## *Complaint Investigation & Resolution Supplement– Table of Contents*

# *Complaint Investigation & Resolution Supplement – Purpose and Definitions*

**Purpose:** This policy is provided as a means to receive, investigate, and resolve complaints regarding licensees falling under the purview of the Sanilac Medical Control Authority (MCA).

## I. Definitions:

A. Appeal Hearing:
A hearing to appeal an Order of Disciplinary Action. This hearing is to examine any new facts and/or re-review the incident to ensure due process has been followed.

B. Order of Disciplinary Action (ODA):
A written document developed by the MCA and sent to a Subject Licensee for the purposes of clearly and plainly identifying the findings of the MCA related to a Complaint, any applicable disciplinary action and any required remediation.

C. Complaint:
Any notification of dissatisfaction or concern regarding medical care rendered by a Subject Licensee, or any issues that involve the performance of the EMS system in whole or in part.

D. Complaint Invalid:
The Compliant was found to have no administrative rule or protocol violation or the protocol deviation was considered acceptable for the situation.

E. Complaint Valid – Minor:
This can be viewed two ways:
1. The Licensee's role in the administrative rule or protocol violation was small.
2. The result of the administrative rule or protocol violation had a minor effect.

F. Complaint Valid – Serious:
This can be viewed two ways.
1. The Licensee's role in the administrative rule or protocol violation was great.
2. The result of the administrative rule or protocol violation had a major effect.

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

H. Formal Inquiry:
A Complaint has been found to either be valid, or that more detailed inquiry is necessary to determine the validity of the Complaint; either of which will require that the Subject Licensee be notified of the specific Complaint. A Formal Inquiry

may involve the gathering of incident reports which provide explanations for care rendered or justification for actions, as well as subject/witness interviews. Some information gathering may not necessitate a Formal Inquiry.

I. Investigator:
The person(s) charged with complaint investigation, including the gathering of information to determine the validity of a Complaint.

J. Just Culture Guidelines:
A high-level statement of the values and commitment of the MCA to treat healthcare workers and agencies fairly in all complaint investigations.

K. Licensee:
Includes both of the following: 1) an individual holding a valid State of Michigan license as a Medical First Responder, Emergency Medical Technician, Specialist, or Paramedic; or 2) an agency (fire department, rescue squad, life support agency, etc.) licensed to operate within the MCA service area. Each individual Licensee shall be employed or otherwise engaged by a an agency licensed to operate within the MCA service area.

L. Privileged Documents:
Privileged documents are those which are collected by the Professional Standards Review Organization (PSRO) of the MCA.

M. Quality Improvement Action:
An action taken to remediate a valid complaint to the MCA.

N. Sentinel Event:
A Sentinel Event is any Complaint which involves 1) at least one (1) Level I Incident; 2) a violation of Michigan or Federal laws, or EMS rules; or 3) two (2) or more Level II Incidents. Information regarding Level I and Level II Incidents may be found in ***Protocol 8-24.2 (Bases for Finding)***.

O. Subject Licensee:
The Licensee that is the subject of the Complaint received by the MCA.

***Complaint Investigation & Resolution Supplement – Process and Procedure***

## I. Complaints

A. Generally

1. Complaints may be received at the MCA directly, at life support agencies or by individuals. Those in receipt of a Complaint which involves violations of protocols, statutes, or administrative rules shall inform the MCA. The MCA will determine if further investigation is necessary.

B. Criteria

1. All Complaints, in order to be considered for action by the MCA, shall meet the following criteria:
   i. A Complaint may be submitted either verbally or in writing. Hearsay or "second hand" complaints may not be accepted or investigated by the MCA.
   ii. The individual submitting the Complaint must provide the MCA with his/her name, address, and telephone number. A request for anonymity by the individual shall be honored by the MCA to the extent possible.
   iii. The Complaint must be directed toward a Licensee undertaking actions/inactions within the MCA service area.
   iv. The Complaint must include a potential violation of Michigan or Federal laws, EMS rules, or MCA protocol.

      1. All Complaint reviews will be based on the MCA approved protocols that were approved and active on the date services were requested.

