# This is Study Guide 1 of Medical Errors Course 2M

**Offered Online by CEU By Net – Pendragon Assoc. Online LLC**

## Risk Management of Medical Errors in Behavioral Health Programs: How to Identify, Evaluate, Correct, Monitor, and Prevent Recurrence.

***Introduction to This Course*:** This Continuing Education course - Course 2M, Risk Management of Medical Errors - is offered online by CEU By Net, LLC for licensed Behavioral Health professionals. The content of the course is a compendium of currently published materials and references pertaining to the nature and management of Medical Errors, including definitions and excerpts from Joint Commission's 2021 Comprehensive Accreditation Manual for Behavioral Health Care; a 2019 publication of the Agency for Healthcare Research and Quality – AHRQ – a division of the US Department of Health and Human Service; and the British Journal of Pharmacology published in the public domain by the National Center for Biotechnology Information. U.S. National Library of Medicine, National Institute of Health; and from material written and published by Marsha Naylor, MA, LPC, owner of CEU By Net LLC.

This course has two Study Guides (or 'chapters'), and each Study Guide has a quiz. Both quizzes must be passed to download a certificate of completion for Course 2M.

Joint Commission (JC) accredits behavioral health treatment programs, including hospitals and other 24-hour treatment settings and some community-based mental health and addiction treatment programs. The *Agency for Healthcare Research and Quality* – AHRQ – is an internationally recognized division of the United States Government which is dedicated to the quality and safety of behavioral health and physical medicine.

Study Guide 1, written by Marsha Watson Naylor, MA, LPC, includes excerpts from CEU By Net's online continuing education course entitled *Essentials of Risk Management*

---

**As commonly defined, Medical Errors are "*human errors or mistakes* committed by healthcare professionals which *did result* or *could have* resulted in harm to a patient."**

In Behavioral Health Programs, *Medical Errors* include human errors or mistakes including these:

- assessment and diagnosis (Diagnostic Errors),
- the prescribing, dispensing, or administration of drugs and other medications (Medication Errors),
- the performance of or misuse of therapeutic procedures,
- the healthcare professional's compliance with program policies and procedures pertaining to the delivery of behavioral health care,
- the use of equipment,
- *or any other action – or failure to act* – which *could have* resulted *or did result* in harm to a patient or client.

***Patient Safety Events (PSEs)*** are any incident, event, action, situation, systemic or equipment malfunction, or other circumstance that *could* have resulted or *did* result in harm to a patient or client. 'Medical Errors' – such as those listed above – are a type of Patient Safety Event (PSE) which is the result of *human errors or mistakes* in the delivery of health care, which did or could have resulted in harm to a patient.

Medical Errors are always a PSE, but PSEs are not always due to Medical Error. And sometimes, an event which potentially harms a patient is a mixture of *human error* and *non-human* error or systemic malfunction. *[2020 Joint Commission E-dition Release, Comprehensive Accreditation Manual for Behavioral Health Care Update Service, now included in the January 1, 2021 Standards.]*

In addition to Medical Errors, PSEs can include events such as fires at a facility, breakdown or malfunction of equipment, automobile accidents while transporting a patient, lack of procedural clarity resulting in unintended harm to a patient, intentional or unintentional violation of rules and regulations which result in legal or regulatory penalties depriving clients of access to services, and other such incidents.

When a Critical or Adverse Patient Safety Event does occur, managers and administrators may *hope or assume* that the event was the result of something *other than* a human error (Medical Error) or a system design issue. Initial reactions may be that the cause was surely an unanticipated breakdown of equipment or technology or was an unpreventable or unexpected clinical outcome or other such random event.

However, to cling to such assumptions is inherently problematic, if our goal is to prevent a recurrence of the harm which *was experienced* or *could have been* experienced by the individual.

In the Risk Management Review of the PSE, we must consider the possibility that a human mistake or error was a cause or a contributing factor in the event, and further, that a system or programmatic flaw or 'workplace culture' issue may have set the stage for human error. *Workplace culture* is a collection of attitudes, beliefs and behaviors that make up the regular atmosphere in a work environment**.**

- Our Risk Management analysis of causative or contributing factors, therefore, must include a focused effort to identify and correct not only human mistakes or errors, but also any system or organizational culture issues which may have contributed to the *potential* for human error. This is commonly referred to as the Systems Approach to Medical Error. Study Guide 2 explores the Systems Approach in some detail.

