

**National EMS Advisory Council
Committee Reporting Template
Final
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Committee: Oversight, Analysis, and Research

Report Number: 001-OAR-007-FINAL

Title: Reducing Adverse Events in EMS: Creating a Culture of Safety

Issue Synopsis:

A. Problem statement

The Oversight, Analysis and Research (OAR) Committee has been charged by the National EMS Advisory Council (NEMSAC) to research, discuss and make recommendations regarding preventable adverse medical events in EMS. The topic of errors in medicine received great notoriety with the Institute of Medicine report "*To Err is Human...*" in 1999. Now, ten years after the report, some solutions are making their way through the health care system. It is not yet clear, however, that these principles have been widely adopted by the EMS Community. This Committee report is meant to provide the background and basis for a set of recommendations that NEMSAC will formally adopt as an official recommendation to NHTSA.

The Committee chose to undertake a review of the current state of patient safety in EMS by identifying examples of the EMS literature regarding patient safety and reviewing state laws and regulations regarding quality and patient safety. In addition, we include a description of other literature and resources that may be beneficial. Our goal was not to conduct a comprehensive review, but give examples of literature and regulations that we used to develop and support our conclusions.

The OAR fundamentally believes that the concepts around patient safety are not yet ingrained in the EMS community. The principles that create a safer environment, particularly leadership that creates and fosters an environment without fear, are not absent from the community, but have not been broadly adopted.

The OAR recommendations are listed below. However, it is important to understand that our main recommendation calls for NHTSA to move forward with the creation of "Culture of Safety" project that will provide all levels of EMS with the framework and appropriate tools to improve safety.

B. Resources/references related to the issue

EMS Literature

(References in Appendix 1)

A review of the medical literature was conducted to evaluate the evidence in the area of patient safety in Emergency Medical Services. We searched the databases of, US National Library of Medicine (PubMed) and the Cochrane Collaboration Library to identify published evidence in the area of patient safety.

We used the key words of “patient safety” and “errors” to identify literature from a ten year period. English language was used as a screen tool (limiter). There were more than 98 thousand patient safety articles identified. Using the phrase “emergency medicine” decreased this number to a little more than 1,000 articles. Further limiting using the phrase “paramedic and/or EMT, EMS, prehospital care” identified some 400 articles.

A review of these 400+ articles revealed 92 articles (Appendix A) that were specifically in the area of patient safety in Emergency Medical Services. Greater than 80% of these articles are from peer reviewed journals. The articles encompass all aspects from systems, educational as well as clinical domains in EMS.

The majority of the research was in the area of airway management, cardiopulmonary resuscitation, cardiac complaints, and medication administration. A few peer reviewed articles reviewed the willingness of EMS providers to disclose errors in practice equal to those of their nurse and physician colleagues

State Rules/Regulations

(References in Appendix 2)

While most states regulate Emergency Medical Services (EMS) organizations as a means to protect the safety of the public, few organizations offer any specific regulation pertaining to patient safety. This section outlines the current state of statutes and regulations across the United States that are either relevant or specific to the areas of patient safety. This is intended to formulate an assessment of the nation and specific states in matters pertaining to patient safety in EMS.

The following steps were taken to develop the analysis and addendum sections within this document:

-The search took place between the Summer of 2008 through February 2009 and covered all 56 states and territories (referred to as “States” from this point on) within the United States.

-The web search reviewed the Emergency Medical Services (EMS) Office or Bureau within each state. The purpose was to find a specific hyperlink, pdf, or other link that led to the appropriate statutes or rules that covered EMS within the State. When no such link was found, a general search beginning with the state’s general website was performed.

- The next step was to search of each electronic statute or rules document for the key words of “safety” or “quality.” In the matter pertaining to patient safety, the consistent message from across the country is that **most States do not have any statutes or regulations specifically regarding the safety of patients as part of their EMS rules and regulations.** Those states having provisions for safety measures mainly deal with vehicle safety including the wearing of seatbelts. Other noted items were:

-No states had any rules pertaining to the administration of medication or the application of procedures (intubation). Note: there were some states that discussed body substance isolation as a “procedure”.

A sound quality management system includes both patient and provider safety as a key objective. However, while general statements such as these made within the EMS rules, the specificity of actual patient safety is unclear. Across the nation there are currently no clear rules or statutes addressing patient safety improvement activities and expectations in EMS. Development of draft legislative language for state rules and regulations may be a first step in defining clear guidance at the state level.

Patient Safety in Other Clinical Environments – Lessons for EMS?

(References in Appendix 3)

Patient Safety in Other Clinical Environments – Lessons for EMS?

EMS can benefit greatly from the patient safety experience and expertise that hospitals have gained in the past decade since the Institute of Medicine’s (IOM) call to action in *To Err is Human* [1]. The acute care industry was motivated by alarming statistics of preventable medical errors caused by the health care system, stories from patients and families and other powerful forces to reduce the harm. In the years that followed the sentinel IOM works, *To Err is Human*, and *Crossing the Quality Chasm*, the

health care industry began to build the infrastructure for patient safety improvement. They developed error and adverse event taxonomies, reporting systems and tailored quality improvement strategies specifically to address patient safety challenges. Strong external forces that drove the change include the National Quality Forum (NQF), the Joint Commission (JC), the Institute for Healthcare Improvement (IHI), the Centers for Medicare & Medicaid Services (CMS) and many others.

