient care report.

(f) Except as provided for in the event of communications failure or standing orders authorized by this chapter, no ALS crewmember shall perform any skill or procedure, administer any pharmaceutical agent or engage in any other activity within his or her approved scope of practice unless the crewmember has first received the direct and specific order of the medical command physician or physician directed registered nurse.

(g) All orders given to ALS crewmembers shall be specific with regard to treatments ordered or medications and dosages to be given and the sequence in which the treatment is to be performed.

(h) ALS crewmembers shall provide the medical command physician or physician directed registered nurse with an appropriate report of patient assessment, patient condition, patient updates after treatment has been rendered and any other information required by the physician.

(i) Communications with the ALS crewmembers shall be performed directly by the medical command physician unless prevented by emergent patient care duties. In that case, a physician directed registered professional nurse may relay the report and orders if the registered nurse:

1. Possesses CPR and ACLS certifications;

2. Possesses PALS certification or has successfully completed the Emergency Pediatric Nurse Course to the standards of the Emergency Nurses Association;

3. Has been trained in the proper use of the base station; and

4. Personally relays the report to the medical command physician and any orders or direction to the ALS crewmembers. All orders shall be prefaced with the name of the medical command physician ordering the treatment.

(j) No medical command physician or physician directed registered nurse shall order any crewmember to perform any treatment or administer any medication outside of the crewmember's approved scope of practice.

(k) The medical command physician shall review the patient care report and affix his or her original signature to it, in accordance with established institutional policies, but not later than 30 calendar days after providing the medical direction. The medical command physician shall inform the medical director of any discrepancies in the patient care report.

(*l*) In an instance where patient care is provided in accordance with approved communications failure protocols, the authority for such treatment shall be deemed to emanate from the medical director.

(m) In every instance where an ALS crewmember has treated a patient, the medical command physician who provided the medical direction to the ALS crewmember shall ensure that the receiving health care facility is notified as soon as possible after providing medical command. The report shall be relayed to either a physician or registered nurse at the receiving health care facility, and shall contain:

1. The patient's chief complaint and presenting signs and symptoms;

2. Treatment ordered for the patient; and

3. The estimated time of arrival of the patient.

8:41–9.7 Medical treatment protocols

Each mobile intensive care program shall develop and maintain written medical treatment protocols that cover most common medical emergencies for patients of all ages. These protocols shall be kept at the base station, where they shall be immediately accessible to all physicians. These protocols shall serve as a guide to the physicians, but shall not be deemed to restrict the treatment ordered in the best judgment of the physicians and within the scope of practice of the ALS crewmembers. The protocols shall be reviewed and signed off by the medical director at least once every 12 months.

8:41–9.8 Required crewmembers

(a) When "in-service," each MICU shall be staffed by at least two persons, as follows:

1. Two EMTs–Paramedic;

2. Two registered nurses who meet the requirements set forth at N.J.A.C. 8:41–9.9; or

3. One registered nurse who meets the requirements set forth at N.J.A.C. 8:41–9.9 and one EMT–Paramedic.

8:41–9.9 Mobile intensive care nurses

(a) No provider shall allow a registered nurse to serve on one of its MICUs in the capacity of a MICN unless that person:

1. Has completed at least one year of full-time nursing care performing advanced clinical skills in the critical care unit or emergency department of an acute care hospital;

2. Possesses EMT–Basic, CPR and ACLS certifications;

3. Possesses PALS or PEPP–Advanced certification or has successfully completed the Emergency Nurse Pediatric Course to the standards of the Emergency Nurses Association;

4. Possesses either PHTLS or BTLS certification;

5. Has successfully completed at least a MICU field internship consisting of at least 100 hours, has successfully intubated at least five patients and has demonstrated proficiency in pre-hospital ALS treatment to the satisfaction of the mobile intensive care program's medical director;

6. Is physically capable of performing the duties of a MICN; and

7. Is endorsed by the medical director of a mobile intensive care program.

i. The director shall forward a letter to OEMS verifying the endorsement to the Department as soon as practical after the endorsement has been issued. The letter shall include a statement attesting to the competency of the person to perform all skills required of EMTs–Paramedic and compliance with the requirements for EMT–Paramedic recertification set forth at N.J.A.C. 8:41A–4.3.

ii. The director shall notify OEMS, in writing, in the event that the medical director revokes, cancels or otherwise rescinds endorsement. Notification shall be made to OEMS within 14 calendar days of the medical director's action.

(b) A person whose MICN endorsement has been revoked, canceled or otherwise rescinded shall not serve on a MICU in the capacity of a MICN.

8:41–9.10 Additional basic equipment and supplies: MICUs

(a) In addition to the equipment and supplies required at N.J.A.C. 8:41–3.4, when "in-service," each MICU shall be equipped with the following:

1. Equipment capable of producing a 12–lead electrocardiogram tracing;

2. Equipment to perform needle chest decompression;

3. Pediatric airway management materials including:

i. Airways, endotracheal tubes and stylets;

ii. Pediatric and infant sized laryngoscope blades;

iii. Pediatric and infant sized oxygen masks; and

iv. 1,000 mL and 450 mL sized bag-valve-mask devices;

4. Pediatric-sized electrodes for the monitor/defibrillator;

5. Pediatric-sized paddles or defibrillation pads for the monitor/defibrillator;

6. Pediatric and infant-sized IV catheters and/or winged infusion sets;

7. Pediatric Intraosseous infusion sets;

8. Pediatric and infant sized blood pressure cuffs;

9. Pediatric sized rigid cervical collars;

10. A pediatric height/weight medication and equipment guide (for example, Broslow Tape);

11. At least two protective multi-use jackets that are both fire and tear resistant, as well as two sets of gloves, head and eye protection that, at a minimum, meet the requirements set forth at 29 C.F.R. 1910.132 et seq., incorporated herein by reference;

12. Nasogastric tubes and irrigation syringes;

13. A long spine board made of impervious, inflexible material, 72 inches long by 16 inches wide with associated strap holes and full-length three-quarter inch runners, or another configuration that protects the crewmembers' hands from injury during patient movement;

14. A set of binoculars;

15. At least 25 disaster tags (that is, Met Tags®);

16. At least four red "biohazard" type bags utilized for disposal of untreated regulated medical waste as defined at N.J.A.C. 7:26–3A.5 and 3A.6. The "biohazard" bags shall meet the requirements set forth at N.J.A.C. 7:26–3A.11 and shall only be utilized for untreated regulated medical waste materials and shall be disposed of after utilization in accordance with all applicable laws, rules and/or regulations; and

17. A current copy of the U.S. Department of Transportation (U.S.D.O.T.) Emergency Response Guidebook (obtainable from The National Highway Traffic Safety Administration, 400 7th Street S.W., Washington, D.C., 20590 or by calling (888) 327–4236 or accessing their website at www.nhtsa.dot.gov/people/injury/ems).

8:41–9.11 Optional equipment and supplies

(a) Each MICU may be, but is not required to be, equipped with the following equipment and supplies:

1. An esophageal gastric tube airway, a laryngeal mask airway and other commercial airways of similar design or function;

2. A Doppler-type stethoscope;

3. A commercially available vest-type upper spinal immobilization device (for example, K.E.D.®);