Monroe-Livingston Regional EMS Council
REMAC Quality & Patient Safety Committee
Policy & Procedure

I. PURPOSE

To facilitate high quality patient care delivered by Emergency Medical Services throughout the Monroe-Livingston region by incorporating the following concepts:

- Commitment to the success of our EMS providers in a challenging and demanding profession;
- Recognition of the fallibility of all providers despite their dedication to their patients;
- Supporting active learning systems to identify and address risks and behaviors in our system; and
- Shaping a well-designed EMS system to maximize patient outcomes. Hello, and welcome to the MLREMS digital letterhead template. You'll notice the logo in the header as well as pertinent information in the footer. The content (what you're reading now) goes in between.

II. AUTHORIZATION

The New York State Public Health Law vests the Regional Emergency Medical Advisory Committee (REMAC) with the authority to conduct quality improvement and quality assurance programs to assist EMS providers and agencies with achieving excellence in patient care. The Monroe-Livingston REMAC Quality & Patient Safety Committee is charged with this responsibility for the Monroe-Livingston region.

III. JUST CULTURE & METHODOLOGY

The Quality & Patient Safety Committee and the Monroe-Livingston REMAC recognize the value of the "Just Culture" model and have integrated it into quality improvement processes. This approach is designed to enhance patient safety by de-emphasizing focus on events, individuals, errors, and outcomes of the event, instead focusing on the quality of the provider's choices, the risk inherent in the choices, and system design. Blind to outcome, the Just Culture model recognizes that even if no one is injured, it does not exclude error.

The Patient Safety Committee's actions will enhance safety within EMS through a positive and structured process. It strives to promote learning from sentinel events, human errors, at-risk behaviors, and reckless behaviors. Whenever possible, interventions will be non-punitive and will focus on identified gaps in education, processes, and system design.

Just Culture serves as a structure to conceptualize and operationalize event investigation and response. In the first step, we determine if an actual or potential (near miss) undesirable outcome occurred. Then, we identify if a duty existed to follow a rule, produce an outcome, or avoid causing harm. If these two criteria are met, then we review the event to understand: 1) what happened, 2) what normally happens, 3) what the procedure requires, and 4) why it happened. We can then classify the provider's involvement into one of the following behaviors:

1. Human Error is inadvertently doing other than what was intended through a slip, lapse, or mistake. We address it by consoling the provider and modifying the system's performance shaping factors.
2. At-Risk Behavior is a behavioral choice that increases the probability of error or risk, where risk is not recognized or mistakenly thought to be justified. We address it by coaching the provider and modifying the system's performance shaping factors.
3. Reckless Behavior is a conscious disregard of a substantial and unjustifiable risk. We consider it unacceptable and address it with remedial or punitive actions and modifying the system's performance shaping factors. This behavior will be very rare.

The Patient Safety Committee recognizes that human error, at-risk behavior, and reckless behavior may have root causes that apply beyond an individual agency or region. Thus, the Committee encourages agencies, hospitals, and EMS providers to refer events, even if no injury occurs, so others may learn.

IV. MEMBERSHIP

Permanent Positions:

1. Associate Regional Medical Director for Quality & Patient Safety (RMD-QPS, Committee Chair)
2. Quality & Patient Safety Committee Coordinator (assigned by RMD)

At-Large Positions:

1. Physicians (5 positions) Qualified physicians will have expertise in

Abbreviations	
AMD	Agency Medical Director
RMD-QPS	Associate Regional Medical Director for Quality & Patient Safety
DO	Director of Operations
EMS	Emergency Medical Services
MLREMS	Monroe-Livingston Regional EMS Council
NYS DOH BEMSAT	New York State Department of Health, Bureau of Emergency Medical Services and Trauma Systems
QA/QI	Quality Assurance/Quality Improvement
REMAC	Regional Emergency Medical Advisory Committee
RMD	Regional Medical Director
SEMAC	State Emergency Medical Advisory Committee
SEMSCO	State Emergency Medical Services Council

Emergency Medicine, and preferably be actively practicing. In addition, expertise in Emergency Medical Services is strongly desired.

2. EMS Providers (10 positions)

   EMS provider positions will ideally represent a cross section of regional EMS:

   - All levels of care provided in the Region (e.g., FR, BLS, ALS, SCT & Air Medical)
   - Urban, suburban, and rural
   - Newer, mid-career, and experienced providers
   - Career and volunteer

3. Other (maximum 3 positions)

   Optionally, the Patient Safety Committee, with approval of the REMAC chair, may elect up to three non-physician, non-EMS professionals who may offer valuable input to the committee. Candidates would include, but not be limited to, pharmacists, nurse practioners, physician assistants, and nurses.