A Quality Improvement Organization (QIO) works under the direction of the Centers for Medicare & Medicaid Services and consists of groups of doctors and health care experts to check on and improve the care given to people with Medicare. One of the responsibilities of QIOs is to look at the quality of medical care that Medicare patients receive. QIOs educate doctors or providers on ways they can improve and to help the doctor or provider to develop a plan to improve future care. Medicare has not contracted with or funded QIOs to assist EMS agencies in improving the care they provide.

The patient safety movement has also spread to ambulatory care. The NQF and Agency for Healthcare Research and Quality (AHRQ) have developed quality standards, some of which have patient safety relevance. The NQF *Safe Practices for Better Healthcare 2009* also partly apply to ambulatory care. A collaboration of the Medical Group Management Association, the Health Research & Educational Trust and the Institute for Safe Medication Practices (ISMP) has published a series of very useful modules, *Pathways for Patient Safety* [2].

The moral imperative to provide the safest care possible is present in both acute care and prehospital care. As Sir Liam Donaldson of the World Alliance for Patient Safety at the World Health Organization stated, “Everyone in healthcare needs to play their part. The stakes could not be higher. Safe care is not an option. It is the right of every patient who entrusts their care to our health care systems.” [3].

There has been extensive work describing the epidemiology of medical errors and adverse events in various inpatient and outpatient settings [4-7]. While the epidemiology studies in prehospital care are not nearly as wide-ranging [8], the indications from other areas of healthcare lead us to assume that there is unrecognized and preventable harm in EMS.

As humans work in systems with highly complex equipment and procedures, they will make errors. The human factors engineering field has described in detail where we are more successful and where we humans tend to fail [1, 9-11]. Design of the equipment and work areas play an important role in the safety of health care [1, 12]. Prehospital systems should consider the wealth of knowledge available.

Additional lessons from acute care safety for EMS

- Reporting systems
- QI systems for health care
- Lessons learned from applying safety strategies from nuclear science and aviation and other high risk industries
- Investigation techniques (RCA and FMEA)
- Prevention strategies
- Team work & communications tools
- Culture of Patient Safety
- Implementation lessons of quality improvement
- Business case for patient safety

Potential barriers

Two things are clear: 1) patient safety in prehospital care could be better and 2) some tools are available to get started. However, many challenges remain. As discussed in this report, there is currently little external motivation (regulatory or financial) for providers to actively pursue patient safety improvement. Quality improvement is hard work and resources for the necessary infrastructure are lacking in EMS. If you can't measure it, you can't manage it. Data systems will be essential for improvement work. Finally, a strong hierarchical structure and punitive culture can prevent open learning from preventable errors.

In summary, as EMS providers learn the acute care lessons in patient safety they can develop a system for improvement that suits the unique needs of prehospital care. They can start by increasing patient safety knowledge and skills for leaders and frontline providers. A better understanding of the epidemiology of prehospital adverse events and the development of basic adverse event taxonomy are an important component. Supporters should also address infrastructure limitations in EMS quality improvement. Finally, developing the culture of patient safety and creating fair accountability systems for providers and leadership will also help EMS succeed.

C. Crosswalk with other standards

Patient safety and medical errors are addressed directly or indirectly in numerous documents ranging from material produced by the US Department of Transportation National Highway Traffic Safety Administration's Office of EMS to the Institute of Medicines Report on Emergency Medical Services. The following is a brief list of documents that contain information, recommendations, or systems to address Emergency Medical Services quality, patient safety, and or medical errors. The list also demonstrates the wide ranging agencies and bodies that provide differing and sometimes conflicting direction.

- IOM *Future of Emergency Care: Emergency Medical Services at the Crossroads*
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- National Highway Traffic Safety Administration
 - o EMS Agenda for the Future
 - o EMS Education agenda for the Future
 - o EMS Rural and Remote Agenda for the Future
 - o A leadership Guide to Quality Improvement for EMS
 - o National Standard Curriculum
 - o National Core Content
 - o National Scope of Practice Model
 - o EMS Workforce Agenda for the Future
 - o National EMS Research Agenda
 - o Trauma System: Agenda for the Future
 - o Emergency Medical Services Outcomes Evaluation
 - o National EMS Information System (NEMSIS)
 - o National Emergency Medical Services for Children Data Analysis Research Center (NEDARC)
- National Association of EMS Physicians:
 - o International Liaison Committee on Resuscitation
 - o Prehospital Systems and Medical Oversight
 - o Improving Quality in EMS
- HRSA Rural Health Policy
 - o Quality Through Collaboration:
The Future of Rural & Frontier Emergency Medical Services in the U.S. Health System

In summary, there is no single group leading the development of standards and methodologies to identify and reduce adverse events in EMS nor a single system to improve patient safety. Further, there is no regulatory or financial system to drive the study of patient safety in EMS. Finally, there is little peer reviewed research focused on

a system approach to medical errors and patient safety within emergency medical services.

The Joint Commission Standards

One of the more comprehensive set of voluntary standards in health care are the accreditation standards established by The Joint Commission (formerly the 'Joint Commission for the Accreditation of Hospital Organizations'). Revised following the publication of the IOM report in 1999, the latest set of standards have established "National Patient Safety Goals" with the specific purpose of addressing improvements in patient safety. Although the Joint Commission standards are designed to address the clinical in-hospital environment, several of the patient safety goals could be adopted to the pre-hospital environment. For example, improving accuracy of patient identification, or requiring that unlabeled medications be discarded, are within the realm of EMS systems. Furthermore, it could be argued that some patient safety activities similar to those set forth in the Joint Commission standards already take place in the pre-hospital environment, such as rapid recognition of changes in patient condition and requesting additional resources (e.g. BLS requesting ALS assistance).