C. Complaints That Might Not Be Considered

1. Complaints regarding conduct of a Licensee, exclusive of medical practice or actions bearing upon medical practice, may be referred to the entity which employs/otherwise engages with Licensee. These Complaints may also be referred to the PSRO for investigation at the discretion of the MCA.

2. The MCA reserves the right to retain the Complaint investigation.

## II. Complaint Delegation/Geographic Scope of Oversight:

A. Complaints directed toward a Licensee acting while employed/otherwise engaged by an agency outside of the jurisdiction of the MCA shall not be accepted or investigated but will be forwarded, or the individual filing the Complaint directed to, the medical control authority/agency under whose jurisdiction it does fall.

B. Medical control authorities, including the MCA, may cooperate on investigations which overlap jurisdictional boundaries. For the purposes of the Complaint review process and

any resultant Quality Improvement Actions, the medical control authority with oversight of the service area where the action or actions being investigated took place shall be considered the jurisdictional medical control authority.

C. Complaints more appropriately investigated at the agency or operational level may be turned over to the life support agency or hospital involved. Investigation results should be reported to the MCA.

## III. PSRO Communications

A. PSRO protected entities, including the MCA, may share PSRO information with other PSRO entities for the following purposes:

1. To advance health care research or health care education.

2. To maintain the standards of the health care professions.

3. To protect the financial integrity of any governmentally funded program.

4. To provide evidence relating to the ethics or discipline of a health care provider, entity, or practitioner.

5. To review the qualifications, competence, and performance of a health care professional with respect to the selection and appointment of the health care professional to the medical staff of a health facility.

## IV. Suspension of Privileges

A. <u>Pending a Hearing</u>

1. Pending a PSRO meeting regarding an alleged Sentinel Event, the MCA Medical Director may temporarily suspend a Licensee's privileges in cases where there is, in the MCA Medical Director's professional opinion, an imminent risk to public or patient health, safety or welfare.

   i. Any such suspension shall remain in effect ending Sentinel Event review and disposition.

B. <u>For Criminal Acts</u>

1. In the event of criminal charges being filed against a Subject Licensee related to acts of violence, diversion of medications, illegal possession of controlled substances, criminal sexual conduct, or other practice which may pose a threat to the community or patients, the MCA may act with suspension of MCA privileges without convening a Sentinel Event PSRO meeting.

   i. The Subject Licensee shall be notified in writing of the suspension.

ii. If the Subject Licensee is found to be guilty (including the entering of a guilty plea or a plea of nolo contendere), MCA privileges will be considered to be revoked.

iii. If the Subject Licensee is found not guilty of charges, the Subject Licensee must provide copies of court documents, including transcripts, to the MCA.

iv. If a court case is dismissed based on procedural failings or errors, the MCA may decline to extend privileges if the conduct of the Subject Licensee may pose a threat to the community or patients. This should occur at a Sentinel Event meeting.

## V. Investigation of Complaints:

A. Initial Review

1. Upon receipt of a Complaint (whether written or via a phone call):

i. The Complaint will be forwarded to an Investigator for initial review.

1. The individual filing a Complaint should be asked if they would like to be contacted by the Subject Licensee. This will allow the individual the opportunity to voice a request to remain anonymous or to allow their information to be provided to the Subject Licensee.

ii. Following the initial review, the Investigator will contact the MCA Medical Directors for consultation regarding whether the Complaint is valid.

iii. If determined to be valid, the Complaint will be brought before the PSRO for review.

iv. In determined to be invalid, the Complaint will be dismissed and considered to be Complaint – Invalid.

B. PSRO Review

1. Once a Complaint is presented to the PSRO:

i. The Investigator will provide PSRO committee members with the original Complaint, patient care report and any notes the Investigator took during the initial review.

ii. Additional documentation of the investigation may include, but is not limited to, the following:
1. The name, address, and telephone number of the individual submitting the Complaint (if known).

2. The date and time of the receipt of the Complaint.

3. A copy of the Complaint acknowledgement, if appropriate.

4. A copy of the notice to the Subject Licensee, if appropriate.

5. A copy of the pertinent protocol(s) and/or policy/policies.

6. Written statements of witnesses including notes from telephone interviews.

7. Copies of pertinent reports, transcriptions of audio tapes; video recordings and copies of other pertinent documents or emails.

