

April 7, 1995

1. Transmitted is a revision of the Department of Veterans Affairs, Veterans Health Administration Manual M -2 "Clinical Affairs," Part I, "General," Chapter 35, "Integrated Risk Management Program (IRMP)," formerly named "PIR (Patient Incident Review)."

2. The principal purpose of Chapter 35 is to provide guidance to the medical centers on the development of an IRMP, as part of the Quality Management and/or Risk Management Program. This revision reduces the medical centers' reporting requirements.

3. Filing Instructions

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35B-1 through 35B-4
35C-1
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35E-1 through 35E-2
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Insert Pages

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35B-1
35C-1 through 35C-9

4. **RESCISSIONS:** M-2, Part I, Chapter 35, dated August 7, 1992, and changes 1 and 2; VHA Directives: 10-92-105 and Supplement 1, 10-93-004, 10-93-009, 10-93-130, and 10-93-136.

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Under Secretary for Health

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RESCISSIONS

The following material is rescinded:

1. COMPLETE RESCISSIONS

a. Manuals

Par. 112f, M10-3.

Pars. 129f and 169, M10-6.

M-2, Part I, changes 2 through 5 through 9, 11, 12, 13, 14, 16, 18 through 21, 25, 30, 32 through 40, 41, 44, 45, 49, 50, 51, 52, 55, 57, 60.

VHA Supplement MP-1, Part I, Chapter 2, Section A and Appendices D and E, change 43, dated October 27, 1987 (Effective October 1, 1992).

VHA Supplement MP-1, Part I, Chapter 2, Section A, change 44, dated July 26, 1991 (Effective October 1, 1992).

M-2, Part I, Chapter 35, dated August 7, 1992 and Supplements 1 and 2.

b. Interim Issues

II 10-156

II 10-161

II 10-184

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II 10-270

II 10-292, pars. I, II, III, App. A

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II 10-381

II 10-68-31

II 10-71-33

II 10-71-26 by M-2, part I, chg. 67

II 10-82-53 de facto by chg. 74

II 10-83-7 by chg. 74

c. Circulars/Directives

261, 1946, Sec.1

10-62-70

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c. **Circulars/Directives** Continued

- 10-92-105 and Supplement 1
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- 10-93-151

d. **Regulations and Procedure**

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e. **Technical Bulletins**

- Par. 2, TB 10A-191
- Pars. 1b, 2 through 5, 6a and 9c, TB 10A-246
- TB 10A-256
- TB 10A-295 (except sec. XXI)
- TB 10A-359
- TB 10A-324 (This completes the rescission of TB 10A-324.)

f. **AB Station Letters and Other Communications**

<u>Date</u>	<u>Subject</u>
December 5, 1949	Officer of the Day Reports
March 3, 1952	Furnishing of Meals to Officers of the Day
April 8 1952	Domiciliary Care for Paraplegics
April 16 1952	Transfer of Quadriplegic Patients
April 17, 1952	Accomplishment of Recheck Examinations and Treatment of current Conditions Involving Paraplegics at VA Hospitals Other Than Paraplegia Centers.
June 23, 1952	Monthly Report of Service-Connected Blinded Veterans and Blinded Military Personnel
August 18, 1952	Proposals for Membership, American College of Physicians
September 19, 1952	Establishment of Paraplegia Organizational Segment
January 4, 1954	Certificate of Medical Feasibility, VA Form 4555b

g. **Instructions (pertaining to Public Law 702, 80th Congress, as amended)**

- Pars. 2d and 2e, Inst. 1-B
- Inst. 1C
- Inst. 1-D

2. **LIMITED RESCISSIONS**

The following material is rescinded insofar as it pertains to this manual.

a. **Manuals**

- M10-3, par. 115h

a. Manuals - Continued

M10-6, pars. 9b, 42e, 70c, 86, and 132h
M10-11, pars. 22b, 92e, 96d, 133b, and 172

b. Circulars

10-65-57, pars.2 and 3

c. Regulations and Procedure

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d. Technical Bulletins

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RESCISSIONS

The following material is rescinded:

1. Manuals

M- 2, Part I, Chapter 35, dated August 7, 1992, and changes 1 & 2.

