Complaint Investigation & Resolution

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

I. Definitions:

A. Allegation/Complaint Invalid:
The allegation or compliant was found to have no administrative rule or protocol violation or the protocol deviation was considered acceptable for the situation.

B. Allegation 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.

C. Allegation 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.

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

E. Order of Disciplinary Action (ODA):
An Order of (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.

F. Complaint:
For the purpose of this policy, a complaint shall be defined as any notification of dissatisfaction or concern regarding medical care rendered by the MCA licensed EMS provider/agency, or any issues that involve the performance of the EMS system in whole or in part.

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

H. Formal Inquiry:
Formal inquiry means that 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 (individual/agency) 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. Just Culture Guidelines:
A just culture policy is a high-level statement of the values and commitment of an organization to treat healthcare workers and agencies fairly in all complaint investigations.

J. Licensee:
A licensee is defined as an individual or an agency (fire department, rescue squad, life support agency, etc.) holding a valid State of Michigan Medical First Responder, Emergency Medical Technician, Specialist, Paramedic, or agency licensed to operate within the Medical Control Authority service area. Said individual licensee shall be an employee of a provider licensed to operate within the Medical Control Authority.

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

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

M. Sentinel Event:
A sentinel event is any complaint which involves at least one single level I infraction, a violation of Michigan or Federal laws, EMS rules, or 2 or more level II infractions, as described in the Medical Incident Review and Corrective Action Policy.

N. Subject Licensee:
The individual provider that is the subject of the complaint received by the MCA

II. Complaints Received:

A. 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. The complainant for a case should be asked if they would like to be contacted by the agency/individual that is the subject of the complaint. This will allow the complainant the opportunity to voice a request to remain anonymous or to allow their information to be provided to the subject of the complaint.

C. All complaints, in order to be considered for action by the MCA, shall meet the following Inclusion Criteria:

1. A complaint may be submitted either verbally or in writing. Hearsay or "second hand" complaints may not be accepted or investigated by the MCA.
2. The complainant must provide the MCA with his/her name, address, and telephone number. A request for anonymity by a complainant shall be honored by the MCA to the extent possible.

3. The complaint must be directed toward a licensee (individual or agency) within the MCA.
4. The complaint must include a potential violation of Michigan or Federal laws, EMS rules, or MCA protocol
    i. All complaint reviews will be based on MCA approved protocols that were approved and active on the date of the EMS call for service.

D. 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 employer of the individual. These complaints may also be referred to the PSRO for investigation at the discretion of the MCA.
2. MCA reserves the right to retain the complaint investigation.

III. Complaint Delegation:

A. Complaints directed toward an individual acting while employed by an agency outside of the jurisdiction of the MCA shall not be accepted or investigated but will be forwarded, or the complainant directed to, the MCA/agency under whose jurisdiction it does fall.

B. MCAs may cooperate on investigations which overlap jurisdictional boundaries. For the purposes of Quality Improvement Actions, the MCA granting Medical Control to the provider or agency where the primary action or actions being investigated took place shall be considered the jurisdictional MCA.

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.

IV. Investigation of Complaints:

A. Once a complaint is received by the MCA, the complaint will be assigned to the PSRO.
1. The person(s) charged with complaint investigation will gather information to determine the validity of the complaint, if valid:
    i. The investigator will utilize the following list to determine if the complaint is a formal inquiry or sentinel event. These criteria are for example purposes 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.
        1. The following categories of incidents are defined as Level I incidents:
            a. Willful neglect of a patient