**Overview of the Risk Management Process.** How is corrective analysis of Medical Errors accomplished in a Behavioral Health treatment program? The process is referred to by Joint Commission as 'Comprehensive Systematic Analyses and Corrective Action Planning'*. In this course and in AHRQ publications and many community-based programs, the process is referred to as 'Retrospective Risk Management Review or simply 'Retrospective Review and Corrective Action'.*

***Retrospective Review*** *is the formal procedure of* looking 'backward' or 'retrospectively' following a Patient Safety Event, to determine the circumstances, actions, or inactions which did contribute or could have contributed to the PSE, including any human errors or systemic or organizational culture issues that were a factor in the event.

- Particularly in Sentinel or Critical Events/Incidents, research has shown that when Human Errors (Medical Errors) result in patient harm, it is rarely simply a matter of failings on the part of individual providers, reflecting inadequate knowledge or skill. [*Agency for Healthcare Research and Quality – AHRQ – a division of the US Department of Health andHuman Services, Sept 2019]*

Research performed by British psychologist James Reason in multiple industries including health care found *that catastrophic safety failures are almost never caused by isolated errors committed by individuals*. "Instead, most accidents result from multiple, smaller errors in environments and serious underlying system flaws [that] *reflect predictable human* failings in the context of poorly designed systems." [*AHRQ*, *Sept 2019].*

In other words, Patient Safety Events are often due to a *combination* of system or program design flaws and human Medical Errors – with the faulty design setting the stage for, and increasing the likelihood of, human mistakes.

The GOALS of Retrospective Review of a Patient Safety Event are these, as delineated by Joint Commission in its 2021 standards for Behavioral Health program operation:

- To have a positive impact on improving care, treatment, or services and in preventing unintended harm.
- To focus the attention of an organization that has experienced a sentinel [critical] event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or workplace culture), and on changing the organization's culture, systems, and processes to reduce the probability of such an event in the future.
- To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention.
- To maintain the confidence of the public, clinicians, and organizations that the safety of individuals is a priority within the organization.

## Details of Risk Management Planning (RMP) to Prevent and Correct Medical Errors

In any responsible behavioral health program, there should be an ongoing, functional Risk Management Plan (RMP) in place to *identify* and *prevent* Medical (Human) Errors which have a high probability of occurring, and to identify and correct any faulty program or system design issues which could contribute to or increase the potential for occurrence. This is the 'prospective' piece of the Risk Management Plan.

Likewise, when Medical Errors and system breakdowns do occur, staff and administrators must analyze every aspect of the event to determine what CAUSED or CONTRIBUTED, or may have caused or contributed to, the occurrence of the event. Based on findings of this exploration, the program develops a strategic plan to correct the issues and prevent recurrence. This is the "retrospective" aspect of the Risk Management Plan.

The foci of these retrospective explorations are referred to as Sentinel (Critical) Events and Adverse Events. The set of goals and procedures with which to implement both PROSPECTIVE and RETROSPECTIVE Risk Management Review is referred to as 'The Risk Management Plan (RMP).'

RMPs seek to *prevent* Critical and Adverse Incidents which are a threat not only to our patients and clients, but also to our legal, professional, and financial safety. When a Critical or Adverse Incident occurs, the RMP seeks to identify and correct the issues or problems which either CAUSED the event or CONTRIBUTED to it – thereby PREVENTING RECURRENCE.

***Inherent Risk and Prospective Risk Management Planning.*** At the front end of the Risk Management process, the first order of business is to identify INHERENT RISKS in the treatment process. Specifically, the staff and management identify and anticipate Critical and Adverse Medical Error Incidents which are *unique to or inherent in the workplace*, which have a significant potential for occurring given the nature of the work and the population served. The RM Plan to PREVENT these events from occurring is then developed. This is the PROSPECTIVE Risk Management Plan – i.e., a Prevention Plan. Prospective RM Plans answer the question, "Now, what can go wrong here?" and seek to prevent the potential Critical or Adverse Incident.