Filling Seats:

1. **January:** An announcement detailing the seats available will be publicly distributed to the Monroe-Livingston Regional Emergency Medical Services (MLREMS) region. Applications are due by February 28.
2. **February:** Applications will be distributed to Committee members at least 5 business days prior to the March meeting. At the meeting, a discussion regarding the applicants will be held without the applicants (including current members) in the room. A vote will be taken by all present Patient Safety Committee members (including those up for re-appointment) to provide the REMAC Chair a recommendation for Committee membership. As per REMAC policy, the REMAC Chair appoints members of committees.
3. **March:** The REMAC Chair will announce the Committee membership.

Seat Terms

Positions are for two years. Membership is limited to two consecutive terms but may be reappointed at a later date. However, if a vacancy remains following the election, then a qualified candidate who has termed out can be immediately reappointed to the committee by the REMAC Chair.

Re-application

Any eligible member of the Patient Safety Committee whose (first) term is expiring may reapply. Those whose second term is expiring may not reapply until the next cycle.

V. PROFESSIONALISM

Member Expectations

1. Attendance: Members are expected to attend a minimum of two-thirds of meetings held during any 12-month period. Excessive absences may result in removal from the Committee by the REMAC Chair.
2. Participation in committee Quality Improvement activities: Members are expected to engage in quality improvement activities conducted by the committee. Such participation, or lack thereof, will be considered by the committee at time of term renewal.
3. Participation in case reviews: Members must periodically participate in Rapid or Routine Reviews. Members that have a conflict of interest are excluded from the Review. Such participation, or lack thereof, will be considered by the committee at time of term renewal.

Confidentiality

All event investigation related proceedings of the Patient Safety Committee are confidential and must not be discussed outside of the Committee meetings or outside Committee business. This confidentiality is critical for the protection of participants in event reviews. As such, Patient Safety Committee members must sign a Confidentiality Agreement. Breach of confidentiality may result in removal from the Committee after investigation by the Committee Chair and others as designated by the REMAC Chair.

Acceptable Communication

Acceptable communication includes written communications such as email and letters delivered in person or by mail. Any communications via the telephone or in person, as related to event investigations, must be recorded in writing, with the date/time, in the investigation file. Communications via the telephone or in person, related to normal daily business of the Patient Safety Care Committee do not need to be documented. Communicating via social networking (Facebook, etc.) is NEVER acceptable.

Conflicts of Interest

Prior to any discussion of an event investigation, a Conflict Evaluation will be performed while in Executive Session. Each Committee member will be required to disclose any conflicts or potential conflicts. The Committee will assess the disclosures and possibly disqualify members from participating in some or all of the discussion. The Patient Safety Committee shall rule upon such conflicts by the vote of a majority of those present, excluding those members who are the subject of the vote. If the RMD-QPS is in conflict, the RMD will assume the RMD-QPS' responsibilities.

When a Patient Safety Committee member has a potential conflict, either financial (e.g., as owner, employee, etc.), personal (e.g., family member, friend, etc.), or of any other sort, he or she shall, at the

time of case consideration, disclose such interest or association to the Patient Safety Committee, Coordinator and/or RMD-QPS will evaluate all potential conflicts. Depending upon the assessment, the conflicted member may be excluded from participating in some or all aspects of the event investigation.

VI. ADVERSE EVENT/NEAR MISS REPORTING SYSTEM

The Quality and Patient Safety committee is charged with the administration of a regional Adverse Event & Near Miss reporting system.

Background

Generally speaking, there are two broad categories of patient safety events – adverse events, in which harm to the patient is realized, and near misses. An adverse event refers to an action or circumstance, preventable or not, that resulted in direct harm to the patient(s). A near miss refers to a similar action or circumstance that differs only in outcome – the patient was not harmed. In a system of Just Culture, which avoids outcome bias, both categories are treated the same.

A highly functioning Quality Improvement and Patient Safety program will encourage and facilitate the reporting of both adverse events and near misses by its providers. Such reporting must be non-punitive and easily accomplished.

Procedure

The Quality & Patient Safety Coordinator and Chair shall review submitted reports on a regular basis and report findings to the Patient Safety Committee at its regular meetings. Cases with particularly notable opportunities for system improvement will be referred to the committee for further exploration and action. Identified opportunities for system improvement and corresponding recommendations will be reported to the REMAC and RMD promptly for further discussion and action.

VII. QUALITY IMPROVEMENT AND PATIENT SAFETY EDUCATION

The Quality and Patient Safety committee is charged with ensuring the availability of quality improvement & patient safety instruction to the prehospital providers of the MLREMS region. While the committee itself is not directly responsible for the delivery of the education, it should strive to ensure that relevant education on quality improvement and patient safety is available to prehospital providers of all levels in the Monroe-Livingston region. The committee will advise the REMAC of such offerings or need thereof.

VIII. REGIONAL QUALITY IMPROVEMENT ACTIVITIES

The Quality and Patient Safety committee strives to be proactive in matters of quality improvement and patient safety. In that vein, the committee will periodically conduct regional prospective quality improvement efforts. As a need is identified, in conjunction with the RMD, the committee will construct and implement a prospective PDSA (plan, do, study, act) cycle and report progress and findings to the REMAC and Regional Medical Director. Suggestions may come from the REMAC, MLREMS Council, Regional Medical Director, the committee itself, or any stakeholder or participant in the MLREMS system.

