EMS Provider
Compliance Guidelines

SECTION B

RULE 157.11 - STEP by STEP

(a) Application.

(1) Information required for an EMS provider license (applications and sample documents available from your public health region office).

a. application
b. documentation verifying volunteer status (if applicable)
c. evidence that governmental entities in the service area are aware that the provider provides EMS service in their jurisdiction and indicating if a 911 or a non-911 service
d map or description of service area
e. service type
f. profit status
g. notarized disclosure of ownership and name of business
h. copies of DBA (Doing Business As) certificates
i. certification of good standing from State Comptroller's Office, if incorporated
j. EMS personnel form
k. EMS vehicle form
l. certificate of insurance with TDH named as the holder or evidence of financial responsibility per Texas State Law
m. staffing plan
n. medical director information form
o. agreement with a medical director
p. protocols, equipment/supply list and medication list with medical director signature indicating date signed, effective date and expiration date which corresponds to the effective and expiration dates of the provider's EMS license
q. responsibility plans
r. mass casualty plan
s. mutual aid / inter local agreements / agreements with other providers (for example for 24/7 coverage)
t. SOP's
u. sample run report
v. list of first responder organizations that provide assistance to your service
w. proof of IRS recognition as Section 501(c)(3) nonprofit corporation (if applicable)
x. fax number

y. e-mail address

z. list of all locations (address and non-emergency telephone numbers) where ambulances under this provider license are housed

aa. list of all dispatch centers (name, address and non-emergency telephone numbers) utilized for this provider license

bb. list of cities and counties in which this service routinely provides 911 service

cc. if offering a subscription service:

(1) department approval prior to soliciting, advertising or collecting subscription or membership fees;

(2) written authorization from the chief elected official of the governmental entity for the service area;

(3) sample of contract or application used to enroll participants;

(4) copy of the advertising;

(5) evidence of a surety bond; and

(6) names and addresses of all subscribers / members.

(2) through (5) Self explanatory.

(b) Licenses and Designations.

Providers are required to comply with all requirements of their license at all times. This means that all legal requirements must always be adhered to. It also means that **911 providers are responsible for providing coverage to their service area at all times**. 911 providers who cannot provide 24/7 coverage must have an agreement with another service to provide that coverage. This is not "mutual aid". This is an agreement to provide coverage on a scheduled basis.

911 providers who cannot respond 24/7 must:

(1) notify all dispatching authority(ies);

(2) have their agreement approved by the medical directors of both (all) services;

(3) notify the governmental entities whose jurisdictions the provider serves;

(4) publish in the local media:

(a) the hours they can respond;

(b) the reason(s) they cannot respond 24/7; and

(c) with whom agreements have been made to provide coverage during the hours the provider cannot.

(1) Licenses.

A copy of the provider's current **license must be displayed:**

(1) in an obvious place in the provider's primary, operational business headquarters. Generally this will be the address of the location listed on the application; and

(2) in the patient compartment of each vehicle where it is easily visible.

(2) Designation.

In addition to the copy of the license, a document indicating the **vehicle's designation must be displayed** in the patient compartment of each vehicle.

When licensed, a provider will be granted a specific number of designations in specific categories. Providers may move designations among vehicles in the fleet. However, if the provider wishes to change the number of designations in any category, the provider must notify the department within 10 days.

EXAMPLE:

A provider is licensed for 4 vehicles. At licensure time the provider indicates that 2 of the vehicles will be designated BLS, and 2 will be designated MICU. The 4 designations may be moved freely among the 4 vehicles in the fleet as long as each vehicle is compliant with the designation it carries (protocols, personnel, equipment). The provider decides to upgrade one BLS unit to MICU. (Now the fleet will consist of 1 BLS and 3 MICU.) The department must be notified of the designation change within 10 days.

(c) Licenses and designations cannot be transferred from one license holder (licensed provider) to another.

EXAMPLE: (license):

Provider X buys Provider Y. Provider Y must submit an application, fee and other required license information for a new license, even if the name of the service stays the same.

EXAMPLE: (designation):

Provider L loans a vehicle designated ALS to Provider M as a substitution for one of Provider M's vehicles which has a blown transmission. Provider L's ALS designation must stay with Provider L's fleet. Provider M must use one of the designations in his own fleet. There is no fee for the substitution. The department must be notified by both providers within 10 days.