b. Abandonment of a patient
c. Failure to obey medical control physician's legitimate orders either by omission or commission in the presence of good communications.
d. Improper and inappropriate care which may result in compromise of wellbeing of the patient.
e. Conviction of a felony or misdemeanor
f. Two or more Level II offenses in any six-month period *
g. Breach of Confidentiality
h. Intentional falsification of EMS documentation, including patient care records.
i. Found to be under the influence of drugs or intoxicants while involved with patient care.
j. Violation of the EMS statute and its attendant rules and regulations, including care outside the scope of practice, as defined by protocol.
k. Practicing in the MCA without a current Michigan EMS provider license.
l. Practicing in the MCA without current privileges on two separate occasions within a single licensure period. Certifications required by the MCA in order to maintain privileges are identified in the **Medical Control Privileges Protocol.**
m. 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.
n. Failure to complete prescribed Quality Improvement Actions from a previous incident. (Or see (n) of LEVEL II)
o. Arrest or criminal charges for criminal sexual conduct of any degree, violent crime, drug diversion or illegal possession or distribution of controlled substances.
p. Failure to notify the MCA of a criminal charge, arrest or conviction within 1 business day
q. Gross negligence or willful misconduct

* Time measured from the time of occurrence of the initial incident to the time of occurrence of the succeeding event.

2. The following categories of incidents are defined as Level II incidents:
    a. 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.
    b. 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. A response shall be submitted in writing and with a signed delivery receipt to MCA staff within the allotted time period.
    c. Abuse and/or loss of system equipment due to neglect.
    d. Significant documentation errors
    e. Failure to accurately perform procedures as defined in protocols, policies and procedures.
    f. 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. This includes verification that a sealed drug and IV box, functional monitor/defibrillator, functional airway equipment, etc. are present on the unit.
    g. Improper or unprofessional medical communications including, but not limited to, any violation of Federal Communications Regulations, and falsification of identification during medical communications.
    h. 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.
    i. Furnishing of information known to be inaccurate in response to any official request for information relative to quality improvement activities or other investigations subsequent to this policy.
    j. Two or more orders of disciplinary action within a 6-month period **

k. 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.
l. Practicing in the MCA without current credentials required in order to maintain privileges, as identified in the Authorization for Medical Control Privileges Policy.
m. Medication error, which has a negative impact on patient care.
n. A determination by the designated PSRO Committee of failure to complete prescribed Quality Improvement Actions within the prescribed time frame.

** Time measured from the time of occurrence of the initial incident to the time of occurrence of the succeeding event.

ii. Will communicate with the employing agency of the subject licensee or agency involved in the complaint.
iii. 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 and/or agency.
iv. All requests for information will be documented in the investigation notes or with attached documentation/emails.
v. The agency and/or the individual will have 96 hours to turn over the requested documentation or provide statements the MCA.
vi. The MCA will redact all PHI prior to sending it to the PSRO for review.

2. Complaints found to be invalid will be closed as unsubstantiated; notification to the individual or the agency of the closure will only occur if prior knowledge of the complaint was provided to, or exists with, the involved individual/agency.
3. Formal notification of the subject licensee will occur if MCA Quality Improvement Actions, formal inquiry, or sentinel are indicated. A copy of the initial complaint, or a complaint summary (if the initial complainant requested anonymity), may be provided upon request.

B. Documentation

The documentation of the investigation of a complaint may include, but is not limited to, the following:

1. The name, address, and telephone number of the complainant (if known)
2. A copy of the stated complaint
3. The date and time of the receipt of the complaint
4. A copy of the complaint acknowledgement, if appropriate.
5. A copy of the notice to the subject licensee, if appropriate.
6. A copy of the pertinent protocol(s) and/or policy/policies.

7. Written statements of witnesses including notes from telephone interviews
8. Copies of pertinent reports, transcriptions of audio tapes; video recordings and copies of other pertinent documents or emails.

V. Due Process:

This policy establishes the initial steps of Due Process. A complaint will be investigated for validity and severity. Subject licensees and agencies shall be notified of formal or sentinel reviews.