IX. PROCEDURES FOR REFERRED CASES

Step 1: Intake and Referral

1. Referrals can be submitted to the Patient Safety Committee by anyone, but must be submitted in writing. Email is acceptable as long as all contact information is included.

US Mail: EMS Patient Safety Coordinator
University of Rochester, Division of Prehospital Medicine
601 Elmwood Avenue, Box 655
Rochester, NY 14642

Email: mlrems@mlrems.org and marked for the Patient Safety Coordinator as “Confidential”.

2. Agencies should refer events to the Patient Safety Committee if they meet any of these criteria:
   - Provider reckless behavior;
   - Provider repetitive at-risk behavior;
   - Sentinel event: Human errors with identified system performance issues;
   - Sentinel event: At-risk behaviors with identified system performance issues;
   - Agency actions with major gravity for the provider, other agencies, or the system;
   - Agency actions that cannot be completed due to the provider leaving the agency.

   Other reasons for referral include but are not limited to the following:
   - Contested Agency Actions related to medical care or protocol/system policy issues;
   - Direct referral by interested parties of events serious enough or widespread enough to warrant system review and possible system action.

3. Initial actions by the Patient Safety Coordinator
   - Obtain approval from the referring agency to access prehospital documentation

- Collect initial information, including available EMS documentation;
- Create a Patient Safety Committee file, including all paperwork and a tracking number
- Assess for actual or potential undesirable outcomes;
- Assess if a duty was imposed;
- Meet with the RMD-QPS to jointly identify the referral category.

4. As demonstrated on the referral flow diagram, there are 6 categories of referrals which reflect the level of concern, the speed in which action must be taken, and the REMAC Patient Safety Committee's jurisdiction. The Coordinator and RMD-QPS will choose one based on the information available, recognizing that the assigned category may change with additional information.

Unfounded

Based on information gathered, there is no identified actual or potential undesirable outcome or duty imposed. Events may also be assigned a final determination of "Unfounded" after the full investigation.

Outside of Jurisdiction

When the agency and/or a certified provider are not part of the MLREMS system, the event is determined to be outside of our jurisdiction. In these events, a referral will be made to that Region's equivalent to the ML-REMAC Patient Safety Committee. When the response is received from the other region, it will be closed if the certified provider is not a cleared provider in the MLREMS Region. If the certified provider is a cleared provider in the MLREMS Region, the response will be reviewed by the Coordinator and RMD-QPS to determine if any need for local investigation exists. If no response is received, then the need for a local investigation will be determined. If no need is identified, the event will be closed. If need is identified, an investigation will be initiated. Referral may be determined Out of Jurisdiction if the provider's actions may be criminal and/or fall under the jurisdiction of the Bureau of Narcotic Enforcement or Bureau of EMS as outlined in Part 800 and/or Part 18 of the New York State Public Health Law. Each referral determined Out of Jurisdiction must be reviewed on an individual basis and confirmed by the full committee.

Category A – Agency Investigation

The event is suitable for referral to the provider's agency at which the incident occurred for internal review only. If at any time the concerns rise to a higher level, action as permitted for that category may be taken.

Category B – Routine Investigation

The event requires further investigation and will be referred to a Routine Investigation Team (possibly the Patient Safety Committee Coordinator alone). The provider may continue to practice during the

investigation. If at any time the facts show that the issue can be handled at the Agency level, the case can be reclassified as a Category "A" and referred to the Agency. If at any time the facts rise to a higher level, action as permitted for that category may be taken.

Category C – Rapid Investigation

The event requires immediate review and will be referred to a Rapid Investigation Team. The provider may continue to practice during the investigation. If at any time the facts rise to a higher level, action as permitted for that category may be taken.

Category D – Immediate Suspension, Full Investigation Pending

This category would be used in collaboration with the Regional Medical Director (RMD) and RMD-QPS, as suspensions are enacted by the RMD. The provider is suspended immediately from providing care as determined by the RMD in the Monroe-Livingston Region, pending a Rapid Investigation. The event requires immediate review and continuing practice by the provider potentially endangers patient and/or public health for credible allegations of any the following (not a complete list):