2. VHA Directives

10-92-105 and Supplement No. 1

10-93-004

10-93-009

10-93-130

10-93-136

CHAPTER 35. INTEGRATED RISK MANAGEMENT PROGRAM (IRMP)**35.01 PURPOSE**

The purpose of the Integrated Risk Management Program (IRMP) is to:

- a. Minimize the probability of adverse events (risk) to patients, personnel and visitors;
- b. Protect facilities' assets and prevent loss by accurately identifying, reporting, trending, reviewing and correcting problems leading to incidents, through risk identification and risk analysis; and
- c. Encourage medical centers to look at risk management as a medical center activity which includes both clinical and administrative services.

35.02 BACKGROUND

a. Risk management (RM) is a mechanism to monitor, identify, evaluate and correct actual or potentially harmful events that may have an adverse impact on the quality of care. Both the Veterans Health Administration (VHA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) identify risk management as an integral part of quality improvement activities. VHA has been active in risk management for many years. Two of VHA's many risk management programs are the Occurrence Screening Program (OS) and Patient Incident Review (PIR) Program.

b. In May of 1987, the General Accounting Office (GAO) recommended that the Department of Veterans Affairs (VA) medical centers be required to implement occurrence screening. This interest resulted in legislation enacted in May 1988, Public Law (Pub. L.) 100-322, Section 201. Along with expanding and assigning higher priority and greater resources to quality-assurance programs and activities at each medical center, this law required the implementation of the review known as "occurrence screening" throughout all VA medical centers. Patients' medical records are reviewed with the maximum use of the facility's computerized management information system for adverse events which are not the natural consequence of the patient's disease, injury, or treatment.

c. The OS Program was developed from the California Medical Insurance Feasibility Study in 1977, which reported that almost 5 percent of hospital admissions were associated with an adverse event that was potentially compensable. In the OS Program, cases are screened against a predetermined list of occurrences or criteria; those cases which involve one or more of the occurrences are reviewed to identify possible problems in patient care. Improvements in the following areas have been attributed to the OS program:

- (1) Education,
- (2) Policy and procedures,
- (3) Expansion of support services,
- (4) Establishment of specialty ambulatory care clinics,
- (5) Purchase of equipment, and
- (6) Development of clinical protocols for the management of care.

NOTE: *The OS Program was modified appropriately based on program evaluation results.*

d. The PIR Program has existed in all VA medical centers since the centralization of veterans health care in VA. In 1974, it became one of the initial programs included under the Quality Assurance umbrella.

Section 204(a) of Pub. L. 99-166, codified in Title 38 United States Code (U.S.C.) 7311, passed in 1985, required VA to establish a comprehensive Quality Assurance Program, of which PIR was a part. In the 1970's, PIR was a part of the Office of the Executive Assistant to the Chief Medical Director. In early 1980, VA transferred the program to the Office of the Medical Inspector. Lastly, in 1991, the program was transferred to the Office of the Associate Chief Medical Director for Quality Management.

e. The goal of the PIR Program is to identify opportunities for improvement in patient care by monitoring, reporting, analyzing, reviewing and investigating (if necessary) any unusual, unexpected or unfavorable incident involving a patient during the course of the patient's medical management. **NOTE:** *Improvements in processes and system issues have been attributed to the PIR Program.*

f. Both the OS and PIR Programs are automated and operate out of the VA's Decentralized Hospital Computerized Programs (DHCP). This allows VA to identify opportunities for improvements through local data analysis and national roll-up.

g. The Office of Quality Management has developed guidance to establish an IRMP that integrates many risk management activities, including: OS, PIR, Analysis of Tort Claim etc., to enhance the quality improvement and/or risk management (RM) processes. This program meets the requirements of Pub. L. 100-322, Section 201, and Pub. L. 99-166. It reduces mandated activity and allows medical centers the flexibility to tailor their program to meet individual facility needs, thus encouraging medical centers to design the program around those activities that provide the greatest opportunity for improving patient care. Duplication is avoided and resource utilization is maximized.

h. The integration of RM activities at the medical center is vital and can occur in a variety of ways. The use of data and information from RM activity outlined in this chapter along with other data and information identified by the medical center, should be integrated into the medical center's overall quality improvement processes to:

- (1) Improve the processes used in the delivery of patient care,
- (2) Facilitate management decisions based on the mission, goals and vision of the facility, and
- (3) Improve patient care.

