



CHARLES COUNTY EMERGENCY MEDICAL SERVICES

Continuous Quality Improvement Plan

Completed By: Captain Robbie Jones

Date Completed: March 7, 2016

Submitted By: James E. Mitchell, MD

Date Submitted: March 7, 2016

Date Revised:



Effective Date: March 7, 2016

OVERVIEW

Charles County Emergency Medical Services (CCEMS) is committed to transitioning from a traditional Quality Assurance program that is focused almost entirely on deficiencies in patient care provided by individual health care workers to a more comprehensive Continuous Quality Improvement (CQI) program that instead focuses on patient care that is provided by the EMS system as a whole. Put simply, CQI is a philosophy that encourages all health care team members to continuously ask how are we doing, can we do it better, and more specifically, can we do it more efficiently?

Continuous quality improvement begins with the culture of improvement for the patient, the practice, and the population in general. Besides creating an inquisitive CQI culture for the EMS system, the key to any CQI initiative is using a structured planning approach to evaluate the current EMS system processes and improve systems and processes to achieve the desired outcome and vision for the desired future state. Tools commonly used in CQI include strategies that enable team members to assess and improve health care delivery and services. Applying CQI across an organization means that the health care components of that organization must understand what works and what does not work in the current state and how the outcomes of CQI processes will change care delivery and quality improvement goals. The CQI plan identifies the desired clinical or administrative outcome and the evaluation strategies that enable the team to determine if they are achieving that outcome. The team also intervenes, when needed, to adjust the CQI plan based on continuous monitoring of progress through an adaptive, real-time feedback loop.

CQI SYSTEM COMPONENTS

Medical Review Committee (MRC)

- i) In accordance with COMAR Title 30.03.04.03, all EMS Operational Programs (EMSOP) must have a Medical Review Committee
- ii) Composition of the MRC shall be determined by the Jurisdictional Medical Director (JMD) in conjunction with the EMSOP. As such, the Charles County Medical Review Committee currently consists of the following:
 - (a) Jurisdictional Medical Director
 - (b) Assistant Medical Director
 - (c) Career Quality Assurance Officer
 - (d) Volunteer Quality Assurance Officer
 - (e) 911/Communications Quality Assurance Officer
 - (f) Career ALS Provider/BLS Provider– both selected by the Department of Emergency Services EMS Chief
 - (g) Volunteer ALS Provider/BLS Provider – both selected by the Charles County Association’s Chief of EMS
 - (h) At times, it may be necessary to include other members of the health care community including hospital staff, EMS Duty Officers, community physicians, etc. These members will be included when their expertise is needed and, as such, they should be considered ad hoc members only.
- iii) Responsibilities
 - (a) The Charles County Medical Review Committee will meet quarterly to review the following:
 - 1. Summary reports issued by the County QA Officers, the QA Subcommittee, and Company QA Officers
 - 2. Plans of remediation and provider progress
 - 3. Data for any system wide process that is currently being evaluated
 - (b) At times, the MRC will need to meet on an ad hoc basis in order to consider complaints, protocol variances or provider deficiencies. These meetings shall occur in a timeframe that is consistent with COMAR requirements.
 - (c) Develop and/or advocate for system wide solutions when root cause analysis points to system wide deficiencies.
 - (d) Provide feedback to the MIEMSS Protocol Review Committee recommending changes to existing or new protocols when necessary.
 - (e) Develop, facilitate and review plans of remediation for individual providers when needed.
 - (f) Direct the CQI Activities of the County Quality Assurance Officers, the Quality Assurance Subcommittee and Company Quality Assurance Officers.

Jurisdictional Medical Director (JMD)

- i) COMAR Title 30.03.03.03 tasks the JMD with “providing medical oversight of patient care, including emergency medical dispatch” and that one of the chief means of facilitating this oversight is through the approval and participation in “a comprehensive quality assurance plan covering all aspects of EMS patient care.”
- ii) Responsibilities
 - (a) Serving on the Medical Review Committee and engaging the responsibilities of the MRC as outlined above.
 - (b) Assist in the development and oversight of remedial training proposals for both individuals and the EMS system as a whole.
 - (c) Determining the ability of a provider to function independently within the EMS operational program.
 - (d) Limiting or suspending the privileges of an EMS provider within the EMS Operational Program if the provider is considered by the JMD to be a threat to the health or well-being of patients.
 - (e) Suspensions or limitations to provider privileges may also be enforced when, after following due process procedures, an EMS provider is found to have violated prohibited conduct as outlined in COMAR or Maryland EMS protocol. Violations of departmental policy and procedures should be governed at the company level. Departmental policy and procedures as defined in this plan shall be limited to items not covered under Maryland State EMS Protocol or Maryland COMAR Regulations.

