PSRO Complaint Investigation & Resolution

Purpose: To provide a consistent framework for how to receive, investigate, and resolve allegations regarding EMS clinicians, or Life Support Agencies (LSA), under the purview of the Medical Control Authority (MCA) that fosters a just culture process focused on producing safer patient outcomes, identifying root causes, and outlining expected behaviors by EMS clinicians and Life Support Agencies.

NOTE: Terms contained in Section X. Definitions, on page 11, are underlined the first time they appear in this document for ease of identification.

I. Allegation Intake:

A. An allegation may be received at the MCA directly, at life support agencies, hospitals, or by the Department.
B. Those in receipt of an allegation which involves violations of protocols, statutes, or administrative rules must inform the MCA in writing.
C. The MCA will conduct an assessment to determine if further review is required.
D. The complainant for a case should be asked if they would like to remain anonymous or to allow their information to be included in the record of the allegation.
   1. The complainant must provide the MCA with his/her name, address, and telephone number. A request for anonymity by a complainant must be honored by the MCA to the extent possible.
E. Allegations considered for action by the receiving MCA, must meet the following criteria:
   1. The allegation must be directed toward an EMS clinician, or a Life Support Agency (LSA), or involve issues of performance of the EMS system within the jurisdiction of the MCA.
   2. The allegation must include a potential violation of Michigan law, Federal law, Michigan EMS administrative rules or local MCA protocols.
   3. An allegation must be in writing or transcribed if by telephone.
   4. Notable deviations from quality improvement projects may be considered for investigation at the recommendation of the Medical Director.
   5. Near misses reported by the EMS system may be accepted for review to determine root causes to develop improvements for system shaping factors.
F. Allegations that will not be considered for action by the receiving MCA include the following:
   1. Hearsay or “second hand” allegations will not be accepted or investigated.
   2. MCA Quality Improvement initiatives will be reviewed through the MCA Quality Improvement process and normal deviations will not be considered allegations.

3. Allegations regarding the conduct of an EMS clinician or LSA not related to medical practice or actions bearing upon patient care, unless covered by MCA protocol. These will be referred to the employer of the EMS clinician, or LSA.
4. Allegations directed toward an individual acting while employed by a Life Support Agency outside of the jurisdiction of the MCA must not be accepted or investigated but will be forwarded, or the complainant directed to, the MCA/agency under whose jurisdiction it does fall.
    a. These allegations may also be retained by the MCA for investigation by the PSRO committee at the discretion of the MCA.

II. Allegation Delegation:

A. MCAs may cooperate on investigations which overlap jurisdictional boundaries. For the purposes of Quality Improvement Actions, the MCA granting Medical Control privileges to the provider or agency where the primary action, or actions being investigated took place must be considered the jurisdictional MCA.
B. Allegations more appropriately investigated at the agency or operational level may be turned over to the life support agency or hospital involved. Investigation results are to be reported back to the MCA for review within 30 calendar days.
    1. Noncompliance by partnering agencies to complete reviews within assigned timeframe will be returned to the PSRO committee for investigation and determination of both the original incident and any subsequent violation(s) by the agency.

III. Investigation of Allegation:

A. Initial Investigation Process:
    1. Once an allegation is determined to meet the criteria, the allegation will be assigned to the Professional Standards Review Organization (PSRO) committee, or an MCA designee for investigation.
    2. All allegation investigations will be based on Department approved MCA protocols, administrative rules, or statutes that were active on the date of the EMS call for service.
    3. The member(s) of the PSRO, or MCA designee, charged with the allegation investigation, will initiate a preliminary review of the allegations and gather information to determine its validity.
    4. To determine validity of the allegation(s), the PSRO or MCA designee may request and review copies of documents, patient care reports, incident reports, video and audio recordings, or other materials relating to the allegation without formal notification to the named EMS clinician or LSA.

a. The EMS clinician, and/or the LSA, will have five (5) business days to provide the requested documentation or statements to the MCA.
b. This timetable may be extended by the PSRO, or MCA designee, based on the circumstances of the case.