(d) Vehicles.

(1) EMS vehicles must be configured, maintained and equipped in such a way that patients can be transported safely, and all required patient care procedures can be carried out effectively. Except for specialized vehicles, ground vehicle body types must correspond in gross configuration to KKK Type I, II or III. Other configurations of ground vehicles, aircraft, and water craft will be evaluated and designated individually. All vehicles used by the provider to respond to emergencies with medical equipment and supplies must be configured in such a way that all the equipment and supplies, including medications, will be properly stored, maintained and secured. All vehicles approved as EMS vehicles must comply with all applicable laws and rules when response ready or in service. The provider's name must be prominently displayed on both sides of each vehicle in the fleet.

(2) EMS vehicles shall be equipped with two way communication which allows the crew to contact "medical resources". Depending upon an area's size, population, geography, transport time/distance and a number of other factors, a variety of medical resources would be considered "appropriate". The preferred

category of medical resources is a physician at the receiving emergency department.

VEHICLE COMPLIANCE can be achieved by having a vehicle which is properly designed, maintained and equipped, has available at least the minimum medical equipment and personnel consistent with the vehicle's designation level and is in compliance with all vehicle laws and rules which are applicable.

(3) (A) Substituting a vehicle means taking one vehicle out of service and temporarily putting another one its place. Replacing a vehicle means taking one vehicle out of service and permanently putting another one its place. **If a vehicle is substituted or replaced, no fee is required, but the department must be notified within 10 days.**

(B) The addition of a vehicle increases the total number of vehicles in the provider's fleet. **An addition requires (1) that the department is notified within 10 days, (2) that a fee is paid (unless the provider is a fee exempt volunteer) and (3) that an additional designation is requested from TDH.**

(e) Required **minimum** staffing.

MINIMUM staffing required 24/7:

(1) BLS - 2 ECA's;
(2) BLS with ALS capability - 2 ECA's;
(3) BLS with MICU capability - 2 ECA's;
(4) ALS - 1 Intermediate and 1 EMT (or above);
(5) ALS with MICU capability - 1 Intermediate and 1 EMT (or above);
(6) MICU - 1 Paramedic and 1 EMT (or above); and
(7) Specialized. The staffing for these vehicles will be decided on an individual basis.

Although at least minimum staffing must be maintained to meet legal requirements, a provider may always choose to staff vehicles with the highest levels of certification/license available. If vehicles are staffed with personnel having a variety of certification or license, the provider must always be certain that the protocols and equipment match the personnel.

EXAMPLE:

A provider has a fleet of all BLS designated vehicles. At any time the provider may place paramedics on any of those vehicles, and the paramedics are permitted to use all procedures allowed by their protocols. However, the provider must be very careful about the equipment on board these vehicles. Paramedics with paramedic protocols MUST have all equipment and supplies to allow them to completely execute their protocols.

"With capability" staffing:

A provider defines a given EMS vehicle at the "with capability" level when the provider assigns certain staff to the unit.

EXAMPLE:

When the provider chooses to assign a crew consisting of any combination of a Paramedic and an EMT (or above) to a BLS with MICU capable vehicle that vehicle becomes an MICU and therefore must have Paramedic protocols and equipment and is subject to all other MICU requirements.

EXAMPLE:

A provider has several vehicles designated as BLS with MICU capability. The provider is never required to staff any of these vehicles at the MICU level. Because the "foundation" designation for these vehicles is BLS, the minimum required staffing for 24/7 operation is 2 ECA's.

In this example, the provider may choose to assign any combination of staffing to these vehicles, but there are several situations the provider should consider:

(1) Personnel staffing the vehicle must comply with the protocols appropriate to their certification/license level. A provider chooses to staff a BLS with MICU capability vehicle with a **Paramedic** and an ECA. **Paramedic protocols** are present. Although the **vehicle** would **not** be defined as an **MICU** (ECA partner not an EMT), the Paramedic would be required to comply with the paramedic level protocols on board. Therefore, all the **equipment and supplies** needed for the Paramedic would be required.