2. The PSRO may request copies of documents, incident reports, video and audio recordings relating to a Complaint without formal notification of the Complaint to the Subject Licensee.

   i. All requests for information will be documented in the investigation notes or with attached documentation/emails.

   ii. The agency and/or the individual will have ninety-six (96) hours to provide the requested documentation or provide statements to the MCA.

   iii. The MCA will redact all PHI prior to sending it to the PSRO for review.

3. Following review of all relevant documentation, the PSRO will determine whether 1) a Formal Inquiry or Sentinel Event designation is warranted related to the Complaint; and 2) the Complaint includes one or more Level I or Level II Incidents. *See* ***Protocol 8-24.2 (Bases for Finding)***.

4. Formal notification of the Subject Licensee will occur if a Formal Inquiry or Sentinel event hearing are determined to be required.

5. Complaints found to be invalid will be closed as Complaint – Invalid. Notification to the Subject Licensee will only occur if prior knowledge of the Complaint was provided to, or exists with, the Subject Licensee.

## VI. Due Process:

A. <u>Initial Timing</u>

1. In the event that the PSRO determines that a Formal Inquiry or Sentinel Event hearing is warranted, the following sequence of events will be initiated:

i. The MCA will provide at least four (4) business days' notice to Subject Licensee prior to convening a PSRO meeting at which the Subject Licensee must appear.*

1. This requirement will also apply in the event that a Complaint/investigation involves both the function of a Subject Licensee and the compliance of their agency or department, unless a postponement is granted to the Subject Licensee or their agency/department, as described below.

2. *EXCEPTION: This notice period shall be shortened to one (1) business day in the event that the MCA Medical Director temporarily suspends a Licensee's privileges pursuant to ***Protocol 8-24.3 (Bases for Finding) Section II.D.7.a*** as in such instances the MCA shall review such action within three (3) business days after the MCA Medical Director's determination.

ii. The MCA will provide a copy of the Complaint Investigation Protocol to the Subject Licensee(s).

iii. Subject Licensee(s) will be provided with copies of all Complaint/investigation related materials at the time of the meeting with the exception of materials that would reveal the identity of an individual that provided information under the condition of anonymity.

1. The Subject Licensee may request the Complaint/investigation related materials in advance of the PSRO meeting.

iv. A Subject Licensee may request a postponement of up to thirty (30) calendar days of a PSRO meeting appearance in order to prepare the Subject Licensee's response to the Complaint.

v. The Subject Licensee must submit a copy of all supporting documentation to the MCA at least five (5) business days prior to the postponed review meeting.

B. <u>Complaint Review During Hearing</u>

1. The following steps shall be taken in the Complaint review process for Formal Inquiries where the allegations could lead to an Order of Disciplinary Action being prescribed by the PSRO and for **<u>all</u>** Sentinel Events:

i. The violation of policy or protocol shall be defined.

ii. The impact on patient outcome will be evaluated.

iii. The Subject Licensee shall be given time to speak on the issue of the Complaint including the opportunity to present supporting documentation.

iv. Subject Licensees failing to appear for PSRO reviews waive their right to representation and are subject to the summary findings of the review body. Failure to appear also constitutes a violation as defined in the ***Protocol 8-24.2 (Bases for Finding)***.

C. Decision of PSRO

1. The PSRO will review the Complaint and related documentation and by majority vote of the members present decide a course of action.

2. All Complaints will be determined as the following for each individual Subject Licensee.
   i. Complaint Invalid
   ii. Complaint Valid – Minor
   iii. Compliant Valid – Serious

3. Counseling, remedial, and/or disciplinary action shall be considered and/or ordered as deemed appropriate by a majority vote of the MCA or their designated and pre-established Professional Standards Review Organization/Quality Review Committee consistent with ***Protocol 8-24.3 (Quality Improvement Actions)***.