5. To determine validity of the allegation(s), the PSRO, or MCA designee, charged with the allegation investigation may conduct fact finding interviews with EMS clinicians, or other individuals involved in the response.
6. The PSRO, or MCA designee, charged with the allegation investigation will then present the findings to the MCA Medical Director, or the PSRO committee, for determining subsequent actions.

B. Disposition of Allegations after initial investigation process:
1. The Medical Director, or PSRO committee, may choose from the following actions based on the initial investigation:
a. **NO ACTION** is required against the EMS clinician or LSA.
1. In this circumstance the Medical Director, or PSRO committee may choose that No MCA action is appropriate when:
a. The allegation was unproven, not factually accurate, or unfounded,
b. The MCA Medical Director supports the LSA's quality improvement plan,
c. There was an identified system shaping factor that created the situation that was outside of the control of the EMS clinician or LSA.
b. The incident was caused by **human error** or **at-risk behavior**.
1. In this circumstance the Medical Director, or designated committee, may issue a Letter of Remediation based on the review of the case after meeting with the EMS clinician or LSA.
2. Specific case circumstances may need increased quality improvement actions (i.e. Order of Disciplinary Action). These cases are to be referred to the PSRO committee for a formal review.
a. Justification must be included to support the decision.
3. Repetitive infractions by the EMS clinician or LSA may constitute a reason to increase the designation and require a formal review by the PSRO.
c. The incident was caused by **justifiable risk**.
1. In this circumstance the Medical Director must refer the situation to the PSRO committee for review to determine the root cause and discuss potential system improvements.
a. No action will be taken against the EMS clinician or LSA when a finding that a system shaping factor created a justifiable risk, or a near miss event performed in the manner documented.

d. The incident was caused by **reckless behavior** or a **substantial and unjustifiable risk**.
    1. In this circumstance the Medical Director may choose from the following:
        a. An immediate Emergency Suspension of MCA privileges when there is a definable risk to the public health and welfare, pending a full review by the designated PSRO committee.
            i. Possible situations where the Medical Director may consider this action appropriate:
                a. Criminal Behavior
                b. Severe Clinical Misconduct
                c. Substance Abuse
                d. Unfit to practice
                e. Violation of medical standards
                f. Insubordination
            ii. Refer to the Emergency Action section of this protocol for process.
        b. Refer the case to the designated PSRO committee for review and decision on outcome.

2. Allegations deemed valid due to **reckless behavior**, or **substantial and unjustifiable risk** by the Medical Director, must:
    a. The MCA must provide formal notice to the EMS clinician or LSA requesting participation at an upcoming Professional Standards Review Organization (PSRO) meeting to discuss the event.
        1. For an EMS clinician, notice will be provided to both the individual EMS clinician and the LSA administrator.
        2. For a LSA, notice will be provided to the agency administrator.
    b. The notice must include, but is not limited to:
        1. A description of the alleged violation.
        2. A list of protocols impacted by the alleged violation, including the Complaint Investigation and Resolution and any other protocols that will be used in the investigation and instructions on how to access.
        3. Instructions detailing any required actions of the subject EMS clinician or LSA (e.g., appearance dates, times, and locations or documentation requests).
    c. Notice must also be provided to individuals requested to appear before the PSRO as witnesses, including those asked to participate in interviews or provide testimony to the full body of the PSRO.
    d. For all nonemergency action reviews, the MCA will provide at least three (3) business days of advanced notice to affected individuals and agencies prior to convening PSRO meetings for which they must attend.

3. Any action issued directly by the Medical Director without the involvement of the PSRO committee must be reported at the next scheduled PSRO meeting for review and to ensure awareness and the identification of system trends.