A difficulty in extending voluntary accreditation standards to the EMS community is the issue of motivation. That is, hospitals and health care organizations have a regulatory and financial imperative to adopt voluntary standards, although there currently exists no such imperative for EMS agencies. If pay-for-performance, or a similar arrangement, is added to the regulatory structure for EMS payment systems, the adoption of some sort of patient safety standards should be made mandatory.

D. Analysis

An initial review of multiple sources reveals that portions of safety culture are working their way through the EMS Community. There is not, however, a systematic approach to patient safety in the industry as a whole. A systematic review of the 400+ articles revealed 92 articles (Appendix A) that were specifically in the area of patient safety in Emergency Medical Services and did demonstrate that EMS providers are willing to report potential errors, similar to their nurse and physician colleagues. Most States do not have any statutes or regulations specifically regarding the safety of patients, while most do have QI regulations in place. It is important to note that while safety and QI may overlap, there are differences. EMS can benefit greatly from the patient safety experience and expertise that hospitals have gained in the past decade since the Institute of Medicine's call to action in *To Err is Human*. There has been extensive work describing the epidemiology of medical errors and adverse events in various inpatient and outpatient settings. While the epidemiology studies in prehospital care are not near as wide-ranging, the indications from other areas of healthcare lead us to assume that there is unrecognized and preventable harm in EMS. The human factors engineering field has described in detail where we are more successful and where we humans tend to fail. Design of the equipment and work areas play an important role in the safety of health care.

E. Committee conclusion

Recommended Actions/Strategies:

- All levels of EMS: From government (State and Federal) through leadership/management, EMS agencies, and educators and to the level of the individual provider should adopt the EMS Culture of Safety.

National EMS Advisory Council

- The NEMSAC OAR should engage with the NEMSIS 3.0 task force to provide feedback on patient safety and quality data indicators.

National Highway Traffic Safety Administration

- NHTSA should move forward with a process: Creating a Culture of Safety in EMS
The project should consider
 - A National EMS Patient Safety Conference as a kickoff event
 - A Patient Safety Reporting System (National vs. State)
 - Consider previous models
 - Firefighter Near-Miss Registry
 - MEPARs
 - Pennsylvania EMS Safety Event Reporting System
 - CONCERN Network
 - Develop Model Statutory/Regulatory Language regarding EMS Patient Safety
 - Defining taxonomy/data dictionary for EMS adverse event reporting
 - Create a list of EMS “Never Events”
 - Create a toolkit for local implementation of an EMS patient safety program
 - Catalog best practices in EMS patient safety
 - Create a national strategy for deploying the EMS Culture of Safety
 - Deliverable: Creating a Culture of Safety: The EMS Agenda
- Consider sponsoring an Annual Award for Best Practices in Patient Safety

Other Department of Transportation

- Invite representation from transportation safety experts from FAA and NASA to provide expertise for developing a national patient safety program.

Federal Interagency Committee on Emergency Medical Services

- FICEMS should adopt the EMS Culture of Safety as a core value and support it in their agency grants, programs and policies.

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- FICEMS should help identify and engage with safety expertise and resources in other Federal agencies. (NTSB, FDA, etc)

- FICEMS should encourage CMS, in any “value-based purchasing” system they develop for EMS, to include a mechanism to financially reward those EMS programs that have implemented a Culture of Safety throughout their organization.

- FICEMS should encourage CMS to help EMS providers improve the quality of services they deliver to Medicare beneficiaries, and all patients, by including ambulance services in the Quality Improvement Organizations’ Statement of Work.

- **Appendix 1: EMS References**

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Prehosp Emerg Care. 2000 Apr-Jun;4(2):190-5. Review.

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Matera P.

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85. Unrecognized misplacement of endotracheal tubes in a mixed urban to rural emergency medical services setting.

Jemmett ME, Kendal KM, Fourre MW, Burton JH.

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McMullan P, Carlton F, Summers RL, Deschamp C, Galli RL.

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Lefrançois DP, Dufour DG.

Resuscitation. 2002 Jan;52(1):77-83.

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Feldman MJ, Lukins JL, Verbeek PR, Burgess RJ, Schwartz B.

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Appendix 2: EMS laws and regulations related to patient safety and quality

EMS Safety Laws and or Rules Addendum

Alabama: None found

Alaska: None found.

American Samoa: None found.

Arizona: None found

Arkansas:

http://www.healthylarkansas.com/ems/pdf/Final_2008_EMS_Regulations.pdf

Where, in the opinion of the Department, the public's health, interest, or safety is jeopardized, or the failure to be in compliance is willful, the Department may temporarily suspend the license of a service or the certificate of an EMT until the matter is decided by the Department.

California: None found

Colorado:<http://www.cdphe.state.co.us/regulations/ems/101503emergencymedicalservices.pdf>

6.2 Good cause for disciplinary sanctions listed in this section shall include, but not be limited to:

6.2.25 violating any state or federal statute or regulation, the violation of which would jeopardize the health or safety of a patient or the public.

Equipment Standards: Body Substance Isolation (BSI) Equipment Properly Sized To Fit All Personnel

Connecticut: None found.

Delaware: None found

District of Columbia: None found

Florida: <http://www.doh.state.fl.us/demo/ems/Rulesstatutes/07-08-2008RULE64E-2FINAL.pdf>

-Safety equipment; safety goggles

-Mandatory safety committee for Air Ambulances: (5) Each air ambulance provider shall establish a safety committee. (Page 12)

Georgia: None found

Guam: None found.