'INHERENT RISK' is risk which is closely associated with the type of program we are operating and the type of clients we serve – and it's invariably present even if the organization is following a good set of Policies and Procedures. The inherent risk for Medical Errors in a Supported Housing program is different than the inherent risk in a 24-hour Crisis Stabilization Unit or a Detox facility.

Does the risk apply primarily to *Medication* Errors? No. Professionals often think that the term Medical Errors is limited to MEDICATION errors. This is a misconception. Medical Errors cover a broad field of human mistakes that can occur in the delivery of medical care. How we implement <u>any part</u> of a treatment plan or an intervention with a client is subject to error – including how we respond to the behavior of clients. The potential for human error extends far beyond the prescribing, dispensing, and administration of medication. [The second part of Study Guide 2 specifically addresses Medication Errors.]

Furthermore, when developing a Risk Management Plan, we must also include consideration of the 'SPIN-OFF RISK' that occurs due to Medical Errors, i.e., those errors which can result in loss

of the availability of programming to serve our clients. This type of risk pertains to loss of the legal permissions and resources to deliver programming to clients because of human errors and administrative missteps which have occurred in the delivery of care.

Examples of spin-off risk include allegations of professional negligence, workforce crises, and violation of critical rules and regulations applying to the delivery of treatment services. Other examples – lack of a fire safety plan or an equipment maintenance program which results in HARM to patients, the loss of licenses and certification, cancellation or reduction in our contractual arrangements, reduction of reimbursement for services, and damage to our community reputation due to such events.

A quick summary thus far: The RMP details the procedures for conducting two types of Risk Management Review:

- *Prospective RM Review.* The RM team does a broad, front-end overview of the program to identify high-priority issues which present the greatest risk that something will 'go wrong.' The Prospective RM Review includes, but is not limited to, identification of issues that have been a recent or past focus or concern of a regulatory agency or contractor, or upon which the continuation of program services depends, as well as conditions or procedures about which staff and management have been known to say, "It's an accident waiting to happen."

- *Retrospective RM Review.* The RM team performs a detailed retrospective analysis of all Patient Safety Events (PSE) which occur within the program, to identify and correct Causative Factors or Contributing Factors which *could* have resulted, or *did* result, in harm to a patient or client. The Causative and/or Contributing Factors *may or may not* include [Human] Medical Error or mistakes. However, when a Medical (Human) Error does occur, there is frequently a 'system' or 'workplace culture' issue which has increased the likelihood of human mistakes occurring.

## Issues of Severity: Sentinel Events vs. Adverse Events

Patient Safety Events (PSEs) – including those involving Medical Errors – occur with various degrees of severity. PSEs range from the most serious events (Sentinel events, a.k.a. Critical Incidents which involve major HARM up to and including death), to less-than-Sentinel events (Adverse Events) which have resulted in HARM, but which do not meet the criteria for a Sentinel or Critical event. PSEs also include NO-HARM events, close calls, and hazardous conditions. [Refer to Box 3 below, from Joint Commission's E-dition January 1, 2020 Release, Comprehensive Accreditation Manual for Behavioral Health Care Update Service.]

The Joint Commission's standards for defining, preventing, and correcting Patient Safety Events serve as a good foundation for understanding the types of PSEs which require careful consideration.

See Boxes 1 and 2 on the following pages, for the definition of Joint Commission's two most significant levels of Patient Safety Event – *Sentinel Events* [typically referred to as *'Critical Incidents'* in community-based programs] and *Adverse Events*. Both levels may include Medical Errors.

**BOX 1 - Sentinel Events [a.k.a. Critical Incidents]**

"A Sentinel Event is a Patient Safety Event (not primarily related to the natural course of an illness or underlying condition of an individual) . . .that results in any of the following:

Death

Permanent Harm

Severe Temporary Harm

In behavioral health, an event is also considered *sentinel* if it is: Suicide of any individual served who is receiving care, treatment, or services in a staffed around-the-clock care setting *or within 72 hours of discharge from such care,* including from the organization's emergency department (ED)."