IV. Emergency Action – Temporary Suspension of Privileges:

A. If the MCA Medical Director believes there is a definable threat to public health, safety, or welfare, they may immediately act by temporarily suspending privileges pending a further review.
   1. In the event the emergency action is related to criminal charges being filed against an EMS clinician or LSA related to acts of violence, diversion of medications, illegal possession of controlled substances, criminal sexual conduct, or other situations which may pose a direct threat to the community or patients, the MCA may act with a suspension of MCA privileges without convening a special PSRO meeting.
      a. The subject licensee or agency shall be notified in writing of the suspension.
      b. If found guilty in a court of law, MCA privileges will be revoked.
      c. If found not guilty of charges, the individual or agency must provide copies of court documents, including transcripts, to the MCA for review and determination of suspension.
      d. If a court case is dismissed based on procedural failings or errors, the MCA may decline to extend privileges if the conduct of the individual or agency may pose a threat to the community or patients. This determination is to occur during a PSRO meeting where the individual or agency is present to provide information relevant to the situation.

B. Formal notification to the EMS clinician or LSA by the MCA of the immediate suspension of privileges as well as the allegations for which the action is based on will be provided by the end of the business day.
   1. The LSA must be included on all communications with the EMS clinician.
   2. Medical Control Authority must notify the Department within one (1) business day of the removal of medical control privileges from an EMS clinician, or LSA.

C. The Medical Control Authority PSRO committee must convene a special meeting within three (3) business days of the Medical Director's decision to review the case and decide the outcome of the case.

D. The EMS clinician or LSA may request, prior to the scheduled date, a one-time postponement of the PSRO meeting of up to thirty (30) calendar days to prepare their response to the allegations.
   1. This request for postponement must be received in writing within one (1) business day prior to the scheduled meeting time.

E. The PSRO committee must provide a written decision to the EMS clinician or LSA following the meeting and within three (3) business days of the emergency action being taken.
   1. If the PSRO committee needs additional time to deliberate, the meeting may be adjourned and additional meeting(s) scheduled.
   2. If additional meetings are needed, a final decision still must be issued to the EMS clinician or LSA by the PSRO committee within three (3) business days of the emergency action being taken.

F. If an EMS clinician or LSA's MCA privileges have been suspended, the EMS clinician or LSA must not provide prehospital care within the MCA until the PSRO committee has made their decision.

V. Due Process:

A. Notice
   1. The EMS clinician or LSA have the right to be informed of all allegations made against them. Formal notification by the MCA to the subject of an allegation will occur if a formal Quality Review Inquiry is opened.
   2. If the subject of a Quality Review Inquiry is an EMS clinician, notification will also be made to the subject's applicable employing LSA at the same time.
   3. Reference to all applicable investigation protocols and instructions regarding how to access them must be included with notification of a Quality Review Inquiry.
   4. The MCA will provide at least three (3) business days of advanced notice to affected clinicians and agencies prior to convening any PSRO meetings to which they must attend.

B. Opportunity to be heard
   1. The subject has the right to present their side of the case, respond to evidence against them, and challenge witness statements or allegations. The subject must be given the opportunity to respond to the allegations, including the opportunity to present supporting evidence.
   2. The subject must be provided with copies of all relevant investigation related materials for review.
   3. The subject will be afforded reasonable time to review such materials prior to being interviewed by the PSRO committee.
   4. The subject may request the related materials in advance of the interview with the PSRO committee. The MCA will make reasonable efforts to accommodate such requests at the discretion of the Medical Director.
   5. Materials that would reveal the identity of an individual that provided information under the condition of anonymity are exempt from this provision.
   6. All investigation materials must be reviewed at a special meeting of the PSRO

called for that purpose and must not be removed or otherwise distributed without the express permission of the Medical Control Authority.

C. Impartial Decision Making
   1. All PSRO complaint investigation committees must be comprised of decision-makers who are able to remain impartial during the review.

D. Representation
   1. Subjects of a PSRO review may have agency representation at proceedings of the PSRO provided PSRO standards are maintained.
   2. The MCA is not a hiring entity and is not subject to collective bargaining. Union representation during proceedings of the PSRO is not permitted.
   3. The MCA PSRO is not an adjudicating body for either civil or criminal investigations and is not subject to the rules and statutes which govern civil or criminal adjudication. Attorneys and legal representation are not permitted in PSRO committees.