Quality Assurance Officer

- i) Two County-level Quality Assurance Officers shall be appointed for Charles County. One shall be appointed by the Charles County Association of EMS in conjunction with the Charles County Medical Director and will oversee Quality Assurance reviews and concerns for volunteer personnel. The second shall be appointed by the Department of Emergency Services (DES) in conjunction with the Charles County Medical Director and will oversee Quality Assurance reviews and concerns for DES personnel. The Quality Assurance Officer shall meet all qualifications as stated in COMAR Title 30.03.04.08
- ii) Responsibilities
 - (a) Oversees the implementation of the Charles County CQI Plan
 - (b) Serves on the Medical Review Committee and engages the responsibilities of the MRC as outlined above.
 - (c) Performs internal audits of medical records to develop strategies for improvement.
 - (d) Assists in the implementation and monitoring of remedial action plans as directed by the Medical Review Committee.

- (e) Tracks and investigates customer complaints and sentinel events.
- (f) Completes summary reports for MIEMSS as required under COMAR Title 30.03.04

Quality Assurance Subcommittee

- i) The Quality Assurance Subcommittee operates under the auspice of the Medical Review Committee. As such, it is responsible for regularly carrying out CQI Activities as directed by the MRC.
- ii) The subcommittee shall consist of Company QA Officers or Representatives from:
 - (a) Each volunteer EMS agency
 - (b) Department of Emergency Services – EMS Division
 - (c) Department of Emergency Services – Communications Division
 - (d) Charles Regional Medical Center
- iii) The subcommittee shall meet no less than four (4) times per year.
- iv) Members of the subcommittee will serve as conduits of information from the Medical Review Committee to the individual stakeholders including volunteer EMS companies, local hospitals and the Department of Emergency Services.

Company Quality Assurance Officer

- i) Company Quality Assurance Officers are quality assurance agents that operate at the individual company level. Each EMS company shall appoint one or more Company QA Officers
- ii) Company QA Officers assist in carrying out CQI Activities for their individual company on a routine basis.
- iii) When selecting Company QA Officers, company officers need to identify candidates that possess a strong EMS background.
- iv) Company QA Officers must obtain MIEMSS Company-level QA Officer training prior to or as soon as possible after appointment. In addition, the EMSOP must train each Company QA Officer on the Charles County Quality Assurance Plan including how they will be expected to carry out their responsibilities as outlined in the plan.

CQI ACTIVITIES

Incident Review

- i) Company QA Officers shall be responsible for the retrospective review of incidents. Whenever possible, it should be the goal of all EMS agencies to review 100% of all patient encounters for that agency. Although it is critical to regularly review high acuity calls such as resuscitative events, often times more can be learned from the review of lower priority calls. It is important to evaluate whether providers are routinely under-triaging patients, if they are following proper procedure when obtaining signed refusals or whether ALS units are performing appropriate assessments prior to releasing patients to BLS transport. This type of information can only be gathered if we are reviewing all patient care reports regardless of disposition. At a minimum however, each department will review a minimum of 50 calls each month or 25 percent of the total runs for that station whichever is greater. In addition, Company QA Officers may be asked to review events for which the QA Subcommittee or Medical Review Committee is seeking data. This might include events such as signed refusals, procedures such as endotracheal intubation, or chief complaints such as chest pain.
- ii) Retrospective reviews should be performed using the Quality Assurance templates that are available for the Charles County eMEDS service. Use of these templates will allow for more consistent and objective reviews.
- iii) The Quality Assurance Officer for the Communications Division will be responsible for reviewing 911 calls for service.

Complaint Handling

- i) In order to ensure consistency and accuracy, it is important for customer inquiries and complaints to be handled in a systematic manner. For this reason, the Complaint Handling Script (Attachment B) should be used whenever recording customer complaints. All relevant information should then be forwarded to the appropriate County QA Officer for further action.
- ii) Internal audits of EMS run reports and 911 calls for service that uncover protocol variances, skills issues that may cause harm to patients, violations of standards of care or prohibited conduct as outlined in COMAR Title 30 must be reported to the appropriate County QA Officer.

- iii) Customer complaints or other provider concerns forwarded to the County QA Officer shall be handled according to the Customer Inquiry Policy outlined in the flowchart found in Attachment D.
- iv) Although all customer inquiries are required to be reported to a County Quality Assurance Officer, it is important for the Company QA Officer to stay apprised of the investigative and resolution process.