Hawaii: None found.

Idaho: None found.

Illinois: None found.

Indiana: None found.

Iowa: None found

Kansas: None found

Kentucky: None found.

Louisiana: None found.

Maine: None found.

Marianas Islands: None found.

Maryland: None found.

Massachusetts: None found.

Michigan: http://www.michigan.gov/documents/FINAL_2001-015_EMS_95428_7.pdf

R325.22132 Ambulance operation; operating requirements.

(d) Maintain written policies and procedures that address safety and accident reduction and comply with all applicable state and federal health and safety laws as prescribed on the department-approved agency inspection form. These procedures shall be maintained by the operation and shall be available to the department upon request.

Minnesota: None found.

Mississippi: <http://www.msdh.state.ms.us/msdhsite/ static/resources/2940.pdf>

107 CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM

116.02 CQI process

5. Training and education needs, individual performance evaluations, equipment or resource acquisition, safety and risk management issues all shall be integrated with the CQI process.

Montana: None found.

Nebraska: None found.

Nevada: None found.

New Hampshire:None found.

New Jersey: None found.

New Mexico: None found.

New York: None found.

North Carolina: None found.

North Dakota: None found.

Ohio: None found.

Oklahoma: None found.

Oregon: None found.

Pennsylvania:

<http://www.pacode.com/secure/data/028/chapter1001/subchapDtoc.html>

Reducing Adverse Events in EMS: Creating a Culture of Safety

Oversight, Analysis, and Research

001-OAR-007-FINAL

<http://www.health.state.pa.us/pdf/hpa/ems/799emsplan/emsoffic.pdf>

PDF contains items about community safety (i.e. Injury prevention)

Rhode Island: None found.

South Carolina: None found.

South Dakota: None found.

Tennessee: None found.

Texas: None found.

Utah: None found.

Vermont: None found.

Virginia: None found.

Washington: None found.

West Virginia: None Found

Wisconsin: None found

Wyoming: None found.

EMS Quality Management Laws and or Rules

Alabama:

<http://www.adph.org/ems/assets/emsrules2008.pdf>

Continuing education courses should be determined through provider service quality assurance and improvement methodologies and should reflect the mission and scope of care of the EMS provider service. Page 55

Records and data may be used by staff of the Department of Public Health and staff of other designated agencies in the performance of authorized quality assurance activities; Page 59

Alaska: None found.

American Samoa: None found.

Arizona: http://www.azsos.gov/public_services/Title_09/9-25.htm

D. An administrative medical director shall: and

5. Approve, ensure implementation of, and annually review policies and procedures for a quality assurance process to evaluate the effectiveness of the administrative medical direction provided to EMTs. Page 10

4. The air ambulance service has a quality management process to review regularly the patient care provided by each single-member medical team, including consideration of each patient's status upon arrival at the destination health care institution; Page 45-46

Arkansas: http://www.healthyarkansas.com/ems/pdf/Final_2008_EMS_Regulations.pdf

The ALS Medical Director of an air ambulance service shall be responsible for the following: Supervising and evaluating the quality of care through a written and approved Continuous Quality Improvement program; Page 53

California: <http://www.emsa.ca.gov/systems/default.asp#Quality>

Colorado:

<http://www.cdphe.state.co.us/regulations/ems/101503emergencymedicalservices.pdf>

2.21 "Medical Director" – A physician holding an active Colorado medical license who authorizes and directs, through established protocols and standing orders, the performance of students-in-training enrolled in state-recognized EMS education programs, graduate EMT-Intermediates or EMT-Paramedics, or state-certified EMTs who perform medical acts, and who is specifically identified as being responsible to assure the performance competency of those authorized individuals as described in the physician's medical continuous quality improvement program.

3.2.8 Applicants for state EMS education program recognition shall submit the following documentation to the Department:

D) program policies and procedures, which at a minimum shall address:

12) a continuous quality improvement plan.

B) Beginning July 1, 2008, the following education requirements shall be in effect for the renewal of a Department-issued EMT certificate without the use of a current and valid NREMT certification.

1) Education required for the renewal of an EMT-Basic certificate shall be no less than thirty-six (36) hours and shall be completed through one of the following:

i) one (1) hour of preparatory content that may include scene safety, quality improvement, health and safety of the EMT, or medical legal concepts.

Connecticut: None found.

Delaware: <http://delcode.delaware.gov/title16/c098/index.shtml#TopOfPage>

9806. EMS medical directors.

(b) As part of their responsibilities, the EMS medical directors shall:

(1) Provide medical oversight and prospective, concurrent and retrospective medical quality control of advanced life support, basic life support and emergency medical dispatch;

District of Columbia:

<http://weblinks.westlaw.com/toc/default.aspx?Abbr=dc%2Dst&Action=ExpandTree&AP=>

(d) The Medical Director shall:

(1) Provide medical oversight for all aspects of pre-hospital medical services provided by the Department, including:

(C) Quality assurance of medical services;

Florida: <http://www.doh.state.fl.us/demo/ems/Rulesstatutes/07-08-2008RULE64E-2FINAL.pdf>

64E-2.004 Medical Direction.

(b) Develop and implement a patient care quality assurance system to assess the medical performance of paramedics and EMTs. The medical director shall audit the performance of system personnel by use of a quality assurance program to include but not limited to a prompt review of patient care records, direct observation, and comparison of performance standards for drugs, equipment, system protocols and procedures. The medical director shall be responsible for participating in quality assurance programs developed by the department.