E. Determination
   1. The PSRO committee must provide notice to the EMS clinician or LSA within fourteen (14) business days of the committee meeting.
      a. If the decision of the committee is to issue an ODA, it must be provided to the EMS clinician or LSA within three (3) business days of the committee's meeting.
   2. If the PSRO committee needs additional time to deliberate, the meeting may be adjourned and additional meeting(s) scheduled.
      a. A final decision must be issued by the PSRO committee within three (3) business days of the initial meeting's date for all ODAs.
      b. A final decision must be issued by the PSRO committee within fourteen (14) business days of the initial meeting's start date for all other quality improvement actions.
   3. The EMS clinician, or LSA will have seven (7) business days from the date of receipt of the ODA to request an appeal of the decision of the PSRO committee. The EMS clinician or LSA must follow the **8.25 Order of Disciplinary Action Appeal** protocol.

F. Americans with Disabilities Act (ADA)
   1. Non-Discrimination:
      The MCA prohibits discrimination based on disability in all aspects, including quality reviews. No individual must be subjected to discrimination or retaliation based on disability.
   2. Reasonable Accommodations:
      Reasonable accommodation will be provided, when possible, for individuals with disabilities to ensure equal access to the investigation and review process.

Reasonable accommodations may include, but are not limited to, providing auxiliary aids, modifying policies or procedures, or adjusting scheduled interviews or proceedings.

3. Communication:
   Investigators must communicate effectively with individuals with disabilities during the investigation process. This may involve using alternative formats, allowing interpreters, or utilizing assistive technology to ensure effective communication.
4. Confidentiality:
   Information related to an individual's disability obtained during the investigation process must be treated as confidential and shared only with those who have a legitimate need to know. Confidentiality safeguards will be implemented in accordance with applicable laws and organizational policies.

VI. Order of Disciplinary Action (ODA) Notification

A. The Medical Control Authority must notify the Department within one (1) business day of the issuance of an ODA to an EMS clinician, or LSA.
B. Once the ODA is issued and any appeals are completed, the EMS clinician or LSA to which the ODA is issued must provide a copy of the ODA to all MCAs in which they are privileged for the other MCA's review.
C. The Medical Control Authority must notify all other Medical Control Authorities which it knows, or has reason to believe, have granted the EMS clinician or LSA Medical Control privileges within one (1) business day.

VII. Disposition of Quality Improvement Action:

A. A primary function of Quality Improvement Action is to ensure the protection and safety of the community and patients.
B. The application of the Quality Improvement Action is intended to promote improvement in clinical and operational performance.
C. The MCA shall engage in a process to ensure that EMS clinicians and LSAs maintain an appropriate level of clinical and operational performance.
D. MCAs should utilize a just culture approach when applying or considering Quality Improvement Actions to create a balance between provider and system accountability.
E. The licensee's agency will be notified of any Quality Improvement Action prescribed by the PSRO.
F. Quality Improvement Actions may or may not be ascending in severity. In cases where misconduct (by action or omission), regardless of where the misconduct occurred, is determined to be reckless, willful, or criminal, ascending discipline may be bypassed with a more severe disciplinary action imposed.