NOTE: *Medical centers' RM activities should be carried out collaboratively and include representatives from all appropriate departments and services. Policies and procedures may be developed to address RM activities that cross cut a variety of departments and services.*

35.03 POLICY

a. It is VHA policy that an IRMP will be developed at each medical center. The program will analyze systematically collected data from all areas of risk management, which includes the PIR, OS, and tort claims, activities required by this chapter, plus any quality management and RM activities a medical center may choose to include. The data will be used to identify opportunities for improvement, identify areas or practices that could be the source of financial loss, and institute preventive or corrective procedures or protocols to avoid this risk. The program will monitor, investigate, report, and analyze events including significant sentinel events that are unusual, unexpected, and result in temporary or permanent disability or death or undue media attention.

35.04 OBJECTIVES

- a. At a minimum, the IRMP will:
- (1) Reflect on the facility's mission and vision;
 - (2) Systematically collect data;

- (3) Identify areas for possible improvement of existing processes;
 - (4) Identify areas or practices that could be the source of financial loss;
 - (5) Select specific high or substantial risk elements;
 - (6) Institute preventive or corrective procedures or protocols to avoid or minimize risk;
 - (7) Monitor, investigate, report and analyze events that are unusual, unexpected, and result in temporary or permanent disability or death ;
 - (8) Monitor certain sentinel events such as readmissions, to identify opportunities for improvement in the quality of care; and
 - (9) Conduct investigations.
- b. The data derived from all RM activities, including those in this chapter, will be aggregated and trended to support improvements in patient care, managerial decisions and operations, and performance improvement activities.
- c. The information management system will be used to compile data and provide for confidentiality, security, integrity, and adequate analysis of the data.
- d. Medical centers will trend data on all reportable events to identify opportunities for improvement, take the appropriate corrective actions for sentinel events as necessary, and ensure that identified improvements are carried out.
- e. Events will be reported as outlined in this chapter to reduce risk, improve processes, and develop and implement Comprehensive Education Programs.
- f. Medical centers must identify, report, and provide any necessary treatment for the patients involved.
- g. Medical centers should define and provide the necessary amount of training which would familiarize employees with their responsibility under IRMP.

NOTE: *Medical centers are not limited to the activities outlined in this chapter and may include any additional RM activities.*

35.05 MANDATORY REPORTABLE RISK EVENTS

Mandatory risk events will be reported by the medical center to the Regional Office, which will report them to the appropriate VA Central Office program office stated. When appropriate, the program office will be notified immediately; otherwise, the event will be reported to the program office when the case is closed by the regions. The following are described risk events with the stated appropriate program office.

a. Suicide

(1) Suicide is the voluntary act of taking one's own life. Cases in which patients commit suicide are reported if the patient is currently receiving inpatient or outpatient care or if the act occurs within 30 calendar days of a VA clinical encounter or visit. A psychological autopsy will be conducted on all cases and a physical autopsy will be performed where appropriate.

(2) Program Office: Mental Health and Behavioral Sciences Services (MH&BSS).

b. Suicide Attempt

(1) This includes a self destructive act requiring inpatient medical or surgical care and other behaviors which carry a high risk for severe injury or death and may require the provision of additional care to respond to the patient's needs. A suicide gesture is a self-destructive act which is manipulative or attention seeking and does not require inpatient medical or surgical care to prevent serious injury or death. Self-destructive acts or other behaviors will be evaluated by a psychiatrist to determine if the act or other behavior constitutes an attempt or gesture. Gestures are not reportable. Patients who attempt suicide are reported if they are currently receiving inpatient or outpatient care or if the act occurs within 30 calendar days of a VA clinical encounter or visit.

(2) Program Office: MH&BSS.

c. Patient Abuse

(1) Patient abuse includes acts against patients which involve physical, psychological, or verbal abuse. The "intent" to abuse is not a requirement for patient abuse. Patient's perception of how that patient was treated is an essential component of the determination as to whether a patient was abused. However, the fact that a patient has limited or no cognitive ability does not exclude the possibility that a patient was abused. The Chief of Staff (COS), or designee, will conduct a preliminary review of the event to determine if there is any suspicion of abuse. If patient abuse is suspected, an investigation will be conducted. All confirmed cases of patient abuse are to be reported. Incidents in which an individual(s) admits to abusing a patient(s) are reportable. In all confirmed cases of patient abuse the medical center Director, COS, service chief and other appropriate personnel will determine what corrective actions should be taken.

(2) Program Office: Regional Director's Office.

d. Missing Patient

(1) A missing patient is one who disappears from the patient care areas, (on VA property, when being transported by VA personnel for treatment) even if found, or returns on the patient's own. This situation constitutes a missing patient if: the patient has a court-appointed legal guardian; is considered a danger to self or other; is legally committed; or lacks cognitive ability to make decisions.