- The provider engaged in (or has been found guilty of) fraud, deceit, incompetence, patient abuse, theft, or dishonesty in the performance of the provider's duties and practice;
- The provider has practiced on at least one occasion with gross negligence or recklessness, or on many occasions with negligence, or has taken actions or has permitted omissions demonstrating a lack of the level of competence necessary to practice at the provider's level of certification such that the provider's continuation of practice is an immediate threat to patients;
- The provider has failed to comply with the requirements of Section 800.15 of the Codes, Rules and Regulations of the Department of Health;
- The provider has engaged in fraud or deceit in the procuring of certification;
- The provider has been convicted of any crime or crimes that could commonly be perceived by a layperson to jeopardize the EMS provider-patient relationship (e.g., murder, sexual abuse, theft, endangering the welfare of a child, sale of drugs) unless the Patient Safety Committee finds that such conviction does not demonstrate a present risk or danger to patients;
- The provider has initiated patient care or driven an ambulance or other EMS response vehicle while under the influence of alcohol or any other drug affecting physical coordination or intellectual functions;
- The provider has knowingly aided or abetted another in practice as an EMT who is not certified as such;
- The provider has presented him or herself as being certified at a higher level than actually certified, or has used skills restricted to individuals holding a higher level of certification.

NOTE: The RMD has the authority granted by the REMAC to suspend a provider independent from the Patient Safety Committee and a Rapid Investigation is not automatically initiated based solely on a provider's suspended status.

Step 2: Provider / Agency Notification

1. Category A

   A phone call will be made by the PS Coordinator to the agency notifying them of the referred event requiring investigation. An email (sent to the Agency's Director of Operations (DO) or ALS Chief and Agency Medical Director (AMD), as long as contact information is available) with the official referral letter and the Agency Investigation Report Form (Appendix A) will be sent within 3 business days of the referral. The email will ask for verification of receipt and if no verification is received within 3 business days, a copy of the letter and form will be sent via certified US Mail, return receipt requested. The letter will specify the concern that was received, any known details and the date the response is due back to the Patient Safety Committee. The letter will be accompanied by supporting educational materials regarding the process used by the PS Committee and this policy document.

2. Category B, C or D

   A phone call will be made by the PS Coordinator to the provider and the involved agency/agencies. The purpose of the provider phone call is to explain the Just Culture model, Patient Safety Committee goals, the investigation process, and answer any further questions. An email (sent to the provider, the DO or ALS Chief, and the AMD, as long as contact information is available) with the official referral letter will be sent within 3 business days of the referral. The email will ask for verification of receipt and if no verification is received within 3 business days, a hard copy letter will be sent via certified US Mail, return receipt requested. The letter will specify the concern that was received, any known details, the members of the investigation team, and will invite the provider to attend the Patient Safety Committee meeting at which the event investigation will be discussed. The letter will be accompanied by supporting educational materials regarding the process used by the PS Committee and this policy document.

   In the event of a suspension of practice, a phone call will be made to the AMD, and to the DO(s) and AMD(s) at all other agencies with whom the provider is affiliated.

3. If the category changes to a more severe category both the provider and the agency will be notified via phone call and a follow up email will be sent to the provider, the agency DO and the AMD.

Step 3: Investigation Process

1. Agency Investigation

   The agency is expected to review the concern that was referred and to complete the Agency Investigation Report Form (Appendix A). This form must be returned to the Patient Safety Committee postmarked no later than the date specified (usually 20 business days from the date of the referral letter/form). It is recommended that agencies follow the Just Culture model and event investigation process. However, we recognize that all will not be proficient with the process.

   After receipt of the Agency review, the Patient Safety Committee Coordinator and RMD-QPS will review the findings, determine if any further questions exist (and address them), and consider system level implications. Additionally, if not already done, they will develop causal diagrams for the case based on the information provided.

   The Patient Safety Committee will be informed of the case, agency findings, agency actions, and system implications at the next Committee meeting.

   If the agency does not comply with the twenty-day notification, a second letter will be sent via email. The second letter will ask the agency to notify the Patient Safety Committee within five business days of the reason for the delay and to assure the committee that they are reviewing the concern within the agency. The letter will allow the agency additional business days to complete their review. If the agency has either not responded to the request for assurance within five business days, or not finished their review within the additional twenty business days, the issue will automatically revert to being handled by the Committee at the Regional level as a Category "B" case.

2. Routine Investigations

   The Routine Investigation Team will be composed of personnel suited for the review and chosen by the Patient Safety Committee Coordinator and RMD-QPS. The review may be performed by the Coordinator alone. Team members will be preferentially chosen in the following order: REMAC Patient Safety Committee, previous Patient Safety Committee members, REMAC and other REMAC Committees, MLREMS, and interested EMS parties. Individuals with Just Culture training will be preferred. A member of the Investigation Team will be excused should a real or perceived conflict of interest be identified.

   The Routine Investigation Team is charged with objectively gathering information regarding the concerns presented to the Patient Safety Committee, summarizing their findings within 10

business days of assembling the Team. The Team will use the Just Culture Investigation Tool and the Just Culture Algorithm to assess for Human Error, At-Risk Behavior or Reckless behavior and assess the quality of the choices that led to the clinical care concern. The Review Team should review any relevant information (e.g., documents, tapes, etc.) and interview any relevant parties (e.g., the person, hospital, or agency making the referral; any witnesses to the event; leadership from the agencies involved, including the Medical Director(s) and chiefs). The RMD-QPS may require certain aspects of the case be reviewed.