(2) If only BLS protocols are on the vehicle, all personnel, regardless of certification/license level shall perform only BLS skills. Unless:

(1) the medical director has issued a blanket protocol indicating that all advanced personnel are to have with them and apply protocols appropriate to their certification/license level at all times; or

(2) advanced personnel are directed by on-line or on-scene medical control. Again, if the Paramedic is to follow paramedic protocols, all equipment and supplies to do so must be present.

(3) Even if advanced protocols are on a vehicle the service's medical director may suspend or revoke any individual's advanced privileges.

STAFFING COMPLIANCE can be achieved by having available at least the minimum staffing required by the vehicle's designation level. Staffing above the minimum required is allowed, actually encouraged, but the appropriate protocols and corresponding equipment must be on board before their skills can be utilized.

(f) Protocols.

Protocols are extremely powerful tools - either positively or negatively. They are the foundation for patient care and for compliance. They limit as well as dictate patient care procedures to be followed. They expand or limit the scope of practice of EMS personnel. They dictate what equipment, supplies and medications must be available.

One set of current protocols must be on each vehicle in the provider's fleet. Protocols must let **each certification/license level** know exactly what procedures are required to be followed. Some services have

chosen to place each protocol on one page, and then divide the protocol by procedures for each certification level. Some services use sections of a protocol book color coded by certification level. If a service frequently uses non-EMS certified personnel such as nurses or respiratory therapists, the protocols should address the expectations of these individuals also.

Protocols, equipment and medications must match. If protocols call for a certain procedure, all equipment, supplies and medications must be present to carry out the procedure. Likewise, if there is equipment or medications that the crew is expected to use, there must be protocols addressing their use. All protocols, equipment lists and medication lists must be dated with two specific dates:

(1) the date the protocols take effect; and

(2) the date the protocols expire. These dates will correspond with the effective and expiration dates of the provider's license.

Protocols must indicate all limitations. For example, does the medical director intend for personnel under his medical direction to operate under the protocols when out of the service area? Does the medical director intend for off duty personnel to operate under the protocols? What protocols does the medical director want followed by allied health personnel or personnel from other services? Protocols should make allowances for individual situations such as on line medical control or in circumstances like transfers of specific unstable patients.

PROTOCOL COMPLIANCE can be achieved by:

(1) having a copy of the protocols on each vehicle;

(2) assuring that personnel are fully versed in the protocols and have the skills to carry them out; and

(3) assuring that all equipment required by the protocols is available.

(g) Equipment and supplies.

Although specific numbers, sizes, varieties and types of equipment will generally be determined by each provider, the equipment must be adequate to meet the needs of patients ranging in size from newborn to large adult. The provider must show that several calls can reasonably be made without restocking. The provider will be required to base selections on factors such as call volume, transport times, restocking resources and so on. All equipment must be clean and in working order. All medication used by the provider must be properly secured, stored and maintained. All equipment required in the protocols must be present, and all equipment must have applicable protocols.

EQUIPMENT COMPLIANCE can be achieved by having available properly working equipment which corresponds to the equipment needed for the crew to carry out patient care to the full extent defined by their protocols and allowed by their certification /license.

157.11 (d)-(g)Vehicles, Staffing, Protocols, Equipment
CATEGORICAL COMPLIANCE SUMMARY

Compliance for designation levels is determined by the **minimum** staff and equipment required to be on approved EMS vehicles. Determining *designation compliance* is a static and therefore relatively easy process:
- properly maintained vehicle of proper type, equipment and staffing present = vehicle is compliant
- vehicle deficient or deficient in equipment or staffing = vehicle is non-compliant

Total **compliance in** the categories of **Vehicles, Staffing, Protocols and Equipment** can be achieved through (1) ongoing compliance with the minimum *designation criteria* for vehicle, staffing and equipment and (2) verification that all other protocol, personnel certification/license and equipment variables are continuously and correctly matched.

(h) See §157.12 and §157.13 for specific air ambulance equipment requirements.

(i) (1) through (3)
Specifics of minimum equipment and supplies will be determined by the provider and the provider's medical director and submitted to the department. All equipment and supplies must meet the criteria in (g) above.