Documentation Requirements

- i) COMAR Title 30.03.04.04 requires that within 24 hours of a call's dispatch, any unit responding to call within the state, responding to a call from within the state, providing EMS care, providing EMS transport or that applies the Maryland Medical Protocols for Emergency Medical Services Providers shall complete a patient care report and submit it to eMEDS. This requirement is further reinforced in Maryland EMS Protocol. Failure to adhere to this policy therefore shall be considered both prohibited conduct and a protocol variance.
- ii) Regularly performed EMS CAD Reconciliation will allow the EMSOP to ensure that patient care reports are being submitted within the required time frame.
- iii) When reports are discovered missing, the Company Officer should work to resolve the issue as quickly as possible. Any report that is outstanding more than seven (7) days should be reported on the PCR Compliance Form (Attachment E) and forwarded to the Quality Assurance Subcommittee.

Reporting Requirements

- i) All Quality Assurance events that are required to be reported to MIEMSS such as Prohibited Conduct Violations and Protocol Variances will be reported in the manner prescribed by COMAR or Maryland State EMS Protocol. Required documents such as the MIEMSS 5-Day Report shall be submitted to the MIEMSS Office of Compliance by the Charles County Quality Assurance Officer.
- ii) Regular Quality Assurance Reports documenting Quality Assurance Activities will be completed and submitted to the MIEMSS Office of Compliance by the Charles County Quality Assurance Officer on a quarterly basis.

DUE PROCESS

- i) When a complaint against an EMS provider is received, the provider shall be notified in writing by the County Quality Assurance Officer of the nature of the complaint within five (5) days.
- ii) If, after the initial investigation, the Quality Assurance Officer deems the complaint to have merit, they will forward a summary of the investigation to the Medical Review Committee for review. If the committee determines that remediation or discipline may be appropriate then the provider shall be afforded the opportunity to interview with the committee. The Medical Review Committee must notify the provider in writing at least fifteen (15) days prior to the meeting. This notification period may be waived by the provider at his or her discretion.
- iii) Chief Officers shall maintain the right to place providers under their command on an inactive operational status pending the outcome of a Medical Review Board hearing.
- iv) Decisions made by the Medical Review Committee are subject to appeal to the Region V Medical Director.
- v) This policy does not otherwise affect the rights of parties under an employer-employee relationship or other contractual relationship including the rights of discipline and termination.

CONFIDENTIALITY

- i) All Quality Assurance Activities are confidential and, as such, complete discretion must be maintained at all times. All QA correspondence, written or email, must indicate that it is ***Confidential and Non-Discoverable and intended solely for Quality Assurance purposes***
- ii) The Medical Review Committee shall be a committee established in MIEMSS subject to the confidentiality and immunity provisions of Health Occupations Article, § 1-401, Annotated Code of Maryland, as well as the other provisions of that statute.
- iii) Each attendee at any meeting of a Medical Review Committee or its subcommittees shall be advised in writing of the confidential nature of committee proceedings. A signed acknowledgment must be obtained prior to any meeting. (See Attachment F)
- iv) Company Officers for Charles County EMS agencies should expect to come into contact with confidential information on a regular basis. This includes patient information that should be considered Protected Health Information according to HIPAA regulations as well as Quality Assurance information which shall be considered confidential and non-discoverable. All company officers therefore should sign and submit Confidentiality Agreements (Attachment G) upon assuming office.
- v) Companies must submit the names of their Company QA Officers to the EMS Chief of the Charles County Association who must then submit an executed Business Agreement (Attachment H) to the Director of Emergency Services for those individuals

CQI PROCESSES

- i) Charles County EMS supports and encourages the organizational change to embrace Continuous Quality Improvement. The best way to improve the quality of the medical care we provide to our patients lies in studying and improving the processes of care. The CQI program encourages the use of the DMAIC model to study and improve processes relating to out-of-hospital medical care. See Attachment I for details on how to apply the DMAIC model.
- ii) Requests for system review of patient care processes may be submitted to the Charles County Medical Review Committee for consideration. Requests should be made using the CQI Process Review form (Attachment J).