4. Subject Licensees shall be notified of the findings of a PSRO review. If disciplinary action results, the Subject Licensee will be provided with any required remediation steps/actions consistent with ***Protocol 8-24.3 (Quality Improvement Actions)***.

5. All system failures shall be addressed by the MCA.

D. Limited Representation at Hearing

1. The MCA is not a hiring entity and is not subject to collective bargaining. Union representation during MCA PSRO reviews is not permitted.

2. The PSRO is not subject to the rules and statutes which govern civil or criminal adjudication; as such, attorneys and legal representatives are not permitted in PSRO reviews.

3. Subject Licensees may have agency representation at PSRO reviews provided PSRO standards are maintained.

E. Restrictions, Exceptions and Considerations Related to Information.

1. The PSRO investigates incidents, complaints, personnel and agencies. While a deed or misdeed may be civil or criminal in nature, the PSRO is not an adjudicating body for either of these conditions.

2. Recording, monitoring, or any manner of duplicating a PSRO review is not permitted unless conducted by the PSRO expressly for PSRO purposes.

3. Disclosure of confidential PSRO materials by Licensees before, during, and after review shall be cause for possible suspension or revocation of MCA privileges, as well as possible statutory violations.

4. The MCA may disclose non-specific information relating to discipline of Licensees. Care will be taken to not compromise any confidential information.

# *Complaint Investigation & Resolution Supplement – Bases for Finding*

I. **Level I and Level II Incidents:**

The PRSO will utilize the non-exhaustive lists below to determine if a Complaint constitutes one or more Level I or Level II Incidents.

These criteria are for example purposes only and do not form an all-inclusive list of potential violations. Violations that are substantively similar in type or severity will fall under the closest, most appropriate classification category.

A. Level I Incidents

1. The following categories of incidents are defined as Level I Incidents:

   i. Willful neglect of a patient.

   ii. Abandonment of a patient.

   iii. Failure to obey an MCA physician's legitimate orders either by act or failure to act in the presence of reasonably clear communications from the physician.

   iv. Improper and inappropriate care which may result in compromise of a patient's wellbeing.

   v. Conviction of a felony or misdemeanor.

   vi. Two or more Level II Incidents in any six (6) month period.

      1. Time measured from the occurrence of the initial Incident to the occurrence of the succeeding Incident.

   vii. Breach of confidentiality.

   viii. Intentional falsification of EMS documentation, including patient care records.

   ix. Under the influence of drugs or intoxicants while involved with patient care.

   x. Violation of the EMS statute and its attendant rules and regulations, including care outside the scope of practice, as defined by protocol.

   xi. Practicing in the MCA without a current Michigan EMS provider license.

   xii. Practicing in the MCA without current privileges on two separate occasions within a single licensure period.

1. Certifications required by the MCA in order to maintain privileges are identified in the **Medical Control Privileges Protocol.**

xiii. Any other patient care offense resulting from violation of policies, protocols and procedures of similar severity not listed above at the discretion of the EMS Medical Director.

xiv. Failure to complete prescribed Quality Improvement Actions from a previous incident. (Or see (xiv) of Level II Incidents below).

xv. Arrest or criminal charges for criminal sexual conduct of any degree, violent crime, drug diversion or illegal possession or distribution of controlled substances.

xvi. Failure to notify the MCA of a criminal charge, arrest or conviction within one (1) business day.

xvii. Gross negligence or willful misconduct.

B. Level II Incidents

1. The following categories of incidents are defined as Level II Incidents:

i. Failure to adhere to system protocols, policies and procedures that had the potential to negatively impact patient care, as determined by the EMS Medical Director.

ii. Failure of personnel or agency to respond within 96 hours of receipt of requests for information or documentation regarding an incident under investigation by the MCA.

1. A response shall be submitted in writing and with a signed delivery receipt to MCA staff within the allotted time period.

iii. Abuse and/or loss of system equipment due to neglect.

iv. Significant documentation errors.

v. Failure to accurately perform procedures as defined in protocols, policies and procedures.

vi. Failure to check and maintain functional equipment necessary to provide adequate patient care at the level of licensure, the failure of which may lead to an inability to communicate with medical control, inability to administer appropriate medications, or otherwise negatively affecting the ability of the personnel to function at his/her level of training in the field.