Joint Commission's *E-dition January* 1, 2020 *Release, ComprehensiveAccreditation Manual for Behavioral Health Care Update Service.*

## BOX 2 – Adverse Events

Joint Commission includes as 'Adverse Events' those patient or safety events that result in HARM, but the events do not meet JC's criteria of Sentinel or Critical events [death, permanent harm, or severe temporary harm]. All significant patient injuries which require assessment and remedial treatment by a medical professional are classified as an Adverse Event – including such Medical Errors as failure to monitor a patient with mobility problems who then slips and falls, sustaining a broken hip, incorrect connection of an IV line which results in an embolism, missed or duplicated medication dosage with negative results, etc.. Adverse Events may also include unanticipated situations which are <u>not</u> due to Medical Error, such as spontaneous mechanical breakdowns resulting in patient harm.

*In community-based* Risk Management programs, we may define <u>Adverse Events</u> somewhat differently: The event *may or may not result in physical harm* requiring acute medical care remediation, *but it may pose potential risk* to patient safety or to the effectiveness of care or may result in disruption of program operation if not corrected. We DO NOT allow such events to occur without a Retrospective Review.

Specifically, Community Programs are advised to classify a broader range of actions or inactions as 'Adverse Events' – including medication prescribing, dispensing, and administration errors *even when acute injury does not result*, as well as errors such as poorly designed self-medication programs which have resulted in confusion and inconsistent self-dosing of needed medication. Also of importance – inattention to contents of medical records, lapses in confidentiality, etc..

A frequent precipitant of Adverse Events in community programs is the *failure of physicians or staff to enter important information about the client or his treatment in the treatment record, or the failure to read such notations which call for action.* Such events of 'omission' can result in inadequate oversight or supervision or failure to modify a treatment regimen; failure to make a change from one medication to another when needed; elopement of a client from a residential or day treatment program; suicide of a client; or failure of staff to make needed changes in a treatment plan [a major factor in terms of determining negligence.]

In community programs, we may also define an 'Adverse Event' as significant disruption of program operation; or damage to the program's reputation by publication of an editorial in the local newspaper about an event in the program; or a program event which has a negative impact upon the credentialing or contractual status of the organization; or monetary loss of various kinds due to failure to meet a specified deadline, and another such events that have implications for the safety of clients and the continuity of the programs which serve them.

In all such situations, <u>*Retrospective Risk Management Review*</u> must be conducted to identify Causative or Contributing Factors which *could* or *did result* in the Adverse Event. These factors may or may not have involved human error; they may have been due to system failure.

In Box 1, note that Joint Commission defines suicide and the serious harm of a patient (including harm caused by Medical Errors) as a **Sentinel Event** IF the event occurs *within 72 hours* of discharge from a 24-hour care facility or ER. JC's short timeframe is set to provide a limited 'window' for defining Sentinel Events which must be formally reported to JC and investigated according to specific post-event requirements. It is not intended to minimize the seriousness of a suicide or serious harm to patients, no matter the timeframe following discharge from a facility.

*However, community-based treatment programs should define, as a '* Sentinel Event' *(a.k.a.,* ***Critical Incident),*** *ALL suicide and serious harm of clients who are participating in a treatment program – thus, to ensure that a detailed Retrospective RM Review is done.*

ALL suicides and serious harm to clients which occur in the context of a community-based treatment program are in fact 'Sentinel' or 'Critical' events, in terms of liability and regulatory considerations. We *must not limit* our focused attention only to events which occur within 72 hours following discharge from a more intensive level of care. Why is that? Because community-based programs are inherently charged with responsibility for the *ongoing* wellbeing and safety of our clients outside the four walls of a 24-hour treatment facility – including those patients who have not been served in an inpatient or detox or other residential facility.

The bottom line: In community-based Risk Management programs, ANY suicide or serious harm of either a patient or staff member which occurs in the context of a behavioral health treatment program is considered a **Critical Incident** – and as such, is *reportable and actionable.*

- This means that the event must be reported to contractors and licensing authorities and must be thoroughly evaluated according to a defined internal Risk Management Review procedure. The Risk Management process searches for the potential presence of a CAUSATIVE or CONTRIBUTING factor,including human Medical Error as well as flaws in the patient care system or organizational culture.