ATTACHMENT A:

GLOSSARY

Glossary

- **Continuous Quality Improvement (CQI)** – A system of continuously improving the medical care provided in a system by defining and measuring health care processes and using the objective data to plan and carry out opportunities for improvement within the process.
- **Continuous Quality Improvement Activities** – CQI activities are tasks that are designed to measure and evaluate the performance of the EMS system and its providers. These activities include such things as the retrospective review of patient care reports, the review of key performance indicators, the handling of customer complaints, and ensuring that providers are adhering to documentation requirements.
- **DMAIC Process** – a problem solving methodology that provides for the systematic review of various processes deployed in the EMS system. The steps of the DMAIC process include **D**efining the problem, **M**easuring the current level of performance, **A**nalyzing process factors that are adversely affecting the process, **I**mproving the system by generating and implementing ideas designed to address identified flaws, **C**ontrol process deterioration by monitoring performance and sustaining improvements over time
- **EMS Operational Program (EMSOP)** – includes all public safety agencies and personnel operating within Charles County that are circumscribed by MIEMSS as an EMS system component. These include the Charles County Commissioners, the jurisdictional medical director, the Charles County Department of Emergency Services, EMS Division and its personnel, the Charles County Department of Emergency Services, 911-Communications Division and its personnel, the volunteer EMS agencies as recognized by the Charles County EMS Association and their personnel, and the volunteer fire departments as recognized by the Charles County Volunteer Fireman's Association and their licensed EMS personnel.
- **Level 1 Inquiry** – the most serious of quality assurance events that includes actions that indicate that a provider may pose a potential danger to patients, that caused death or worsening of a patient's condition, or that violate COMAR Title 30's Prohibited Conduct. These events must be reported to the Charles County Quality Assurance Officer Career or Volunteer within 24 hours of their discovery. Notification should be made via email.
- **Level 2 Inquiry** – less serious quality assurance events that include protocol variances. These events must also be reported to the Charles County Quality Assurance Officer. Notification should be made via email within 24 hours of their discovery.
- **Level 3 Inquiry** – minor quality assurance events that are simple and routine in nature. These are limited to events not covered by COMAR regulations such as issues with provider attitude, unintentional property damage or patient injury not related to care.

ATTACHMENT B:

Complaint Handling Script

Complaint Handling Script

Tips

- Thank the person for their complaint. This lets them know that their input is valued. In addition, it starts the conversation off on the right foot and increases the chances that it remains pleasant. An example, "Thank you Mr. Jones for calling us. We really appreciate the opportunity to hear from our customers and your input helps us improve our service."
- Don't be defensive or argumentative. You may not agree with everything or even anything the customer is saying but remember that you are only taking their complaint. You are not defending the provider, your company or your system.
- When you have taken all the necessary information, summarize their complaint. This will help ensure that you have understood the complaint as the customer perceives it.
- Ensure the customer that you will forward the information to the appropriate person and that someone will contact them. They may ask to speak with someone else from the start, perhaps your chief officer or the quality assurance officer. Never give the customer personal contact information for these individuals. Instead, ensure them that you have the customer's contact information and that someone will contact them.

Information to Collect

Customer Name		Contact Information	
Date of Service		Relation to Patient	
Date/Time Called		Person Receiving Complaint	
Nature of Concern			

ATTACHMENT C:

FACT FINDING GUIDE

	Charles County Emergency Medical Services		
	Office of the Medical Director		
	Department: CQI		
	Document: Fact Finding Guide		
Notes: Information contained throughout this document shall be considered Confidential and Non-Discoverable.			

GENERAL INFORMATION

Event Type	Quality Assurance – Standard of Care		
Date Notification Received		Person Notified	
Notification Made By		Method of Notification	
Incident Date		Incident Number	
Incident Address			

PRIMARY CONCERN

Nature of Concern			
Subject of Concern		eMEDS PCR Number	
Unit Number		Station Number	

SECONDARY CONCERN

Nature of Concern			
Subject of Concern		eMEDS PCR Number	
Unit Number		Station Number	

NOTIFICATION MADE BY

Notification Made By		Relationship to Patient	
Mobile Phone		Home Phone	
Address			
Email			

PATIENT INFORMATION

Name		Age or DOB	
Mobile Phone		Home Phone	
Address			
Email			

PERSONNEL INVOLVED IN INCIDENT

Provider 1

Name		MIEMSS ID	
Unit Number		Station	
Certification	• EMR • EMT • CRT • Paramedic • EMD	eMEDS PCR Number	

Provider 2

Name		MIEMSS ID	
Unit Number		Station	
Certification	• EMR • EMT • CRT • Paramedic • EMD	eMEDS PCR Number	

Provider 3

Name		MIEMSS ID	
Unit Number		Station	
Certification	• EMR • EMT • CRT • Paramedic • EMD	eMEDS PCR Number	

Provider 4

Name		MIEMSS ID	
Unit Number		Station	
Certification	• EMR • EMT • CRT • Paramedic • EMD	eMEDS PCR Number	

Provider 5

Name		MIEMSS ID	
Unit Number		Station	
Certification	• EMR • EMT • CRT • Paramedic • EMD	eMEDS PCR Number	