Georgia: <http://rules.sos.state.ga.us/cgi-bin/jump.cgi?ID=5105&d=1>

3. It will be the responsibility of the local medical director to provide for medical direction and training for the ambulance service personnel in conformance with acceptable emergency medical practices and procedures.

e. Continuous quality improvement of patient care.

Guam: None found.

Hawaii: None found

Idaho: None found.

Illinois: None found

Indiana: None found

Iowa: <http://www.legis.state.ia.us/Rules/Current/iac/641iac/p132/p132.pdf>

132.8(3) Service program operational requirements. Ambulance and nontransport service programs shall:

m. Implement a continuous quality improvement program that provides a policy to include as a

minimum:

- (1) Medical audits.
- (2) Skills competency.
- (3) Follow-up (loop closure/resolution).

132.9(2) The medical director's duties include, but need not be limited to:

g. Developing and approving an applicable continuous quality improvement policy demonstrating type and frequency of review, including an action plan and follow-up.

Kansas: <http://www.ksbems.org/allregulations.htm#109-1-2>

109-2-5 Ambulance service operational standards.

(w) Each operator shall provide a quality improvement program which establishes medical review procedures for monitoring patient care activities. This program shall include policies and procedures for reviewing patient care report forms. Each operator shall review patient care activities on at least a quarterly basis each year to determine whether the service's attendants are providing appropriate patient care.

109-2-15 Ambulances based outside of Kansas .

(5) a copy of any quality improvement reports as described by K.A.R. 109-2-5. (Authorized by K.S.A. 65-6136; implementing K.S.A. 65-6136; effective Jan. 9, 1998.)

Kentucky: None found.

Louisiana: None found.

Maine: <http://janus.state.me.us/legis/statutes/32/title32sec92-A.html>

Marianas Islands: None found.

Maryland: <http://www.dsd.state.md.us/comar/30/30.03.04.02.htm>

30.03.04.02 Quality Assurance Plan.

A. Every EMS operational program shall have a written quality assurance plan approved by its medical director.

B. The quality assurance plan shall include provisions for:

- (1) Reviewing data concerning patient care rendered by EMS providers affiliated with the EMS operational program;
- (2) Identifying and analyzing trends in EMS care rendered by EMS providers affiliated with the EMS operational program;
- (3) Annually reporting to MIEMSS on quality assurance issues on a form required by MIEMSS;
- (4) Providing remedial action to resolve any patient care issues involving EMS providers or the EMS system which should be addressed at the jurisdictional level;
- (5) Identifying violations of the Maryland Medical Protocols for Emergency Medical Services Providers;
- (6) Notifying MIEMSS within 30 days of discovery of any incidents, protocol variations, or trends which in the opinion of the medical director:
 - (a) May have resulted in harm to a patient,
 - (b) May require disciplinary action by MIEMSS, or
 - (c) Suggest the need for changes to the Statewide EMS system by MIEMSS; and
- (7) Reviewing oral or written allegations that:

(a) An EMS provider failed to act in accordance with applicable law or protocols, or

(b) Prehospital patient care was below the applicable standard of care.

Massachusetts: <http://www.mass.gov/Eeohhs2/docs/dph/regs/105cmr170.pdf>

170.050: The State EMS Plan

(B) The components to be addressed in the state EMS plan include, but are not limited to, the following:

(8) Evaluation and continuous quality improvement;

170.300: Affiliation Agreements

(A) To be licensed to provide ALS services, each ambulance or EFR service must have a current written contract with one hospital licensed by the Department to provide medical control. This agreement shall contain a reasonable and effective plan for medical control and include the following features:

(4) Operation of an effective quality assurance/quality improvement (QA/QI) program coordinated by the affiliate hospital medical director and with participation of on-line medical direction physician(s) and service medical director, if different from the affiliate hospital medical director, that includes, but is not limited to, regular review of trip records and other statistical data pertinent to the EMS service's operation, in accordance with the hospital's QA/QI standards and protocols, in those cases in which ALS services were provided or in which ALS established direct patient contact;

Michigan: http://www.michigan.gov/documents/FINAL_2001-015_EMS_95428_7.pdf

R325.22132 Ambulance operation; operating requirements.

(i) Participate in data collection and quality improvement activities authorized under medical control authority protocols.

R 325.22142 Nontransport prehospital life support operation; operating requirements.

(i) Participate in data collection and quality improvement activities authorized under medical control authority protocols.

(h) Protocols that ensure a quality improvement program is in place. The quality improvement program shall include a requirement that each life support agency collects and submits data to the medical control authority. Data shall be reviewed by the medical control authority professional standards review organization. Data shall be protected in accordance with section 20919(1) (g) of the code.

Minnesota: <https://www.revisor.leg.state.mn.us/statutes/?id=144E.265>

144E.265 MEDICAL DIRECTOR.

Subd. 2. Responsibilities. Responsibilities of the medical director shall include, but are not limited to:

(5) participating in the development and operation of continuous quality improvement

Mississippi: http://ems.ms.gov/pdf/ems_rules_regs_2008.pdf

The off-line medical director shall be responsible for overseeing the development and maintenance of a quality assurance or a continuous quality improvement program.