(2) Program Office: Regional Director's Office.

e. Homicide

(1) A homicide is the taking of a life of a patient or staff member, either accidentally or intentionally. Death of a VA patient, while an inpatient or an outpatient, which is not attributable to the course of the patient's disease or therapeutic misadventure, should be investigated. This includes homicides that occur on VA property in both inpatient and outpatient areas, while patients are being transported by VA personnel for treatment, patients out on pass, and those involved in VA recreational activities. These types of situations should immediately be reported to the region. VA Police will be notified and will investigate these events in conjunction with the Federal Bureau of Investigation (FBI), and other appropriate local law enforcement authorities. In situations where the homicide or the investigation takes place off of VA property VA police may interview individuals regarding this incident, but they may not exercise law enforcement authority.

(2) Program Offices: Director, Police and Security Service and MH&BSS.

f. Assault

(1) Unwanted and unconsented to physical contact, including contact of a sexual nature, constitutes an assault and are to be reported as follows:

(a) All sexual assaults, either attempted or completed, must be reported;

(b) Other physical contact that results in injury, including bruises or lacerations, must be reported;

- (c) Physical contact that results in no injury need not be reported.

NOTE: *Reportable assault are those that occur between patient to patient and patient to staff.*

- (2) Program Offices: Director, Police and Security Service and MH&BSS.

g. **Other**

(1) Any risk event resulting in serious harm or temporary or permanent disability. An injury that is disabling and/or disfiguring to a degree that the patient has any degree of temporary or permanently lessened function requiring intervention is reportable. This includes, but is not limited to, medication errors, adverse drug events, falls, unexpected occurrences. Medical centers should continue to report these incidents, where appropriate, through the Food and Drug Administration(FDA), Safe Medical Devices Act, and Surgical Package, etc. For example, an adverse drug event that results in death to a patient should be reported through the IRMP and to the FDA MedWatch Program.

- (2) Program Office: Clinical Programs

h. **Death (an OS Element)**

(1) Reportable deaths are those which occur in the operating room, in the recovery room during induction of anesthesia (including in procedure rooms), during or within 24 hours of a procedure (if determined to be related to a procedure). Also reportable are deaths due to equipment malfunction or during use of a medical device, misdiagnosis or failure to treat. This includes deaths reportable to and accepted by the medical examiner and deaths of patients who are on the medical center grounds, but not necessarily being treated at the time. These deaths are reportable if they occur in the inpatient, outpatient, or admitting area. The death of those patients admitted for palliative care and those designated Do Not Resuscitate (DNR) are not reportable, unless death is due to something other than the patient's illness.

- (2) Program Office: Clinical Programs

35.06 READMISSION A NON - REPORTABLE EVENT

- a. Readmission is an OS element.

b. The review of readmissions is mandated in this chapter but is not reportable. Medical centers will determine locally how readmissions will be monitored based on the following goals: improving patient care and reducing readmission rates. The current OS software package that allows for the enrollment of select diagnosis for the evaluation of readmission will continue to operate out of DHCP. The intent is to allow VA medical centers to continue moving from a case-by-case review of readmissions to a system oriented Continuous Quality Improvement (CQI) approach to process improvement.

35.07 SEVERITY OF INJURY LEVELS SCALE

A physician will assign one of the following severity levels to each reportable event on the VA Form 10-2633, Report of Special Incident Involving a Beneficiary.

- a. **Level 0.** No injury or disability.

b. **Level 1.** Minor (injuries are minor in nature, and if they do require any medical intervention, they do not extend the patient's hospital stay except for observation or to obtain laboratory and/or radiology results).

c. **Level 2.** Major (injuries which require medical or surgical intervention, increased hospital stay, or are disabling and/or disfiguring to a degree that the patient will have any degree of permanently lessened function or require surgical repair).

d. **Level 3.** Death.