(4) Generally self explanatory.
Notes:
- Emergency warning devices should not present a fire hazard (flares not acceptable) and should be visible from a distance (chemical light sticks not acceptable).
- Fire extinguishers must be current.
- At least 2 "No Smoking" signs - one of which must be in the patient compartment.

(5) Many times optimal patient care will require personnel on an EMS vehicle in addition to the EMS crew. The provider is responsible for assuring that these individuals have applicable protocols or orders and that they have corresponding equipment and supplies.

(j) National Accreditation.
Providers wishing to use this mechanism to get exemption from some portions of Texas licensure requirements should contact their regional office.

(k) Subscription or Membership services.
This is a somewhat involved option that does not include most providers. Providers who wish to become or renew as subscription services should contact their regional office.

(l) (1) through (15) Responsibilities.

Providers should thoroughly familiarize themselves with these responsibilities and should review them periodically. These are serious responsibilities. Failure to maintain compliance with them could result in disciplinary action. If there are any questions about the requirements of this section, contact your regional EMS office.

(m) License renewal process.

(1) Although the department has the responsibility of sending expiration/renewal notices, the final responsibility for renewal lies with the provider. Contact must be made with the department no less than 90 days prior to expiration.

(2) The renewal process is essentially a repeat of the initial licensure process. However, much of the renewal process is usually quicker and easier because there is only the need to verify or update information or documents.

(3) Provider licenses expire on the last day of the month of expiration. After that day, providers who continue to operate, do so in violation of the law and are subject to applicable penalties. If a provider has not met all requirements for relicensure by the expiration date, the provider may request a provisional license. The request must be accompanied by a $25 late fee and documentation justifying the request. The request for the provisional license will be granted only if there is evidence that failure to grant the request would have a negative impact on the health and safety of the provider's service area. A provisional license may be granted for any amount of time up to 60 days. Only one provisional license per license period will be granted.

(n) Organization may be considered volunteer if they have 5 or fewer paid staff (no limitations regarding whether they are medical, maintenance, clerical etc.). If there are more than 5 paid staff, but 75% or more of all personnel are volunteers, the organization may advertise as "volunteer". However, the provider must pay applicable fees for the vehicles in the fleet. Displays on vehicles may not be false, misleading or indicate any level of care that the provider cannot provide. The provider may display only wording consistent with the vehicle's designation. Providers shall prominently display the provider name on each vehicle. Such displays are not considered advertising.

(o) Prior to the issuance of an initial provider license the department will conduct an in depth, comprehensive survey. Surveys will assess the ability of the provider to comply with applicable requirements of the Health and Safety Code, Chapter 773 and 25TAC, Chapter 157. Comprehensive surveys may also be conducted in the course of an official investigation, subsequent to an unannounced inspection which identifies significant deficiencies or for other reasonable cause to assure compliance with EMS rule and law.

(p) Unannounced ("spot") inspections may be conducted at any time to determine provider compliance. These inspections are conducted as a result of complaints, but are also conducted on providers at random. All components required for provider licensure are subject to review during unannounced inspections.

Reasonable time will be allowed for correction of deficiencies. However, "reasonable" time can vary from deficiency to deficiency. For example, the time allowed to add to a "deficient" (by the approved equipment list), yet reasonably adequate, supply of 4x4's or triangular bandages might be greater than the time allowed to replace expired cardiac medications or an inoperative monitor/defibrillator. In many cases, correction of deficiencies can be verified without another inspection (purchase order for deficient equipment, work order for repaired vehicle, etc.). However, subsequent to an inspection which was failed for significant deficiencies the department may conduct a follow up inspection. If such a reinspection is required, the provider will be required to pay a $25 fee. **Even if the provider passes the second inspection it does not eliminate possible administrative penalties and disciplinary actions from having failed the first inspection.**

(q) Significant deficiencies identified during spot inspection, deficiencies not corrected in the time allotted and/or repeated deficiencies subject the provider to penalties under as indicated by §157.16.

END OF §157.11 STEP BY STEP

In addition to compliance criteria required of vehicles, equipment and staffing, there are **performance criteria** for which provider organizations and their crews are accountable.