Provider 6

Name		MIEMSS ID	
Unit Number		Station	
Certification	• EMR • EMT • CRT • Paramedic • EMD	eMEDS PCR Number	

WITNESSES TO INCIDENT

Name		Phone	
Address			
Email			
Notes			

Name		Phone	
Address			
Email			
Notes			

Name		Phone	
Address			
Email			
Notes			

Name		Phone	
Address			
Email			
Notes			

CONVERSATION LOG

Name		Interview Date	
Location		Method	
Phone		Witness	

DISCUSSION

CONVERSATION LOG

Name		Interview Date	
Location		Method	
Phone		Witness	

DISCUSSION

CONVERSATION LOG

Name		Interview Date	
Location		Method	Phone
Phone		Witness	

DISCUSSION

CONVERSATION LOG

Name		Interview Date	
Location		Method	Phone
Phone		Witness	

DISCUSSION

INFORMATION TO GATHER

REPORT	DATE	INITIAL
CAD PRINTOUT		
eMEDS REPORT – 1		
eMEDS REPORT– 2		
eMEDS REPORT – 3		
PATIENT REFUSAL		
CHARLES CO 911 AUDIO		
EMRC AUDIO		

NOTIFICATIONS

PERSON	DATE NOTIFIED	
	INITIAL	FINAL
Provider		
EMS QA Officer		
Jurisdictional Medical Director		
Volunteer EMS Chief		
Career EMS Chief		
Station Chief		
State EMS Medical Director		
MIEMSS 5-Day		
MIEMSS 35-Day		
Complainant		

FINDINGS OF FACT

ROOT CAUSE ANALYSIS

RESOLUTION

REMEDIATION PLAN

DISPOSITION

	SUSTAINED	ALL OR PART OF THE ACT OCCURRED AS ALLEGED. A FINDING OF 'SUSTAINED' MUST BE BASED UPON THE EXISTENCE OF SUBSTANTIAL FACT IN SUPPORT OF REASONABLE PROOF
	NOT SUSTAINED	THE INVESTIGATION PRODUCED INFORMATION INSUFFICIENT TO EITHER PROVE OR DISPROVE THE ALLEGATIONS
	EXONERATED	THE ACT OCCURRED BUT WAS JUSTIFIED, LAWFUL AND PROPER
	UNFOUNDED	THE ALLEGED ACT DID NOT OCCUR
	FORWARDED	

MEDICAL DIRECTOR STATEMENT

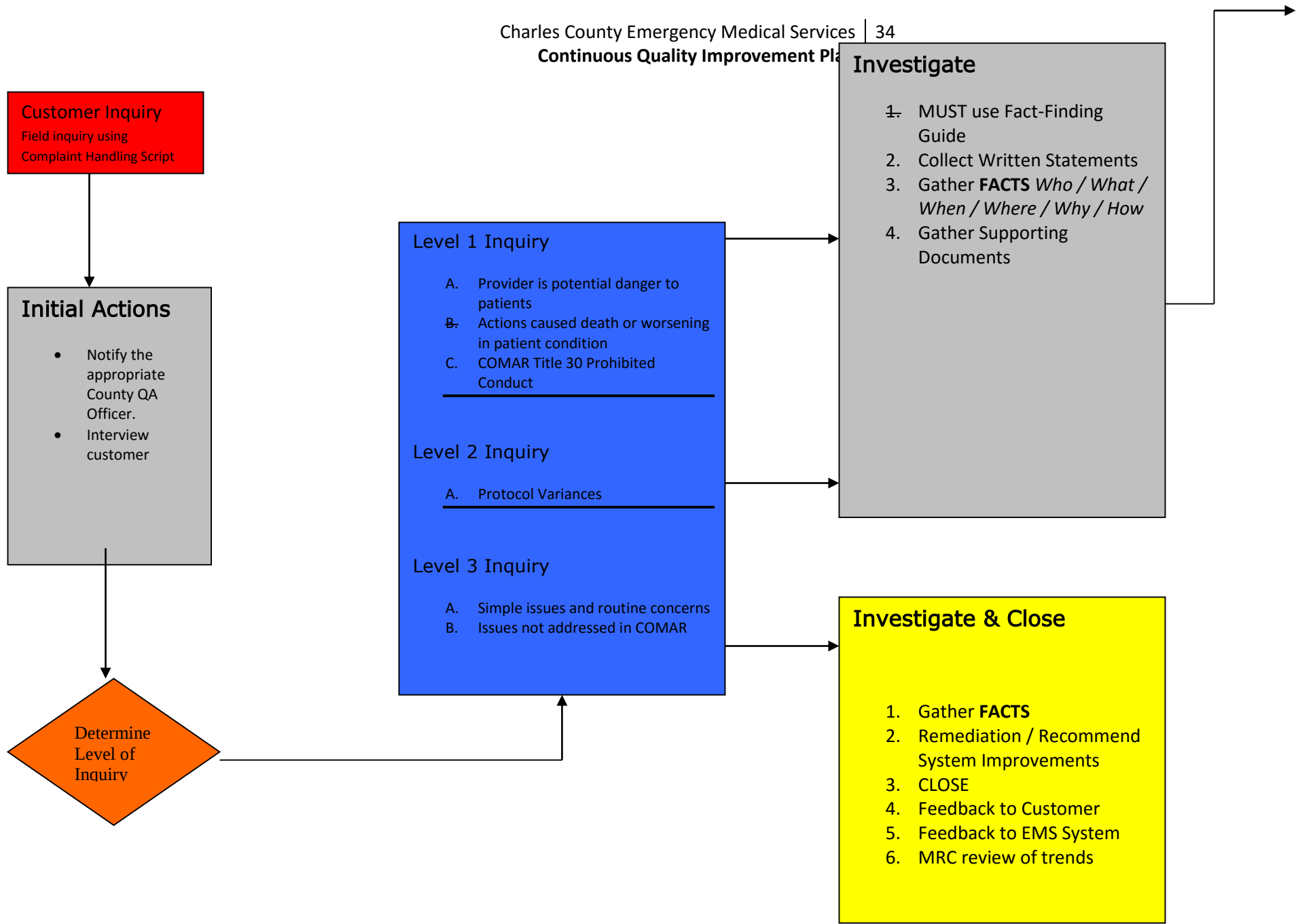
I have reviewed the information contained within this Fact Finding Guide in conjunction with the Charles County Medical Review Board. My signature below indicates that I agree with the aforementioned Resolution(s) and Plan of Remediation. Final disposition of this case is based upon the summation of all testimony contained herein which is accurate and truthful to the best of our knowledge. Neither I nor the members of the Charles County Medical Review Board shall be held responsible for outcomes based upon inaccurate or untruthful information, either verbal or written.