35.08 INITIATING AND COMPLETING VA FORM 10-2633

a. Mandatory reportable risk events will be documented on VA Form 10-2633, without delay, and should include:

- (1) A brief summary of the incident,
- (2) Its effect on the patient's prognosis, and
- (3) The proposed plan for dealing with the sequelae and/or minimizing complication or future disability.

b. Regardless of position or discipline, the employee who witnesses or who is the first to become aware of the incident will initiate VA Form 10-2633. If the employee who first becomes aware of the incident is a non-clinical staff member, this employee will confer with the clinical staff who will fill out the information regarding diagnosis and other clinical information required for completion of the incident report form. **NOTE:** *This form is not used for incidents which only involve visitors or employees.* This reporting requirement applies to inpatients and outpatients under active treatment, including those in VA Nursing Home Care Units, Domiciliaries, and on admission from contract nursing homes.

c. The report will include a description of the incident, where it occurred, and pertinent factors such as the diagnosis, date of birth, mental status, medication taken by the patient within 24 hours of the incident and a medical evaluation. Only factual information is recorded on the incident report form. No admissions, accusations of fault or subjective opinion will be included. The physician responsible for the patient's care at the time of the incident should be notified immediately. During other than regular operating hours, this may be the Officer of the Day (OD).

d. After completion of Part I of VA Form 10-2633, the form will be given to the physician responsible for the patient's care at that time or the practitioner who examined the patient following the incident. The practitioner receiving the VA Form 10-2633 will record a brief statement of the findings of the evaluation in Part II of the form and rate the level of severity known at the time, based on the Severity of Injury Scale contained in this chapter. The COS, or designee, will review and sign all VA Form 10-2633's no later than 10 working days following the event or the discovery of the event. The medical center Director, or designee, will determine if the appropriate action plan has been developed, determine if a board of investigation will be conducted, and if so, appoint a board.

e. If a nurse practitioner or physician assistant examines the patient, the notes in the medical record and VA Form 10-2633 are to be co-signed by the physician supervisor.

f. Risk events occurring while an outpatient is physically on VA premises or when an inpatient is engaged in a VA sponsored activity, such as a recreation event or on pass, are reportable events.

g. Patients involved in an incident while being treated at another VA facility will be reported by the VA medical center providing treatment, e.g., a patient from VA (facility A) being transported daily to another VA (facility B) for radiation treatment, falls while getting off the table where the patient just received treatment and sustains a severe head injury. This incident would be reported by the treating facility, (facility B). Incidents involving a patient in transit between facilities are to be reported by the VA medical center having responsibility for that patient. The examining practitioner will fill out Part II of the VA Form 10-2633.

h. Incident reports will not be placed in the medical or the administrative sections of the patient's record. The event should be documented in the Progress Note and include what occurred, the results of the evaluation and any necessary treatment. The Progress Note should not be taken from the 10-2633, but should be derived independently. **NOTE:** *No mention of the 10-2633 should be made in the medical record.*

i. Once completed, all VA Form 10-2633's are to be filed so that they cannot be retrieved by personal identifiers such as name and/or Social Security Number (SSN). Medical centers may establish local policy to circulate the form through the appropriate service chief, quality manager, or others prior to delivery to the COS.

j. VA Form 10-2633 is protected under 38 U.S.C. Section 5705, Confidentiality of Quality Assurance Record, unless VA Form 10-2633 is generated based on the findings of a Board of Investigation. For example, a Board of Investigation is looking at an employee's misconduct and discovers during the course of the investigation that there was patient abuse. If an incident report is then completed, it would not be confidential. VA medical center personnel are to label the VA Form 10-2633 as "5705 protected."

k. Data from the VA Form 10-2633 will be entered into the DHCP data base. VA medical centers will analyze this data to identify patterns and trending which may not be detected by individual case review. A DHCP software patch will be developed for system-wide use in IRMP. This software patch will allow both local and national roll-up of the mandatory risk events outlined in this chapter. Until it is completed, it will be the responsibility of each facility to track and trend and report data according to this chapter and JCAHO standards. Data maintained in electronic form remain protected by 38 U.S.C. 5705 until it becomes aggregate data, if ever. Aggregate data are not protected by Section 5705. Facilities are to ensure that the data cannot be retrieved in an individually identified form by a personal identifier associated with the individual to whom the data pertains, such as a name or SSN.

l. Mandatory risk events will be reported immediately to the Regional Director's field office by, electronic mail message or facsimile. Reports of Boards of Investigation and other information relevant to the incident, e.g., VA Form 10-2633, Progress Notes, peer reviews, morbidity and mortality (M&M) reviews, autopsies etc., will be submitted within 45 calendar days of the date the medical center became aware of the incident (see App. 35A). The Region will notify and forward any required documents to the appropriate VA Central Office program office outlined in paragraph 35.05.