VIII. PSRO Quality Improvement Determinations

A. No Action –
   1. Allegation Unsubstantiated
      a. The MCA PSRO committee, or Medical Director, will compose a letter to the individual alleging the concern that the incident was reviewed through the MCA's confidential Professional Standards Review Organization.
      b. If the MCA PSRO committee, or Medical Director, discusses the allegation with the involved EMS clinician(s), or Life Support Agency, as part of the preliminary review, then the MCA PSRO committee, or the Medical Director should provide verification that the incident was reviewed as part of the MCA's PSRO quality review process and those involved were found compliant with the current standards.
   2. Cause was due to system design factors
      a. The MCA PSRO committee, or Medical Director, will compose a letter to the individual alleging the concern that the incident was reviewed through the MCA's confidential Professional Standards Review Organization.
      b. If the MCA PSRO committee, or Medical Director, discusses the allegation with the involved EMS clinician(s), or LSA, as part of the preliminary review, then the MCA PSRO committee, or Medical Director, should provide confirmation that the incident was reviewed as part of the MCA's PSRO quality review process.
      c. These cases are to be referred to the appropriate MCA committee for review and to develop a system improvement plan to mitigate a reoccurrence.
      d. These plans, and cases, must then be reviewed by the MCA Board to assess and implement actions that are available to improve the EMS system.
   3. No Action – support of LSA quality improvement plan
      a. The MCA PSRO committee, or Medical Director, will compose a letter to the individual alleging the concern that the incident was reviewed through the MCA's confidential Professional Standards Review Organization.
      b. If the MCA PSRO committee, or Medical Director, discusses the allegation with the involved EMS clinician(s), or Life Support Agency, as part of the preliminary review, then the MCA PSRO committee, or Medical Director, should provide confirmation that the incident was reviewed as part of the MCA's PSRO quality review.

B. Letter of Remediation
   1. The Letter of Remediation is a written quality improvement action plan for an EMS clinician or LSA which includes a timeline, SMART goals, and a plan to assess desired outcome.

2. This quality improvement action may include:
   a. Requiring the EMS clinician to work with a provider at an equal or higher level of licensure, for a certain period. i.e. complete a field training program, or work with a supervisor for oversight.
   b. Additional education that does not restrict the EMS clinician's or LSA's privileges within the MCA.
   c. A probationary period with additional remediation requirements as deemed appropriate.
3. The Medical Control Authority may choose to issue a Letter of Remediation, when the actions of the EMS clinician's or LSA's were determined to be contributing factor and related to simple human error.

C. Order of Disciplinary Action
1. An Order of Disciplinary Action (ODA) is a written document developed by the MCA and sent to a subject EMS clinician or LSA for the purposes of clearly and plainly identifying the findings of the MCA.
2. Disciplinary actions available for inclusion in an ODA:
   a. Restriction of privileges:
      i. May entail reducing the EMS clinician's or LSA's level of privileging to a lower level, i.e. from Paramedic to AEMT.
   b. Suspension of Privileges:
      i. An EMS clinician's or LSA's medical privileges are suspended for a specified period within the local MCA.
      ii. If an EMS clinician's or LSA's MCA privileges have been suspended, the EMS clinician or LSA must not provide prehospital care until MCA privileges are reinstated.
   c. Revocation of Privileges:
      i. An EMS clinician's or LSA's medical privileges are revoked within the MCA and will require the provider to reapply for privileges after a minimum of one (1) year.
3. The ODA must include the following provisions:
   a. Details of the violation of Michigan law, Federal law, Michigan EMS administrative rules or local MCA protocols,
   b. The restriction of local medical control privileges determined by the PSRO committee,
   c. Any additional remediation activities that may be required of the EMS clinician or LSA prior to resolution of the ODA,
   d. The timeframe assigned to complete the PSRO Committee's requirements.

e. Copies of, or detailed instructions on how to access referenced protocols as well as the **8.24 PSRO Investigation & Resolution** and **8.25 ODA Action Appeal** protocols.
f. The MCA must demonstrate good faith to ensure that an ODA is received by the EMS clinician or LSA in a timely manner.
g. Notice of disciplinary action must be forwarded to the EMS clinician's employer, or board in the case of an LSA.

D. Emergency Action – Temporary Suspension of Privileges
1. The Medical Director may temporarily suspend an EMS clinician or LSA's privileges in cases where there is a definable risk to the public health and welfare.
2. The Medical Control Authority's designated PSRO committee must convene a special meeting within three (3) business days of the Medical Director's decision to decide the outcome of the review as outlined in the Emergency Action and Due Process sections.
3. A final decision must be issued to the EMS clinician or LSA by the PSRO committee within three (3) business days of the emergency action being taken.
4. If an EMS clinician or LSA's MCA privileges have been temporarily suspended, the EMS clinician or LSA must not provide prehospital care within the MCA until the designated PSRO committee has made their decision.