Medical Director – Signature

Date

ATTACHMENT D:

CUSTOMER INQUIRY POLICY



Quality Assurance Officer

1. Ensure concerned provider is notified
2. Continue investigation
3. Notify Jurisdictional Medical Director
4. File MIEMSS 5-Day Report
5. Finalize Fact Finding Guide with Findings of Fact, Root Cause Analysis and Recommended Course of Action

Actionable Areas

Code of Conduct

General Performance Issues

Resource Problems

Communications Problems

Recommendations

Remediation

Re-education

System Improvements

Lessons Learned

Medical Review Committee

Review Root Cause Analysis

Review Remediation Plan

Review System Improvements

Review Lessons Learned

Closure

- Remediation & Follow-Up
- Implement System Improvements
- Publish Lessons-Learned
- Final Notifications
- MIEMSS 35-Day Form
- Complete Database

Follow Up with Customer

*Feedback to EMS
System*

ATTACHMENT E:

Patient Care Reporting Compliance

Patient Care Reporting – Compliance (Reports Pending Completion or Completed > 7 Days from Incident Date)

Station		QA Officer		Period Covered	
Incident Date	Incident Number	No of Days Late	Provider Responsible	Date Report Completed	

ATTACHMENT F:

CONFIDENTIALITY FORM

CHARLES COUNTY EMERGENCY MEDICAL SERVICES

Confidentiality Agreement

I, _____, understand that as part of my position and/or responsibilities, I will come in contact with patient care reports. The reports contain medical information about patients evaluated, treated, and/or transported by Charles County EMS. These reports include both paper and electronic records.

I understand that under Maryland Law and the Health Insurance Portability and Accountability Act, the unauthorized disclosure of protected health information is unlawful and could subject me to civil and criminal penalties. Furthermore, I understand, acknowledge and agree that I will not reveal the name, address or any identifying information pertinent to any medical record which I may come in contact with during the course of my quality assurance duties.

In addition, I acknowledge and understand that all quality assurance meetings are to be considered confidential and no information discussed at these meetings may be disclosed to any other party.

I further understand that Charles County EMS and its agencies are entitled to undertake such action as is deemed appropriate to ensure that confidentiality is maintained. This includes disciplinary action necessitated by any breach or threatened breach of this agreement. I further understand that willful or knowing release of information deemed confidential could result in criminal penalties.