Severe penalties can result from performance which violates patient care standards or which jeopardizes the health or safety of patients, the public or other responders. These penalties may be levied against the provider organization, individual EMS personnel or both.

The following information is intended to assist providers and indivividual certificate / license holders in understanding that **compliance with EMS law and rule requires more than just meeting the standards for vehicles, equipment and staffing.**

"level of care"

Patient care is offered (providers "operate" or "function") through the application of numerous combinations of personnel, equipment, procedures and medical control. The results of these various combinations are often referred to as "levels of care". However, there are NO defined "levels" of care. For example, patient care is not provided at the "MICU level" or at the "Paramedic level". Care may be provided IN an MICU, BY a Paramedic, but the CARE is not "MICU" or "Paramedic".

Although guidelines for patient care are established by medical control, protocols or specific patient orders, the responsibility for actually performing the proper care unique to each patient is the responsibility of the EMS crew.

"standard of care"

Whereas "level of care" addresses the degree of care provided, "standard of care" addresses the quality of care provided. The definition of standard of care is influenced by a variety of factors, but important determiners of adequate standard of care for EMS providers are the provider's protocols and standard operating procedures. Among other things, standard of care is defined by completeness, correctness and timeliness of actions as well as other acts of omission or commission which impact patient outcome. Standard of care is also determined by applying the "reasonable and prudent person" test. That is, determining if

equivalent patient care has been carried out by another person of same or similar training, experience and certification in the same or similar situation?

THE FOLLOWING EXAMPLES ARE LOOSELY BASED ON REAL CASES BROUGHT TO THE TEXAS DEPARTMENT OF HEALTH FOR INVESTIGATION. IN ALL OF THEM, ACTION WOULD LIKELY BE AGAINST SOME COMBINATION OF: *ONE OR BOTH CREW MEMBERS*, THE *SERVICE DIRECTOR* AND/ OR THE *PROVIDER ORGANIZATION*.

(1) An EMS crew responds to a motor vehicle crash involving a vehicle that ran off a bridge. The patient has multiple contusions and lacerations around the head. The patient was complaining of abdominal pain and shortness of breath, but he is now only responsive to pain. He has distinct bruising of the abdomen and chest and has some swelling of the abdomen. No extrication is required, but on scene time is 25 minutes. A Level II trauma center has a helicopter available in 15-20 minutes, but the patient is transported 40 minutes to a Level IV facility (in a direction opposite the Level II facility). Staff at the Level IV facility call for the helicopter to transport the, now seriously deteriorated, patient to the Level II center. Round trip flight is 1 hour. The choice of first destination for this patient was in violation of the service's protocols. The times allowed on scene and created for final arrival at a trauma center are contrary to any reasonable standard of care for a trauma patient in this condition.

(2) A patient is ejected from a motor vehicle which rolled over while traveling at a high rate of speed. On arrival of the EMS unit the patient is lying face down, motionless. When the patient is rolled over a large contusion on his forehead is obvious. When questioned, the patient has no recollection of the crash and has no idea where he is. Bystanders tell the crew that the patient was completely unresponsive until just before EMS arrived. The crew decides to walk the disoriented patient to the ambulance. Only when in the ambulance does the crew perform a physical exam. They then apply an extrication collar and backboard. This patient management was in clear violation of the service's protocols. In addition, in the absence of any threats to the lives of the crew or the patient, no reasonable EMS person would have moved this patient prior to the application of spinal stabilization.

(3) Law enforcement requests assistance for a drug overdose. Shortly after EMS arrival the patient stops breathing. The patient is intubated. During transport, the patient's oxygen saturation is checked and found to be less than 60. Management remained unchanged. When asked if tube placement was ever checked the medic responded, "Yes, but when we bagged him there was so much noise over the belly I couldn't hear breath sounds". Although the steps in the protocol for management of respiratory arrest were followed, the unrecognized, uncorrected placement of the ET tube in the esophagus was a catastrophic error.

(4) An MICU responds to a possible drowning. The patient's EKG clearly shows ventricular fibrillation. The Paramedic interprets the dysrhythmia as asystole and proceeds with the steps in the asystole protocol. Consequently, the patient receives incorrect medication, is never shocked and subsequently dies.