Using the Case Review Template (Appendix B) the Routine Investigation Team will provide the Patient Safety Committee Coordinator with a written preliminary report, including a summary of the concern within 10 business days. If the Coordinator did the review alone, the report will be given to the RMD-QPS for review. The Review Team should be debriefed by the Committee Coordinator after the investigation is complete and their report has been submitted is to gain feedback on the process and make improvements where needed.

The RMD-QPS will then determine whether the case can be held until the next Patient Safety Committee meeting or if immediate action is required. If the RMD-QPS believes immediate action is required, he/she will work with the RMD to determine what action is necessary.

If no immediate action is needed, the RMD-QPS will work with the Committee Coordinator and/or the Program Agency Education Specialist to develop a customized educational plan that will be recommended following the case presentation at Patient Safety Committee Meeting.

The Committee Coordinator will present the details of the case, the summary of findings, and the causal diagram at the Patient Safety Committee meeting during executive session. The provider(s) and/or agency involved will be invited to attend the next Patient Safety Committee meeting so that the Committee may ask questions of the provider if clarification is needed. The RMD-QPS will lead a discussion regarding the recommended actions, as well any agency or system level performance shaping factors.

3. Rapid Investigations

   The Rapid Investigation Team will be composed of personnel suited for the review and chosen by the Patient Safety Committee Coordinator and RMD-QPS. The review may be performed by the PS Coordinator alone. Team members will be preferentially chosen in the following order: REMAC Patient Safety Committee, previous Patient Safety Committee members, REMAC and other REMAC Committees, MLREMS, and interested EMS parties. Individuals with Just Culture

training will be preferred. A member of the Investigation Team will be excused should a real or perceived conflict of interest be identified.

The Rapid Investigation Team is charged with objectively gathering information regarding the concerns presented to the Patient Safety Committee, summarizing their findings within 5 business days of assembling the Team. The Review Team should review any relevant information (e.g., documents, tapes, etc.) and interview any relevant parties (e.g., the person, hospital, or agency making the referral; any witnesses to the event; leadership from the agencies involved, including the Medical Director(s) and chiefs). The RMD-QPS may require certain aspects of the case be reviewed.

Using the Case Review Template (Appendix B), the Rapid Investigation Team will provide the Patient Safety Committee Coordinator with a written preliminary report, including a summary of the concern within 5 business days. The Review Team should be debriefed by the PS Coordinator after the investigation is complete and their report has been submitted is to gain feedback on the process and make improvements where needed.

The RMD-QPS will then determine whether the case can be held until the next Patient Safety Committee meeting or if immediate action is required. If the RMD-QPS believes immediate action is required, he/she will work with the RMD to determine what action is necessary.

If no immediate action is needed, the RMD-QPS will work with the PS Coordinator and/or the Program Agency Education Specialist to develop a customized educational plan that will be recommended following the case presentation at Patient Safety Committee Meeting.

The PS Coordinator will present the details of the case, the summary of findings, and the causal diagram at the Patient Safety Committee meeting during executive session. The provider(s) and/or agency involved will be invited to attend the next Patient Safety Committee meeting so that the Committee may ask questions of the provider if clarification is needed. The RMD-QPS will lead a discussion regarding the recommended actions, as well any agency or system level performance shaping factors.

Nothing contained herein shall prevent the RMD and/or REMAC from imposing an emergency suspension of any or all privileges of the provider.

4. Immediate Suspension, Full Review Pending

If a provider is suspended at the regional level, a Rapid Investigation will be required to fully investigate the allegations. As such, the process for Rapid Investigations will be followed.

If a suspension is involved, the local representative from the New York State Department of Health Bureau of Emergency Medical Services (NYS DOH BEMSAT) must be notified as these cases likely represent reckless behavior and have broader implications.

5. The Investigation Process

The steps of the event investigation follow the Just Culture model. Five fundamental questions should be asked by the team:

1. What happened?
2. What normally happens?
3. What does the procedure require?
4. Why did it happen?
5. How was the organization managing the risk?

As the event investigation is conducted, the following occurs:

1. Identify the undesirable outcome: Usually performed by the Committee Coordinator and RMD-QPS, but may also be performed by the investigation team.
2. Search for causes: Ask the five fundamental questions listed above to understand what happened.
3. Build a cause and effect diagram: Keep asking why until no further causes can be included.
4. Test the strength of the causal links: Review each link and ensure there is sufficient evidence to prove the link.
5. Explain the human errors: Are there performance shaping factors, at-risk behaviors, or reckless behavior present that increase the likelihood of the human errors?
6. Explain the knowing violations: What were the perceptions of risk? Are there system or individual performance shaping factors at play?
7. Explain the mechanical failures: If applicable, is this an anticipated failure of a part? If not, why did it happen?
8. Explain other causal conditions: Are the conditions understood and manageable?
9. Remove non-causal data: Did a duty to act exist? If not, the item must be removed from the causal explanation.
10. Build a narrative: Write the event investigation report using the template, including all direct and probabilistic causes but excluding non-causal data.