107 CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM

116.02 CQI process

1. The licensee shall have an ongoing collaborative process within the organization that identifies issues affecting patient care.
2. These issues should address the effectiveness and efficiency of the organization, its support systems, as well as that of individuals within the organization.
3. When an issue is identified, a method of information gathering shall be developed. This shall include outcome studies, chart review, case discussion, or other methodology.
4. Findings, conclusions, recommendations and actions shall be made and recorded. Follow-up, if necessary, shall be determined, recorded, and performed.
5. Training and education needs, individual performance evaluations, equipment or resource acquisition, safety and risk management issues all shall be integrated with the CQI process.

Montana: None found.

Nebraska:

12-003.04H Medical Direction Standards: Responsibilities of a physician medical director include but are not limited to the following and those identified in 172 NAC 12-003.04B1, 12-003.04D1, 12-003.04D2, and 12-003.04G item 7:

5. Supervising the development of a medical quality control program for each emergency medical service being directed. The quality control program must include, but is not limited to:
 - a. An annual review of protocols and standing orders;
 - b. Medical care audits as needed; and
 - c. Continuing medical education for the emergency medical services personnel.

Nevada: None found.

New Hampshire:

Older rule with the stipulation that to have a QM system one needs to have an State-approved plan as a means to quality for QM protections.

New Jersey:

CHAPTER 40. MOBILITY ASSISTANCE VEHICLE AND BASIC LIFE SUPPORT AMBULANCE SERVICES

8:40-6.15 Additional requirements for BLS ambulance services providing emergency response

(a) Each BLS ambulance service that provides emergency response shall utilize the services of a medical director.

2. The medical director shall be responsible for providing medical consultation (as needed), as well as medical quality assurance oversight regarding the administration of BLS services by the provider's crewmembers.

i. Medical quality assurance oversight shall include, but is not limited to, review of utilization of the AED, as well as interpretation of treatment protocols and documentation standards.

(e) A BLS ambulance service providing emergency response shall:

1. Maintain at least one additional back-up BLS ambulance, which can be utilized to provide emergency response;

2. Develop a plan for continuous quality assurance of the services that it provides. This plan shall include quality indicators such as, but not limited to, dispatching of vehicles, safe driving, quality of medical care provided, documentation, utilization of advanced life support care, triage of patients and other areas the provider identifies as necessary. This plan shall include an identified person responsible for the quality assurance, the identification of outside resources (if necessary), and provision for feedback to the crewmembers;

CHAPTER 41 ADVANCED LIFE SUPPORT SERVICES; MOBILE INTENSIVE CARE PROGRAMS,

8:41-3.12 Standard operating procedures manual

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

12. The quality assurance plan;

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.

(g) There shall be an ongoing process of monitoring patient care. Evaluation of patient care on the MICU, SCTU or AMU shall be criteria-based, so that certain review actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

(h) The provider shall follow up on its findings to assure that effective corrective action is taken, including, at a minimum, policy revisions, procedural changes, educational activities and follow-up on recommendations, or shall establish that additional actions are no longer indicated or needed.

(i) The quality assurance program shall identify and establish indicators of quality care specific to the MICU, SCTU or AMU that are monitored and evaluated that encompass, as applicable:

1. Medical calls;
2. Trauma calls;
3. Pediatric calls;
4. Cardiac/respiratory arrest incidents;
5. Patients triaged to BLS;
6. Utilization of communications failure protocols;
7. Utilization of, and adherence to, standing orders;

8. On-scene times;
9. Utilization of special procedures;
10. Triage to specialty care facilities; and
11. Other areas the medical director finds necessary to track in this manner.

(j) The director or specialty care coordinator, as applicable, shall ensure that all patient medical records meet the following standards:

1. Completeness of the patient care report;
2. Adherence to policies regarding treatment and triage of patients including the guidelines for pediatric and adult patients in Chapter Appendices E and F, incorporated herein by reference, as applicable;
3. Compliance with the requirements of this chapter;
4. Documentation of excessive time spent at the scene or receiving health care facility, as applicable, based on the nature of the call, deviations from established protocols, unsuccessful procedures, communications failure, and other unusual incidents; and
5. The conditions set forth in (i) above.

(k) The medical director or his or her physician designee shall review at least 10 percent of all calls during which a patient was evaluated by the crewmembers (excluding the calls listed in (m) below). The method of determining which 10 percent of the calls will be reviewed shall be at the discretion of the medical director. The review shall determine:

1. Consistency with accepted treatment and triage protocols, as applicable;
2. Consistency of the written record with any voice recording of the call;

3. Appropriateness of orders issued by the medical command physician;
4. Appropriateness of the carrying out of orders received by the ALS crewmembers; and
5. Completeness of the patient care report.

(l) The quality assurance review shall be completed within 120 calendar days from date of service and shall encompass at least 10 percent of all calls, excluding cancelled calls.

(m) The quality assurance review for rapid sequence inductions, percutaneous needle cricothyrotomy, needle chest decompression, central venous access, intraosseous access and any patient who is triaged to BLS and subsequently admitted to a critical care unit shall be completed by the medical director within 120 calendar days from date of service and shall encompass 100 percent of the calls (not to be included into the 10 percent of calls required in (k) above).

1. Quality assurance reviews for rapid sequence inductions shall be maintained for the first 24 months that the procedure is utilized by a provider's ALS crewmembers. The patient care report shall be sent to the Department for review within 14 days after the procedure is conducted.

(n) Each provider shall keep written records of medical director reviews and shall produce them upon demand to an authorized representative of the Department. Medical director reviews shall include the comments of the medical director or his or her physician designee in accordance with (i) and (j) above. The provider shall keep quality assurance reviews for a period of one year from the date of the view.