A. The MCA will provide at least 4 business days notice to affected providers and agencies prior to convening PSRO meetings to which they must attend.
B. The MCA will provide a copy of the Complaint Investigation Protocol to the subject licensee(s) of the complaint.
C. Subject licensee(s) and agencies of a complaint 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. The subject licensee or agency may request the complaint/investigation related materials in advance of the PSRO meeting.
D. Based on the complaint information and/or evidence the MCA Medical Director may temporarily suspend the privileges of a subject licensee or agency pending a sentinel event meeting.
    1. Any MCA suspension enacted as a measure to ensure the safety of the community or patients shall remain in effect pending sentinel event review and disposition.
    2. In the event of criminal charges being filed against a provider or agency 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.
        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 considered to be revoked.
        c. If found not guilty of charges, the individual or agency must provide copies of court documents, including transcripts, to the MCA.
        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 should occur at a sentinel event meeting.
E. A subject licensee or agency may request a postponement of up to thirty (30) calendar days of a PSRO meeting appearance in order to prepare his/her individual or agency response to the complaint. The subject licensee must submit

a copy of all supporting documentation to the MCA at least one week (5 business days) prior to the postponed review meeting.

F. The MCA is not a hiring entity and is not subject to collective bargaining. Union representation during MCA PSRO reviews is not permitted.
G. The MCA's PSRO investigates incidents, complaints, personnel and agencies. While a deed or misdeed may be civil or criminal in nature, the MCA's PSRO is not an adjudicating body for either of these conditions. 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.
H. Recording, monitoring, or any manner of duplicating a PSRO review is not permitted unless conducted by the PSRO entity and expressly for PSRO purposes.
I. Disclosure of confidential PSRO materials[1] by individuals or agencies both before and after review shall be cause for possible suspension or revocation of MCA privileges, as well as possible statutory violations.
J. The MCA may disclose non-specific information relating to discipline of individuals or agencies. Care must be taken to not compromise any confidential information.[2]
K. Subject licensees or agencies may have agency representation at PSRO reviews provided PSRO standards are maintained.
L. Subject licensees or agencies 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 Incident Classification Section.
M. 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 be prescribed by the PSRO and ALL Sentinel Events:
    1. The violation of policy or protocol shall be defined.
    2. The impact on patient outcome will be evaluated.
    3. The subject licensee shall be given time to speak on the issue of the complaint including the opportunity to present supporting documentation.
    4. 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.
N. The PSRO of the MCA will review the alleged violation(s) and by majority vote of the members present decide a course of action.
    1. All alleged violations will be determined as the following for each individual subject licensee and/or agency.
        a. Invalid

[1] MCL 331.533
[2] MCL 331.533

b. Valid – Minor
c. Valid – Serious

O. All valid allegations shall be followed by a Quality Improvement Action.
P. All system failures shall be addressed by the MCA.
Q. Subject licensees or agencies shall be notified of the findings of a PSRO review. If disciplinary action results, the individual or agency will be provided with any required remediation steps/actions and a copy of the **Disciplinary Action Appeal Protocol**.
R. In the event that a complaint/investigation involves both the function of an individual and the compliance of their agency or department, the requirement for a 4-business day notice of any special meeting shall apply, unless a postponement is granted to the individual agency or subject licensee.

VI. 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 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 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.

VII. Orders of Quality Improvement Action:

A. No Action (Warning Letter)
   1. A letter can be sent to the subject licensee or agency or individual advising them that although the incident was determined to be valid; there will be no action taken at this time.
   2. The MCA may provide recommendations to prevent future occurrences.
B. Remediation
   1. The Medical Control Authority may issue an order of remediation to correct substandard clinical performance.
   2. A defined time period for completion of remedial activity shall be stated in the order.
   3. Subject licensees or agency 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 a remedial order, or the order itself, shall be forwarded to the licensee's employer (or MCA board in the case of an agency provider).
5. A subject licensee or agency shall be allowed only one opportunity for remediation of repetitive substandard performance in a twelve-month period. Subsequent episodes of substandard performance of the same nature occurring within the same twelve-month period shall be addressed under the disciplinary portion of this policy.