1. This includes verification that a sealed drug and IV box, functional monitor/defibrillator, functional airway equipment, etc. are present on the unit.

vii. Improper or unprofessional medical communications including, but not limited to, any violation of Federal communications regulations, and falsification of identification during medical communications.

viii. Failure to appear before the EMS Medical Director, designated PSRO committee or MCA Governing Body when so requested by the MCA, as defined in the Complaint Investigation, Quality Improvement and Disciplinary Action Policies.

ix. Furnishing of information known to be inaccurate in response to any official request for information relative to Quality Improvement Activities or other investigations related to this policy.

x. Two or more orders of disciplinary action within a six (6) month period.

1. Time measured from the occurrence of the initial Incident to the occurrence of the succeeding Incident.

xi. Any other patient care offense resulting from violation of policies, protocols and procedures of similar severity not listed above at the discretion of the EMS Medical Director.

xii. Practicing in the MCA without current credentials required in order to maintain privileges, as identified in the **Authorization for Medical Control Privileges Policy**.

xiii. Medication error, which has a negative impact on patient care.

xiv. A determination by the designated PSRO committee of failure to complete prescribed Quality Improvement Actions within the prescribed time frame.

# *Complaint Investigation & Resolution Supplement – Quality Improvement Actions*

## I. Application 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 Licensees maintain an appropriate level of clinical and operational performance.
D. MCAs should utilize Just Culture Guidelines when applying or considering Quality Improvement Actions. There should be a balance between provider and system accountability.
E. The Subject 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 failure to act), 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.

## II. Orders of Quality Improvement Action:

A. No Action (Warning Letter)
   1. A letter can be sent to the Subject Licensee advising them that although the incident was determined to be valid; there will be no action taken at that time.
   2. The MCA may provide recommendations to prevent future occurrences.

B. Order of Remediation
   1. The MCA may issue an Order of Remediation (OOR) to correct substandard clinical performance.
   2. A defined time period for completion of remedial activity shall be stated in the OOR.
   3. Subject Licensees shall be required to perform remedial activity under the supervision of an appointed proctor to correct an identified performance shortcoming.
   4. For Subject Licensee(s): Notice of an OOR, or the OOR itself, shall be forwarded to the Subject Licensee's employer/contracting entity (or MCA board in the case of an agency provider).
   5. A Subject Licensee shall be allowed only one opportunity for remediation of repetitive substandard performance in a twelve (12) month period. Subsequent episodes of substandard performance of the same nature occurring within the same twelve (12) month period may be subject to disciplinary action.

C. Probation which does not include a restriction of privileges:
   1. A probationary letter shall be issued to a Subject Licensee stating:
      a. the details of the substandard performance
      b. the details of the probation
      c. the remedial action required
      d. the time of probationary period
      e. the consequences for repetitive noncompliance
   2. Notice of probationary action shall be forwarded to the Subject Licensee's employer/contracting entity (or MCA board in the case of an agency provider).

D. Order of Disciplinary Action
   1. An Order of Disciplinary Action (ODA) is a written document developed by the MCA and sent to a Subject Licensee for the purposes of clearly and plainly identifying the findings of the MCA, any disciplinary action and any required remediation.
   2. The ODA must be delivered in a way that confirmed receipt by the Subject Licensee may occur.
   3. The Subject Licensee that receives an ODA must provide a copy to all medical control authorities in which they are privileged.
   4. Subject Licensees receiving an ODA from another medical control authority must provide a copy of the ODA to this MCA.
   5. An ODA may be accompanied by assignment of additional remedial activity.
   6. ODAs include, but are not limited to, written reprimands, written notice of suspension, written notice of revocation, a letter of warning and a letter of reprimand.
      a. In each instance outlined in Sections 8-11 below, the following shall apply:
         1. Notice of disciplinary action shall be forwarded to the Subject Licensee's employer/contracting entity (or MCA board in the case of an agency provider).
         2. A copy of the **Disciplinary Action Appeal** policy shall be included in the notice to the Subject Licensee.