Signature: _____ Date: _____

Title/Affiliation: _____

Telephone: _____

Email: _____

ATTACHMENT G:

CONFIDENTIALITY FORM

CHARLES COUNTY EMERGENCY MEDICAL SERVICES

Confidentiality Agreement

I, _____, understand that as part of my position and/or responsibilities, I will come in contact with patient care reports. The reports contain medical information about patients evaluated, treated, and/or transported by Charles County EMS. These reports include both paper and electronic records.

I understand that under Maryland Law and the Health Insurance Portability and Accountability Act, the unauthorized disclosure of protected health information is unlawful and could subject me to civil and criminal penalties. Furthermore, I understand, acknowledge and agree that I will not reveal the name, address or any identifying information pertinent to any medical record which I may come in contact with during the course of my duties.

In addition, I acknowledge and understand that all quality assurance reviews and investigations are to be considered confidential and no information gathered or reviewed during these processes may be disclosed to any other party.

I further understand that Charles County EMS and its agencies are entitled to undertake such action as is deemed appropriate to ensure that confidentiality is maintained. This includes disciplinary action necessitated by any breach or threatened breach of this agreement. I further understand that willful or knowing release of information deemed confidential could result in criminal penalties.

Signature: _____ Date: _____

Title/Affiliation: _____

Telephone: _____

Email: _____

ATTACHMENT H:

Charles County Business Agreement

BUSINESS ASSOCIATE AGREEMENT

Between Charles County Government and the , Inc.

RECITALS

WHEREAS, Covered Entity, Charles County Government ("County"), wishes to engage the services of Business Associate, , Inc. with respect to protected health care information;

WHEREAS, Covered Entity wishes to disclose certain information to Business Associate, some of which may constitute Protected Health Information ("PHI") (defined below).

WHEREAS, Covered Entity and Business Associate intend to protect the privacy and provide for the security of PHI disclosed to Business Associate, in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 (the "HITECH Act"), and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the "HIPAA Regulations") and other applicable laws.

WHEREAS, as part of the HIPAA Regulations, the Privacy Rule and the Security Rule (defined below) require Covered Entity to enter into a contract containing specific requirements with Business Associate prior to the disclosure of PHI, as set forth in, but not limited to, Title 45, Sections 164.314(a), 164.502(e) and 164.504(e) of the Code of Federal Regulations ("C.F.R.") and contained in this Agreement.

NOW THEREFORE, in consideration of the mutual promises below and the exchange of information pursuant to this Agreement, the parties agree as follows:

Definitions

Catch-all definition:

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules:

Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

Specific definitions:

(a) Business Associate. "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean the Waldorf Volunteer Fire Department, Inc.

(b) Covered Entity. "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean Charles County Government.

(c) HIPAA Rules. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

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Obligations and Activities of Business Associate

Business Associate agrees to:

- (a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;
- (b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement;
- (c) Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware;
- (d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information;
- (e) Make available protected health information in a designated record set to the covered entity as necessary to satisfy covered entity's obligations under 45 CFR 164.524;
- (f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity's obligations under 45 CFR 164.526;
- (g) Maintain and make available the information required to provide an accounting of disclosures to the covered entity as necessary to satisfy covered entity's obligations under 45 CFR 164.528;
- (h) To the extent the business associate is to carry out one or more of covered entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and
- (i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.
- (j) Indemnification. Business Associate shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Business Associate in connection with the representations, duties and obligations of Business Associate under this Agreement. The parties' respective rights and obligations under this Section shall survive termination of the Agreement. "

Permitted Uses and Disclosures by Business Associate

- (a) Business associate may only use or disclose protected health information as required and limited by the Business Associate Agreement between the parties.
- (b) Business associate may use or disclose protected health information as required by law.
- (c) Business associate agrees to make uses and disclosures and requests for protected health information consistent with covered entity's minimum necessary policies and procedures.
- (d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity.

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(e) Business associate may use protected health information for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.

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(f) Business associate may disclose protected health information for the proper management and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law, or business associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(g) Business associate may provide data aggregation services relating to the health care operations of the covered entity. **Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**

(a) Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity under 45 CFR 164.520, to the extent that such limitation may affect business associate's use or disclosure of protected health information.

(b) Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate's use or disclosure of protected health information.

(c) Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect business associate's use or disclosure of protected health information.

Permissible Requests by Covered Entity

Covered entity shall not request business associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by covered entity.

Term and Termination

(a) Term. The Term of this Agreement shall be effective with the County and the ., and shall terminate upon appointment of a new Quality Assurance Officer(s) by the business associate or on the date the covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business associate authorizes termination of this Agreement by covered entity, if covered entity determines business associate has violated a material term of the Agreement.

(c) Obligations of Business Associate Upon Termination.