C. Probation which does not include a restriction of privileges:
1. A probationary letter shall be issued to a subject licensee or agency 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 licensee's employer (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. 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.
3. The ODA must be delivered in a way that confirmed receipt by the licensee may occur.
4. The licensee that receives an ODA must provide a copy to all MCAs in which they are privileged.
5. Licensees receiving an ODA from another MCA must provide a copy of the ODA to this MCA.
6. An Order of Disciplinary Action may be accompanied by assignment of additional remedial activity.
7. Temporary Suspension of Privileges
   a. The Medical Director may temporarily suspend a licensee's privileges in cases where there is a clearly definable risk to the public health and welfare. The Medical Control Authority shall review such action within three business days after the Medical Director's determination.
   b. If a licensee's MCA privileges have been temporarily suspended from a licensee, the licensee shall not provide prehospital care until MCA privileges are reinstated.
8. Written Reprimand
   c. A written reprimand shall be issued to a 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

d. Notice of disciplinary action shall be forwarded to the licensee's employer (or MCA board in the case of an agency provider).
e. A copy of the **Disciplinary Action Appeal** policy shall be included in the notice to the licensee.

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
   b. Notice of probationary action shall be forwarded to the licensee's employer (or MCA board in the case of an agency provider).
   c. A copy of the **Disciplinary Action Appeal** policy shall be included in the notice to the licensee.
10. Suspension of Privileges - A licensee's medical privileges shall be suspended for a specified period of time.
   a. A written notice of the suspension shall be issued to the 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. Notice of disciplinary action shall be forwarded to the licensee's employer, if employed (or MCA board in the case of an agency provider).
   c. A copy of the **Disciplinary Action Appeal** policy shall be included in the notice to the licensee.
   d. If a licensee's MCA privileges have been suspended from a licensee, the licensee shall not provide prehospital care until the MCA privileges are reinstated.
   e. The Medical Control Authority must notify the department within one (1) business day of the removal of medical control privileges from a licensee.
11. Revocation of Privileges
   a. The notice of revocation shall state the violation(s) of protocol and/or policy.
   b. Notice of disciplinary action shall be forwarded to the licensee's employer (or MCA board in the case of an agency provider).
   c. A copy of the **Disciplinary Action Appeal** policy shall be included in the notice to the licensee.

d. The Medical Control Authority must notify the department within one (1) business day of the removal of medical control privileges from a licensee.
e. Within one (1) business day of the removal of medical control privileges, the Medical Control Authority must notify all other Medical Control Authorities which it knows, or has reason to believe, have granted the licensee or agency Medical Control privileges.

E. A subject licensee and/or agency must notify the MCA of disciplinary action from the State of Michigan.
F. Additional Agency Quality Improvement Actions
   1. The Medical Control Authority will notify the department chief or agency official of the alleged protocol violation.
   2. If a minor protocol violation is determined by the Medical Control Authority to have occurred, a letter of warning will be sent to the EMS agency.
   3. If an initial serious violation or a second minor protocol violation within a six-month period is determined to have occurred, a letter of reprimand will be sent and the EMS agency may be required to submit, within 15 days, a written statement of actions it will take to prevent future protocol violations.
   4. At the discretion of the Medical Control Authority, notice of these actions may be made public.
   5. The MCA may assess restrictions or limitations upon a licensed life support agency for non-compliance with protocols.
   6. If a third of more frequent minor protocol violation is determined by the Medical Control Authority to have occurred within a period of 18 months, or if the violation is a second serious violation within 18 months, the Medical Control Authority 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 Medical Control Authority may take any other action within its authority to prevent further protocol violations. Notice of this action shall be made public.
   7. An EMS agency may appeal a decision of the Medical Control Authority. The EMS Agency must follow the **Disciplinary Action Appeal** policy.
G. The complainant shall, to the extent allowed under confidentiality statutes, be notified of the outcome of the complaint review process.
H. Reapplication after Revocation
   1. Following revocation of an involved party's privilege to practice in the MCA, the involved party may reapply to the MCA for privileges after no less than 24 months have elapsed from the date of revocation. Those issued a permanent revocation may not reapply for privileges at any time.
I. Financial Penalties

   The MCA may not apply financial penalties to individuals, per this policy. No such prohibition exists within statute; however, the MCA wishing to establish individual financial penalties must purposely develop an addendum to this policy.

J. PSRO Communications

PSRO protected entities may share PSRO information with other PSRO entities for the following purposes[3]:

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.

Protocol Source/References: [1] MCL 331.532