11. Eliminate possible biases from the narrative: Avoid vague terms and negative descriptors.
12. Test the product: This, in many ways, occurs during the Patient Safety Committee meeting, where the report is reviewed and tested.
13. Develop risk reduction strategies

6. New Topics Identified During the Event Investigation

During the review of the case, new issues related to the original complaint or additional clinical care issues may become evident. Additionally, serious issues unrelated to the original referral may become evident. The Patient Safety Committee should consider how it wants to handle these issues using the Just Culture Model, but it is important for the Committee to balance the value of identifying and addressing these findings with the scope of the referral and investigation. A patient safety case does not give the Committee carte blanche to investigate all aspects of the individuals and agencies involved, but the Committee has a general responsibility to advance its mission and identify relevant agency and system performance shaping factors.

The Patient Safety Committee may address these new issues as they fit within the Just Culture Model; it is impossible for a policy to address the varied possibilities that may occur and the committee may elect to deal with new issues as a new case if agency or system performance shaping factors are present. Alternatively, the Committee may add findings and interventions to the existing case based on human error or at-risk behavior. The Committee may decide that the identified issue is outside the scope of the investigation and/or not of serious enough nature to require intervention.

Step 4: Patient Safety Committee Meetings With Providers

Any time an individual or organization is being investigated by the Patient Safety Committee, the individual or organization representatives are invited to address the Committee regarding the event and answer questions. The provider or organizational representatives cannot attend the discussion of the event investigation, which occur during executive session. As an education-based, quality improvement process, attorneys are not allowed to participate. A supportive individual may accompany the individual or organizational representatives, but he/she may not address the Patient Safety Committee. The individual or organizational representatives must notify the Committee at least five business days in advance of the meeting that they are attending in order to make time on the agenda. Minutes of this portion of the meeting will be kept separately in the Patient Safety Committee event investigation case file.

Step 5: Consoling, Coaching, Remedial Actions, and Disciplinary Actions

The Patient Safety Committee will identify certain actions that should result from the event and event investigation. The Committee will vote while in executive session to demonstrate agreement to the action plan. Actions that include any type of limitations of practice (e.g., suspension of privileges, preceptor status) or that address highly significant issues will be read during open session and voted on by the REMAC. These actions are not considered final until approved by REMAC.

In keeping with the Just Culture Model, corrective actions will be based on the following:

1. Human Error: Console the provider and modifying the system's performance shaping factors.
2. At-Risk Behavior: Coach the provider and modifying the system's performance shaping factors. For instance, have them talk with an expert (e.g., physician, educational specialist) to discuss their behavioral choice. Common practice is to provide education support to assist with the coaching and will be tailored to the provider's or agency's perceived needs.
3. Reckless Behavior: Address with remedial or disciplinary punitive actions and modifying the system's performance shaping factors.

It is expected that the majority of cases will fall into the categories of Human Error or At-Risk Behavior and the coaching (corrective actions) recommended and/or provided will be educational in nature. This educational plan can include (but is not limited to) didactic education, remediation of skills, specialty course completions, and testing, based on the identified needs of the provider. Please note that a regional suspension is most often not disciplinary in nature, and is more commonly used as a timeframe in which coaching and education support can be delivered to prevent potential patient harm.

1. Agency Based Plans
   The agency must provide written documentation within 30 business days to the Patient Safety Committee that the corrective action plan is at least in place and provide a timeline for completion. The agency must notify the Committee when the entire corrective action plan is complete and attest to successful completion. In the event the agency does not provide the proper documentation to the Committee in the time frame specified, the case will be referred to the Committee for full review and disposition. Further, the agency's failure to complete the corrective action plan will be investigated.

2. Patient Safety Committee Based Plans
   Actions that include any type of limitations of practice (e.g., suspension of privileges, preceptor status) or that address highly significant issues must be reviewed by REMAC at their next meeting. This review will occur during executive session, voted during executive session, and

read during open session. All other actions are not made public. The Patient Safety Committee will present the case to the full REMAC plus Patient Safety Committee members while the REMAC is in Executive Session.

The burden of proof of the REMAC in any matter that seeks suspension or revocation of privileges shall be "Preponderance of Evidence." Preponderance of Evidence shall be defined as "the existence of the fact being more probable than its non-existence." In all other matters, the burden of proof shall be "Substantial Evidence." Substantial evidence shall be defined as "such relevant proof as a reasonable mind may accept as adequate to support a conclusion or ultimate fact."

The REMAC may make a referral to the New York State Department of Health, Bureau of EMS and Trauma Systems, local law enforcement agencies and/or the NYS DOH Bureau of Narcotic Enforcement (BNE).