IX. Special Circumstances

A. EMS Clinician, or Life Support Agency, practicing in the MCA without a current Michigan EMS license.
1. These cases are to be referred to local law enforcement agencies and the Department for investigation.

X. Definitions

A. Allegation:
For this policy, an allegation must be defined as any notification of dissatisfaction or concern regarding medical care rendered by an EMS clinician or LSA within the MCA, or any issues that involve the performance of the EMS system in whole or in part.

B. Allegation Unsubstantiated:
The allegation or compliant was found to have no administrative rule or protocol violation or the protocol deviation was considered acceptable for the situation.

C. At-risk behavior:
Describes a situation where an action, or activity, has the potential to be harmful or dangerous, where risk is not perceived or mistakenly believed to be justified.

D. Due Process:
A course of formal proceedings carried out regularly and in accordance with established rules and principles.

E. Emergency Action:
Situations where the MCA Medical Director believes there is a definable threat to public health, safety, or welfare of the community.

F. EMS Clinician:
One who has a current EMS patient care license in the State of Michigan.

G. Human error:
Describes a situation where an action, or activity, when an unintended sequence of actions does not achieve its intended outcome. Could be considered a slip, lapse of judgment or mistake.

H. Just culture:
A just culture process is a high-level statement of the values and commitment of an organization to treat EMS clinicians and agencies fairly in all investigations.

I. Justifiable choice/deviation:
Describes a situation where an action, or activity, when there is a deviation from protocol, process, or procedure due to the circumstances and change in expected process is deemed safer than if the accepted process was followed.

J. Letter of Remediation:
This is a written defined quality improvement plan for an EMS clinician or LSA which includes a timeline, SMART goals, and a plan to assess desired outcomes.

K. Life Support Agency (LSA):
Refers to an agency and/or the employer of an EMS clinician against which an allegation has been received.

L. Near miss:
Describes a situation where an action, or activity, has the potential to lead to an error occurring, however, due to a system, process, or procedure the situation was identified prior to the error occurring and remedied.

M. No action:
The allegation or complaint did not warrant action by the MCA against the EMS clinician or LSA. This could be because no administrative rule or protocol violation or the protocol deviation was found, the MCA supported the action of the LSA, or there were factors outside of the control of the EMS clinician or LSA.

N. Order of Disciplinary Action (ODA):
This is a quality improvement action taken by an MCA that meets one of the following criteria and must be reported to the Department within one (1) business day:
1. Revocation of MCA privileges of a licensee, or
2. Suspension of MCA privileges of a licensee, or

3. Restriction of MCA privileges of licensee (i.e., paramedic licensee restricted to working as an EMT or required to complete training prior to returning to the original licensure level within the MCA).

M. Quality Improvement Action:
An action taken to produce safer patient outcomes, identifying root causes, and outlining expected behaviors by an EMS clinician and/or a Life Support Agency.

N. Reckless behavior:
Describes a situation where an action or activity, when there is a conscious decision to disregard approved MCA protocol(s), statue, or Administrative Rules that leads to unjustifiable risk.

O. Repetitive human error:
Describes a situation where an action, or activity, when there is continued human errors which occur by an EMS clinician or LSA after remediation actions have been attempted without correcting actions. Errors may or may not be related.

P. Repetitive at-risk behavior:
Describes a situation where an action, or activity, when there is continued at-risk behavior which occurs by an EMS clinician or LSA after remediation actions have been attempted without correcting actions. At-risk behaviors may or may not be related.

Q. Root Cause Analysis:
Describes a wide range of tools used to improve system performance which uncovers the cause of situations that allowed for an unintentional outcome.

R. SMART goals:
A framework for setting and achieving goals by ensuring they are Specific, Measurable, Achievable, Related (or Realistic), and Time-bound.

S. Substantial or unjustifiable risk:
Describes a situation where an action, or activity, is determined to be intentional and the risk of harm outweighs any benefit.

T. System Shaping Factors:
Describes variables that can impact an EMS clinician or LSA and system performance.