Upon termination of this Agreement for any reason, business associate, with respect to protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, shall:

1. Retain only that protected health information which is necessary for business associate to continue its proper management and administration or to carry out its legal responsibilities;
2. Return to covered entity or, destroy the remaining protected health information that the business associate still maintains in any form;
3. Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in this Section, for as long as business associate retains the protected health information;
4. Not use or disclose the protected health information retained by business associate other than for the purposes for which such protected health information was retained and subject to the same conditions set out at above which applied prior to termination; and
5. Return to covered entity or, destroy the protected health information retained by business associate when it is no longer needed by business associate for its proper management and administration or to carry out its legal responsibilities.

Effective Date: March 7, 2016

(d) Survival. The obligations of business associate under this Section shall survive the termination of this Agreement.

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Miscellaneous

(a) Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

(b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

(c) Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

IN WITNESS WHEREOF, the parties hereto have executed this Business Associate Agreement this _____, 201_, and do hereby warrant each unto the other that the person affixing his signature and seal hereto was duly authorized to execute same on behalf of each party.

WITNESS: , INC.

BUSINESS ASSOCIATE

By: President

Named Quality Assurance Officer:

Named Assistant Quality Assurance Officer:

WITNESS: COUNTY COMMISSIONERS OF CHARLES COUNTY, MD

COVERED ENTITY

By: Peter Murphy, President

Effective Date: March 7, 2016

ATTACHMENT I:

DMAIC MODEL FOR PROBLEM SOLVING

Introduction to the DMAIC Method

The DMAIC method is one of many models that can be used to organize and manage performance improvement projects. This process is not used solely for tackling EMS issues and one of the strengths of this method is that it can be applied widely across many sectors with equal success. Approaching project analysis in an organized, systematic manner increases the chances that your project will be executed successfully.

The DMAIC method consists of five phases: Define, Measure, Analyze, Improve, and Control.

Define

The most crucial part of any project is defining the nature of the problem that the project is designed to correct or the opportunity for improvement that it is designed to address. Beginning projects haphazardly with only vague goals in mind will often lead to frustrating outcomes. You should be as clear and concise as possible when defining the issue. Stick to bite-size problems. A defining statement for example that focuses on improving survival rates for cardiac arrest patients may certainly sound worthwhile, but it will be difficult to achieve significant results without clearer direction. Instead, focus on a single component of the overall system. For example, instead of trying to improve resuscitative rates for cardiac arrest victims, we can be more specific and focus on the early initiation of CPR. We can define the problem even more narrowly and ask how we might improve instances of dispatch-assisted CPR. A defining statement that is defined in such a concise way will likely yield more fruitful results.

Measure

The main goal of the measure phase is to develop a thorough understanding of how the process is designed and operates, along with a baseline measurement of its current level of performance. There are often many metrics available for measuring performance, so it will be important to identify the most relevant performance indicators. In the case of the cardiac

arrest study, we would most likely want to measure from the time of arrest to the time when CPR was first initiated. Establishing benchmarks gives us an idea of how efficiently the process is working and, more importantly, it allows us to compare our performance after changes are made to the process.

Analyze

The main goal of the analyze phase is to identify what problems or factors are adversely affecting the process. If we are experiencing long gaps between the onset of cardiac arrest and the initiation of CPR, we need to ask why. Potential causes include poor recognition of cardiac arrest, a low number of bystanders trained or who are willing to perform CPR, elderly spouses unable to follow dispatch commands, etc. At times, the list of potential problems are long and it is during the analyze phase that the most likely causes are identified.

Improve

Once you think you have identified opportunities for improvement, it is time to test your ideas and determine which solutions provide significant positive change. When developing potential solutions to be implemented and evaluated, be sure to consider the practical aspects to your proposed changes. How long will it take to put your ideas into effect? How much will it cost? What resources will you need and what is their availability?

Evaluate your results. Be objective. Were improvements noted and, if so, to what extent? If you did not achieve the results you were hoping for, try something else. Add another component and re-evaluate. If your changes brought improvement, advocate for their incorporation on a larger, more full-time scale.

Control

During the control phase, you will develop steps to prevent performance from deteriorating. Develop a way to monitor performance over time and address how to make sure those improvements are sustained over time.

ATTACHMENT J:

Request for CQI Process Review

Request for CQI Process Review

Define the nature of the deficiency or the opportunity for improvement as you perceive it. Be concise and specific.
Identify what you believe are the most significant metrics to gather and evaluate.
What do you feel are the most important contributors to deficient performance?
What changes do you believe should be implemented on a pilot basis that might lead to system improvement?

Submitted By: _____

Date Submitted: _____

Phone Number: _____

Email Address: _____