8:41-7.2 Applicability and restrictions

(g) Each case utilizing these standing orders shall be fully documented on the

patient care report. The provider's quality assurance plan shall include provisions for review of calls where standing orders are utilized, in accordance with the standards set. Cases that do not follow the standing orders as set forth in this chapter or where contact is never made with the medical command physician shall be forwarded to the medical director for a mandatory review.

8:41-9.15 Patients triaged to BLS ambulances

(e) In order to ensure compliance with this chapter and to achieve quality assurance goals, the medical director shall review 100 percent of the calls triaged to a MICU or BLS provider where the patient was subsequently admitted to a critical care unit.

New Mexico: None found.

New York:

http://www.health.state.ny.us/nysdoh/ems/pdf/quality_improvement_for_prehospital_providers.pdf

<http://www.health.state.ny.us/nysdoh/ems/pdf/06-06.pdf>

1. All existing ambulance and or emergency medical services within the proposed area in terms of but not limited to: ...quality assurance;

North Carolina: www.EMSPIC.org

North Dakota:

Quality Management: See NHTSA Assessment document. No other document exists.

<http://www.health.state.nd.us/EMS/pdfs/North%20Dakota%20Reassessment%20Final%20Report.pdf>

Ohio:

www.ems.ohio.gov/rpab/medcourse/EMS%20Dir%20Book%20Chapter%2011.pdf

<http://www.ems.ohio.gov/datacenter/2006%20Regional%20PI%20Benchmarks.pdf>

<http://codes.ohio.gov/orc/4765.12>

Oklahoma: <http://www.ok.gov/health/documents/SystemsGuidebook20-20EMS.pdf>

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Continuous Quality Improvement

Traditionally reserved for hospitals and metropolitan agencies, Continuous Quality Improvement (CQI) has not often been utilized in rural or BLS systems. CQI should be adopted and embraced by all levels of EMS and in all demographic areas. How do EMS decision-makers know that what the EMTs are doing makes a difference unless they take a critical look?

Some questions to be asked include:

What are we doing?

How often are we doing it?

How well are we doing it?

How do we know we are doing it well?

What are we doing it with?

Under what conditions are we doing it?

To whom are we doing it?

Why are we doing it?

What are our desired consequences for doing it?

How well are we documenting what we are doing?

How much did it cost for us to get ready to do it?

How much will it cost for us to continue doing it?

What is the benefit if we do it this way, or another?

Who is doing it?

Should we be doing it at all?

Continuous Quality Improvement involves planning, implementing the plan, monitoring, analyzing, improving the plan, working the improved plan, monitoring the improved performance, etc. In this way, EMS systems are continuously seeking to provide their constituents the most up-to-date services they can and as efficiently and cost-effectively as they can.

A Continuous Quality Improvement program may be handled in a team concept. CQI team members should include at a minimum the following people:

physician medical director

training coordinator

a senior EMT

If the EMS system plans for quality, monitors quality, and improves quality, then the EMS system will continuously deliver quality care to their patients.

Just as we asked a series of questions in the BLS chapter of this Guidebook, we should continue to ask the same questions at the ALS level. These questions are all the more pertinent as we are now dealing with invasive skills and procedures, high-tech biomedical equipment, and medications of various types that interact with and react to each other in various ways.

The same Continuous Quality Improvement planning, monitoring, and improvement process should be conducted at the ALS levels and can be adapted for any process being studied.

The ALS CQI Team should include:

Physician Medical Director

Training Coordinator

Communications Manager

Data Management Person

Patient Accounts Person

Senior EMT or Paramedic

Peer Review is one concept that works in some areas. It allows for EMTs and Paramedics to review one another's reports, learn from the successes and mistakes of others, and helps the physician medical director to key in on potential areas of concern for improvement or outstanding recognition.

Oregon: http://arcweb.sos.state.or.us/rules/OARs_300/OAR_333/333_250.html

333-250-0041

Ambulance Service Personnel Educational Requirements and Quality Improvement

(4) The licensee must have a written quality improvement program that is approved by the EMS Medical Director.

Pennsylvania:

<http://www.pacode.com/secure/data/028/chapter1001/subchapDtoc.html>

A regional EMS council, after considering input from participants in and persons served by the regional EMS system, shall develop and implement a regional EMS quality improvement program to monitor the delivery of EMS...

<http://www.health.state.pa.us/pdf/hpa/ems/799emsplan/emsoffic.pdf>

Refers to the 1996 Quality Improvement Guide

Rhode Island: None found.

South Carolina: <http://www.scdhec.net/administration/regs/docs/61-7.pdf>

Each licensed provider that provides patient care shall retain a medical control physician to maintain

quality control of the care provided, whose functions include the following:

A. Quality assurance of patient care including development of protocols, standing orders, training, policies, and procedures; and approval of medications and techniques permitted for field use by direct observation, field instruction, in-service training or other means including, but not limited to:

1. Patient care report review;
2. Review of field communications tapes;
3. Post-run interviews and case conferences;

4. Investigation of complaints or incident report.

South Dakota:

<http://legis.state.sd.us/statutes/DisplayStatute.aspx?Type=Statute&Statute=34-11-11>

34-11-11. Development of quality assurance program for advanced life support providers-- Requirements--Reviews--Reports. Any ambulance service that provides advanced life support shall conduct a quality assurance program. The quality assurance program shall include, at a minimum, a review of the appropriate use of oxygen therapy, the appropriate use of intravenous therapy, medication administration, and the appropriate use of cardiac monitors. The Department of Public Safety shall develop a quality assurance program that meets the requirements of this section. The ambulance service may use the program developed by the department or the ambulance service may develop its own quality assurance program. The ambulance service shall compile the quality assurance reviews into an annual report, which shall be kept on file for at least three years and made available to the Department of Public Safety upon request.