**NOTE:** Careful post-event assessment (a.k.a., Retrospective Review) can yield surprising underlying issues which require remediation. It is a fact that staff and administrators are often taken aback and unhappily surprised when a Medical Error (a human factor) is identified as a Causative or Contributing Factor during a Risk Management Review. [This author was once asked to leave the facility by an angry administrator when he was presented with a consultative conclusion that a Medical Error appeared to be a causative or contributing factor in a suicide death of a client.]

- Understanding at the front end that there is a potential for RM reviews to uncover previously unrecognized Causative or Contributing Factors will not only reduce the possibility that a problem may be overlooked, but also prepares management for action when needed.

Joint Commission surveyors are famously noted for a moto that is recognized by all accredited facilities: *'Every problem that is identified through a Risk Management or Quality Management Plan is an opportunity for improvement.'*

Further, some JC surveyors have also embraced the moto:

*'Your worst day is an Opportunity for Improvement.'*

Such 'opportunities for improvement' include the opportunity to engage in comprehensive analysis, to identify unrecognized risk issues, to plan and implement corrective actions, to review and sustain progress, and to improve the care we deliver to our patients and clients.

In Retrospective Review, we also attempt to determine if the event was PREVENTABLE. This type of assessment is important in the development of a Corrective Action Plan and in the prevention of recurrence. There are three categories which are to be considered here:

- Preventable critical and adverse events: Those that are due to error or failure to apply an accepted strategy for *prevention* [i.e., failure to take preventative action which is recognized as the Prevailing Standard of Care in the behavioral health field]

- Ameliorable critical and adverse events: Events that, while not preventable, could have been less harmful if care had been different

- Critical and adverse events due to negligence: Those events due to care that falls below the standards expected of clinicians in the community and in the profession, i.e., the PREVAILING STANDARD OF CARE. [In legal proceedings, the question of whether the actions of medical personnel were consistent with the Prevailing Standard of Care becomes *the most critical issue in determining liability*.]

## Close Calls, No-Harm Events, and Hazardous Conditions

Joint Commission identifies a third category of actionable event – those events which have not resulted in harm, but which present potentially serious consequences. These situations are identified as Close Calls, No-Harm [but potentially harmful] Events, and Hazardous Conditions. Although harm was averted, action must be taken to prevent the situation from becoming a Patient Safety Event with critical or serious consequences. See Box 3 for a view of this perspective, in a quotation from Joint Commission.

**BOX 3 - No-Harm Events, Close Calls, And Hazardous Conditions**

"No-harm events, close calls, and hazardous conditions are tracked and used as opportunities to prevent harm, in accordance with the organization's process for respondingto patient safety events . . . The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as close calls ['near misses'] or good catches) to hazardous conditions, adverse events, and sentinel events . . .

No-harm events, close calls, and hazardous conditions are tracked and used as OPPORTUNITIES to prevent harm, in accordance with the organization's process for respondingto patient safety events . . . Such opportunities include comprehensive analysis, risk identification, and corrective action, implementation and sustainment."

Joint Commission's *E-dition January 1, 2020 Release, Comprehensive Accreditation Manual for Behavioral Health Care Update Service.*

As it pertains to Box 3, In behavioral health programs, recall that we engage in ***Prospective*** Risk Management Review and Planning in the *prevention* of Medical Errors. This type of RM review often identifies events and situations which are of the 'close call' or 'no-harm' or 'hazardous condition' variety.

As an analogy, we don't wait for the 'train to jump the track.' We regularly review the condition of the track, identify any issues which have the potential to cause a significant, harmful event, and make currently needed adjustments and anticipatory upgrades in identified conditions.

For example, we review the instructions for self-medication which we provide to our clients, to ensure that the instructions are not confusing or may result in double dosing of medication, and similar issues. *This is anticipatory risk management*. It is PROSPECTIVE Risk Management. The desired outcome is PREVENTION of medical and other programmatic errors.