Step 6: Adverse event reporting systems

1. All cases, including all root causes determined by review, may be submitted to external databases which will allow identification of trends and (anonymous) sharing of information in order to minimize the chance of reoccurrence. No provider or patient identifiers will be included.
2. When punitive actions are recommended by the Patient Safety Committee, but the involved provider's agency uses an adverse event reporting system with an immunity clause, the Committee recommendations will honor the immunity from punitive action under the contracted terms if the following conditions are met: 1) the provider meets criteria of the contract and 2) the event was reported to the adverse event system prior to being reported to the Patient Safety Committee.

Step 7: Notification of Actions

If the event investigation results in any actions, whether they are consoling, coaching, or counseling, the PS Coordinator will call the relevant individuals and agencies the first business day after it is finalized. If there is a loss of privileges, the appropriate agency medical director(s) will also be called.

A letter will also be emailed to all parties outlining the actions taken within 2 business days. The email will ask for verification of receipt and if not received within 3 business days, a copy of the letter will be mailed via certified US Mail, return receipt requested.

Step 8: Appeals Process

Any provider shall have the right to appeal a Patient Safety Committee decision or REMAC decision. The appeal must be received in writing by the REMAC Chair within 30 business days of the decision. The REMAC will hear the appeal (in executive session) within 60 business days of the date the appeal request was received. A quorum of voting members must be present. Non-voting members will also have the opportunity to be present and will contribute to the discussion and may give input to the voting members. Patient Safety Committee members who are not part of REMAC may also be present.

The provider may request in writing to have documentation sent to them for their appeal. Documents may only be sent to the provider and not to any third parties. Documents that may be requested include:

a. A copy of the initial letter, notifying the provider of the referral;
b. A copy of the final letter, notifying the provider of the REMAC decision;
c. A copy of the summary of the interview with the Patient Safety Committee;
d. The causal diagram;
e. The event investigation summary from the Committee review.

As an education-based process, attorneys are not allowed to participate. During the appeals process the provider shall have the right to bring another individual if they feel they need support, but only the provider may address the REMAC and/or appeals committee. If the provider insists on their attorney's presence, they will be advised that the presence of an attorney may make the results of such proceedings discoverable.

If the provider wishes to appeal the REMAC appeals decision, the provider has the right to appeal to the State Emergency Services Advisory Committee (SEMAC) as state policy provides as outlined in Article 30 of the PHL (3004a-4).

Providers No Longer in the MLREMS System

If an EMS provider leaves the Region or if an EMS provider is no longer affiliated with an agency in the Region, the case will remain open at the Regional level in the event the provider returns to the Region to allow for completion of the event investigation or actions required. In addition, a letter will be sent to the local NYS DOH BEMSAT representative informing them of the existence of an open case within this Region that we are unable to act upon due to jurisdictional issues.

X. OTHER CONSIDERATIONS

Requesting Event Investigation Documents

Only a limited number of documents can be requested, and for the documents to be released the requesting party must have a compelling reason. Generally, documents are not released in order to

ensure their continued confidentiality and integrity under the New York State Quality Assurance regulations.

If a provider changes agencies, they can request, in writing, a copy of the final event investigation letter detailing the actions taken. This request must have the name of the agency quality assurance leader to whom the letter is to be sent to. The letter will be sent directly to the new agency.