Tennessee: <http://www.state.tn.us/sos/rules/1200/1200-12/1200-12-01.pdf>

(a) Medical Director - Each service classified or otherwise providing advanced or extended life support shall retain a medical director to maintain quality control of the care provided, whose functions shall include the following:

1. Quality Assurance of patient care, including development of protocols, standing orders, training, policies, and procedures; and approval of medications and techniques permitted for field use by service personnel in accordance with regulations of the department; quality assurance of field performance as may be provided by direct observation, field instruction, inservice training or other means including, but not limited to:

- (i) Ambulance Run Report Review
- (ii) Review of field communications tapes
- (iii) Post-run interviews and case conferences
- (iv) Critiques of simulated or actual patient presentations
- (v) Investigation of complaints or incident reports

Texas: None found.

Utah:

26-8a-205. Pediatric quality improvement program.

The department shall establish a pediatric quality improvement resource program.

Vermont: None found.

Virginia: <http://169.134.226.36/Rules&Re.nsf/>

PART 2. EMS AGENCY, EMS VEHICLE AND EMS PERSONNEL STANDARDS

Article 1. EMS Agency Licensure and Requirements.

12VAC5-31-600 Quality management reporting. An EMS agency shall have an ongoing Quality Management (QM) Program designed to objectively, systematically and continuously monitor, assess and improve the quality and appropriateness of patient care provided by the agency. The QM Program shall be integrated and include activities related to patient care, communications, and all aspects of transport operations and equipment maintenance pertinent to the agency's mission. The agency shall maintain a QM report that documents quarterly PPCR reviews, supervised by the operational medical director.

PART 4. EMS PHYSICIAN REGULATIONS.

Article 1. EMS Physician Regulations.

12VAC5-31-1890 Responsibilities of operational medical directors.

6. Reviewing and auditing agency activities to ensure an effective quality management program for continuous system and patient care improvement, and functioning as a resource in the development and implementation of a comprehensive mechanism for the management of records of agency activities including prehospital patient care and dispatch reports, patient complaints, allegations of substandard care and deviations from patient care protocols or other established standards.

Washington: <http://www.doh.wa.gov/hsqa/emstrauma/download/WACS/246-976-910.pdf>

West Virginia: <http://www.wvoems.org/Portals/2/law/64csr48.pdf>

2.29. Off-Line Medical Direction. – the component of medical direction given to EMS

personnel and agencies through the OEMS Medical Direction System which includes all the

activities of the State, Regional, and Agency Medical Directors; and Medical policy and Care

Committees; including but not limited to, medical treatment protocols, policies and procedures,

educational requirements, quality improvement, scope of practice, privilege to practice, medical

command center operation, and all other issues of a medical nature.

5.3.c. Quality Assurance.

5.3.c.1. The EMS Agency regularly provides findings from quality reviews to those involved in the activities reviewed. The findings may call for change in operations, or specific inservice training for individuals or the entire agency. The medical director insures that such findings are binding, implemented, and sufficiently documented - ten (10) points.

5.3.c.2. The EMS agency conducts quality reviews. The findings may call for a change in operations, or specific inservice training for individuals or the entire agency. The medical director or delegated EMS professional is involved in the findings but does not sufficiently document that they are binding and implemented - five (5) points.

Wisconsin: <http://www.legis.state.wi.us/rsb/code/hfs/hfs112.pdf>

L) A quality assurance and improvement plan including the name of the quality assurance director, copies of policies and procedures to be used in medical control, implementation and evaluation of the program.

Wyoming: None found.

NATIONAL STANDARD

(Excerpt from State of North Dakota: A Reassessment of Emergency Medical Services, April 8-10, 2008. Performed by the National Highway Traffic Safety Administration Technical Assistance Team)

Standard

A comprehensive evaluation program is needed to effectively plan, implement and monitor a statewide EMS system. The EMS system is responsible for evaluating the effectiveness of services provided victims of medical or trauma related emergencies, therefore the EMS agency should be able to state definitively what impact has been made on the patients served by the system. A uniform, statewide out-of-hospital data collection system exists that captures the minimum data necessary to measure compliance with standards (i.e., a mandatory, uniform EMS run report form or a minimum set of data that is provided to the state); data are consistently and routinely provided to the lead agency by all EMS providers and the lead agency performs routine analysis of this data. Pre-established standards, criteria and outcome parameters are used to evaluate resource utilization, scope of services, effectiveness of policies and procedures, and patient outcome. A comprehensive, medically directed, statewide quality improvement program is established to assess and evaluate patient care, including a review of process (how EMS system components are functioning) and outcome. The quality improvement program should include an assessment of how the system is currently functioning according to the performance standards, identification of system improvements that are needed to exceed the standards and a mechanism to measure the impact of the improvements once implemented. Patient outcome data is collected and integrated with health system , emergency department and trauma system data; optimally there is linkage to data bases outside of EMS (such as crash reports, FARS, trauma registry, medical examiner reports and discharge data) to fully evaluate quality of care. The evaluation process is educational and quality improvement/system evaluation findings are disseminated to out-of-hospital emergency medical care providers. The lead agency ensures that all quality improvement activities

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have legislative confidentiality protection and are non-discoverable.

Appendix 3: Lessons from other Health Care references

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