   7. Temporary Suspension of Privileges
      a. The MCA Medical Director may temporarily suspend a Licensee's privileges in cases where there is, in the MCA Medical Director's professional opinion, an imminent risk to public or patient health, safety or welfare. The MCA shall review such action within three (3) business days after the MCA Medical Director's determination.
      b. If a Licensee's MCA privileges have been temporarily suspended under this section, the Licensee shall not provide prehospital care until MCA privileges are reinstated.

   8. Written Reprimand

a. A written reprimand shall be issued to a Subject Licensee stating:
   1. the details of the substandard performance
   2. the remedial action, if required
   3. the time allowed for completion of remedial action
   4. the consequences for repetitive noncompliance

9. *Probation* – that includes restriction of privileges:
   a. A probationary letter shall be issued to a licensee stating
      1. the details of the substandard performance
      2. the details of the probation
      3. the remedial action required
      4. the restriction of privileges, if applicable
      5. the time of probationary period
      6. the consequences for repetitive noncompliance

10. *Suspension of Privileges* - A Subject Licensee's MCA privileges shall be suspended for a specified period of time.
   a. A written notice of the suspension shall be issued to the Subject Licensee stating:
      1. the details of the substandard performance
      2. the violation(s) of protocol and/or policy
      3. the term of suspension
      4. the remedial activity, if required
      5. the time allowed for the completion of the remedial activity
   b. If a Licensee's MCA privileges have been suspended, the Licensee shall not provide prehospital care until the MCA privileges are reinstated.
   c. The MCA must notify the Michigan Department of Health and Human Services (MDHHS) within one (1) business day of the removal of MCA privileges from a Licensee.

11. Revocation of Privileges
   a. The notice of revocation shall state the violation(s) of protocol and/or policy.
   b. The MCA must notify the MDHHS within one (1) business day of the removal of MCA privileges from a Licensee.
   c. Within one (1) business day of the removal of MCA privileges, the MCA must notify all other medical control authorities which it knows, or has reason to believe, have granted the Licensee medical control privileges.

E. Additional Agency Licensee Quality Improvement Actions
   1. The MCA will notify the department chief or agency Licensee (Agency Licensee) official of the alleged protocol violation.
   2. If a minor protocol violation is determined by the MCA to have occurred, a letter of warning will be sent to the Agency Licensee.

3. If an initial serious violation or a second minor protocol violation within a six (6) month period is determined to have occurred, a letter of reprimand will be sent and the Agency Licensee may be required to submit, within fifteen (15) days, a written statement of actions it will take to prevent future protocol violations.
4. If a third of more frequent minor protocol violation is determined by the MCA to have occurred within a period of 18 months, or if the violation is a second serious violation within 18 months, the MCA may suspend or revoke its medical control oversight for the EMS agency. The EMS agency shall not provide pre-hospital care until medical control is reinstated. At its discretion, the MCA may take any other action within its authority to prevent further protocol violations. Notice of this action shall be made public.
5. An EMS agency may appeal a decision of the MCA. The EMS Agency must follow the **Disciplinary Action Appeal** policy.
6. At the discretion of the MCA, notice of these actions may be made public.
7. The MCA may assess restrictions or limitations upon a licensed life support agency for non-compliance with protocols.

F. Additional Considerations

1. Notification to MCA by Licensee
   A Licensee must immediately notify the MCA of disciplinary action from the State of Michigan.

2. Notification to Individual Filing Complaint
   In each instance of a Quality Improvement Action, the individual who submitted the Complaint shall, to the extent allowed under confidentiality statutes[1], be notified of the outcome of the Complaint review process.

3. Reapplication after Revocation
   a. Following revocation of a Licensee's MCA privileges, the Licensee may reapply to the MCA for privileges after no less than twenty-four (24) months have elapsed from the date of revocation.
   b. A Licensee issued a permanent revocation may not reapply for privileges at any time.

4. Financial Penalties
   The MCA may not apply financial penalties to Licensees, per this policy. While no such prohibition exists within applicable statute, the MCA may only establish individual financial penalties pursuant to an addendum to this policy which is approved by MDHHS.

**Protocol Source/References**: MCL 331.532 & MCL 331.533