Closing / Trend Tracking

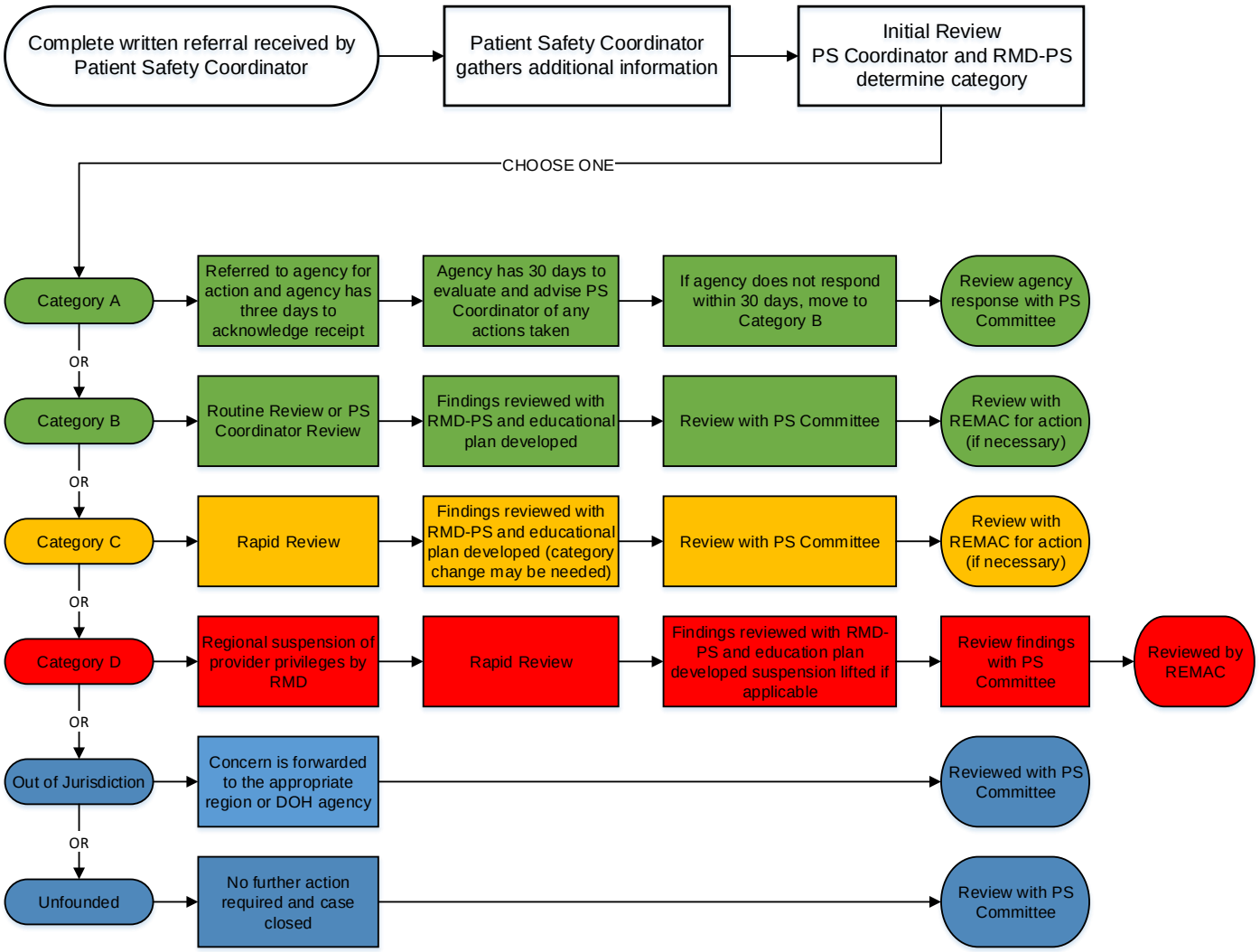
1. A case is closed once all the paperwork is complete and the Patient Safety Committee is given a final report by the PS Coordinator. Copies of all documentation are kept in the event investigation file.
2. Each event is categorized into one of the following:
    a. Unfounded
    b. Out of Region
    c. State Reportable
    d. Operational Issue
        i. Response
        ii. Chart Lock Times
        iii. Policy/Procedure
    e. Clinical Issue
        i. Protocol Deviation
        ii. Medication Error
        iii. Hospital Destination
        iv. Refusals
        v. Other
3. Trends will be followed to help determine topics for regional lectures and continuing education.
4. Depending on the findings, the Patient Safety Committee or the RMD-QPS may decide that it is both appropriate and beneficial to provide feedback to the party that made the initial referral.

XI. INVESTIGATION CONSIDERATIONS

1. Have two team members interview key individuals;
2. Interview all applicable parties, including the individual that has submitted the case.
3. Write a summary of the interview and provide it to the key individuals so that they can document their agreement with the summary or request revisions to the summary;

- This summary should be completed at or as soon as possible following the interview, to encourage freshest recollection of all parties.
- If there is a discrepancy between what the interviewed person recalls, and what the interviewers recall, from the discussion, both versions should be documented and attributed appropriately based on the potential for recall bias.

4. The provider should be interviewed first; consider interviewing the provider again at the end of the investigation if there are additional questions or concerns;
5. Interviews should not be recorded electronically (audio or video).


Complete written referral received by Patient Safety Coordinator
Patient Safety Coordinator gathers additional information
Initial Review PS Coordinator and RMD-PS determine category
CHOOSE ONE
Category A
Referred to agency for action and agency has three days to acknowledge receipt
Agency has 30 days to evaluate and advise PS Coordinator of any actions taken
If agency does not respond within 30 days, move to Category B
Review agency response with PS Committee
OR
Category B
Routine Review or PS Coordinator Review
Findings reviewed with RMD-PS and educational plan developed
Review with PS Committee
Review with REMAC for action (if necessary)
OR
Category C
Rapid Review
Findings reviewed with RMD-PS and educational plan developed (category change may be needed)
Review with PS Committee
Review with REMAC for action (if necessary)
OR
Category D
Regional suspension of provider privileges by RMD
Rapid Review
Findings reviewed with RMD-PS and education plan developed suspension lifted if applicable
Review findings with PS Committee
Reviewed by REMAC
OR
Out of Jurisdiction
Concern is forwarded to the appropriate region or DOH agency
Reviewed with PS Committee
OR
Unfounded
No further action required and case closed
Review with PS Committee

APPENDIX

A. Agency Event Investigation Form
B. Case Review Template