## Risk Management of Medical Errors Is MORE Than Just Policies and Procedures!

Despite the international growth of Risk Management programs, there are still many managers and senior employees who have difficulty with the concept of a formal Risk Management program. The three primary questions are:

- Why do we need an additional layer of managerial responsibility?
- Isn't it a bad thing to document our failures?
- Aren't Policies and Procedures enough to protect us?

If you work in this field long enough, you know that despite a comprehensive set of Policies and Procedures, Critical Incidents CAN and DO occur – and it's not something we can hide by failure to document. Policies and Procedures *are not sufficient* to prevent Critical Incidents in mental health and addiction treatment programs.

When a Critical Incident occurs – aside from the need to carefully address emotional responses to theevent within the organization and with any affected family members – we must recognize it as an Opportunity for Improvement, i.e., to *identify* the Causative and Contributing Factors, develop a *plan of correction*, and *reduce the risk* of it happening again.

### *What is the essential difference between 'Policies & Procedures' and 'Risk Management Plans?'*

- First, note that Policies & Procedures (P & Ps) are primarily 'upbeat' and present t he picture that *everything is expected to 'go as planned.'* P & Ps are the 'broad stroke' of organizational operation – hitting the high points of normal operation and routine safety plans – serving as the key requirements of contract and regulatory compliance. P & Ps focus upon how things are expected to be. P & Ps do not focus upon 'what can go wrong.'
- Risk Management Plans (RMPs), on the other hand, take the attitude that there is no such thing as 'going as planned' – that certain things can and do go wrong and can cause great damage to the organization from a legal, professional, and financial perspective.

- The FOCUS of Risk Management is identification of potential and actual PROBLEMS –procedures which are NOT 'going as planned' or could potentially 'jump the track.'

- The RM process develops strategies for PREVENTION of problems and IMMEDIATE CORRECTION of things that go seriously wrong – i.e., prevention of the problems that are inherent in the workplace, and correction of those which have 'jumped the track.'

- Policies & Procedures are predominantly 'absolute' – 'It IS this way.' However, Risk Management is always looking ahead and behind to monitor how things are *actually* functioning in the light of day – recognizing that things can and do go seriously wrong.

- *Prospective* Risk Management Plans focus upon control of the vulnerabilities that are inherent in the workplace – as if to say, *"We know that this event has a high potential to 'go wrong' and we are determined to prevent it."*

- *Retrospective* Risk Management Reviews serve to address those Critical or Adverse Incidents that have *already occurred* – focusing upon WHAT happened, WHY it happened, and HOW can we fix it? What can we do differently to *prevent a recurrence* (i.e., what improvements can we put into place)?

- Retrospective RM Reviews look closely at whether the Policies and Procedures have been violated, including the requirement to train employees and document the training. Were the Policies & Procedures insufficient or 'off target' in the first place? Was something missing? Do we need to modify our P & Ps? This is, therefore, an OPPORTUNITY for IMPROVEMENT.

End of Study Guide 1 of Course 2M

Author: This portion of Medical Errors Course 2M (Study Guide 1) is authored and copyrighted by Marsha Watson Naylor, MA, LPC – CEU By Net LLC. Ms. Naylor is the owner of *CEU By Net - Pendragon Assoc. Online LLC*, in Austin, TX. She is a former Assistant Deputy Commissioner for Texas Department of MHMR, with twenty-five years' experience in program operation and administration in the mental health and addiction fields, for inpatient and outpatient Mental Health and Addiction services, at the state and local level. Additionally, Naylor served for fifteen years as a national level consultant to multiple entities including Behavioral Health Provider Networks, the Managed Care Industry, State Agencies, Legislators and Advocacy groups, the Annie E. Casey Foundation, the Center for Health Care Strategies, and other mental health and addiction organizations.

**This is the END of Study Guide 1, of Medical Errors Course 2M. You may take the quiz for this study guide now, or you can move on to Study Guide 2 of this course, which also has one quiz. You must pass the quizzes for both Study Guide 1 and Study Guide 2, plus complete and submit the Feedback Form, to download your CE Certificate for Course 2M. Return to your My Home Page to access the links to quizzes.**

**Cheers!**
**CEU By Net LLC**