35.09 NOTIFICATION OF PATIENT AND FAMILY

When risk events as described occur, the medical center will inform the patient and/or the family, as appropriate, of the event, assure them that medical measures have been implemented, and that additional steps are being taken to minimize disability, death, inconvenience, or financial loss to the patient or family. The Office of District Counsel should be contacted prior to notification of the patient or family for guidance whenever appropriate. However, the patient and/or family should be notified promptly. District Counsel will advise the medical center Director about informing the patient and/or family of their right to file VA Form 21-526, Application for Compensation and Pension, as authorized by 38 U.S.C. 1151, or to file an administrative tort claim under 28 U.S.C. 2671 through 2680. All facts regarding the patient's condition, as well as notification to the patient or family, will be documented in the patient's Consolidated Health record (CHR).

35.10 EMPLOYEE AND VISITOR RISK EVENTS

a. Personal injury and illness sustained while in the performance of duty is compensable under the Federal Employee's Compensation Act (FECA). FECA is administered by the Office of Workers' Compensation Program (OWCP), U.S. Department of Labor. Employees who sustain an injury while on duty should report immediately to their supervisor and then to the employee health unit or their private physician for evaluation and treatment.

b. OWCP Form CA-1, Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation, or CA-2, Notice of Occupational Disease and Claim For Compensation, needs to be completed as soon as possible. VA Form 2162, Report of Occupational Injury or Illness, must be completed and a copy filed with the Safety Office. **NOTE:** *Facts about compensation for employees and other forms used to document these events are detailed in OWCP Pamphlet, CA-11.*

c. Visitors who are involved in an incident are evaluated and treated on a humanitarian basis at the medical center. VA Form 10-10 M, Medical Certificate, will be used in the evaluation of a visitor involved

in an incident. Other appropriate forms will be used to create a record of the event, e.g., progress notes, etc. A copy of VA Form 10-10 M and other forms used to record the events must be filed in the Safety Office.

35.11 INVESTIGATIONS

a. The medical center Director must convene a Board of Investigation in all cases where patient abuse is suspected and will determine whether to convene a Board of Investigation for other instances of reportable risk events. The Board will be appointed by the Director via a memorandum that identifies the:

- (1) Type of incident involved,
- (2) Scope of the investigation,
- (3) Size, composition and membership of the board, and
- (4) The time-frame for completion of the investigation.

b. The Board composition should have sufficient representation to ensure objectivity and peer representation. Individuals on the Board should not have direct involvement in the incident nor should they supervise the individual involved in the incident.

c. When an investigation is conducted, the Board will take testimony under oath. Testimony will be recorded, transcribed verbatim and signed by the testifier once transcribed. Any interviews or formal testimony of bargaining unit employees must be conducted in accordance with employees' rights to union and other representation which may arise under statute or local or national collective bargaining agreement. There can be only one member of the bargaining unit representing an employee; this individual cannot interfere with the testimony. Employees should be informed of their rights and obligations in relation to the investigative process (see App. 35B).

d. With the exception of VA Form 10-2633 initiating the report, documents generated by this type of investigation are not protected by the confidentiality requirements of 38 U.S.C. Section 5705, Confidentiality of Quality Assurance Records.

e. Requests for release of information pertaining to investigations should be forwarded to the facility component responsible for responding to request for release of records and information. That facility component may consult with District Counsel when necessary.

f. Should the need arise to extend the investigation beyond the scope of authority delegated by the medical center Director, e.g., during the course of investigating an incident of alleged abuse, it appears another patient was allegedly abused by the same staff member, the investigation will cease and the Director will determine whether the Board should expand the scope of the investigation. A determination as to whether to conduct a Board of Investigation and any subsequent proceedings will proceed regardless of related legal or administrative actions.

g. Investigations will be completed and submitted to the Regional Director's field office within 45 calendar days from the date the medical center becomes aware of the event. Extensions may be granted by the Regional Director's office when circumstances warrant. Such extensions must be requested by the medical center Director, or designee; approval will be documented.

h. The Regional Director's field office will review all documents generated to determine whether investigations have been appropriately conducted and whether the actions taken are sufficient to close the case. Documents will then be forwarded by the region to the appropriate VA Central Office program office.

- i. The report of the investigation will be prepared using the following headings as a format:

- (1) Authority,
- (2) Purpose,
- (3) Scope,
- (4) Exhibits,
- (5) Findings,
- (6) Conclusions, and,
- (7) Recommendations.

j. Opportunities for improvements identified through the investigative process will be incorporated into the medical center's quality improvement activities. Follow-up to ensure implementation of accepted recommendations will be documented.

k. In cases where a healthcare professional leaves employment with VA under circumstances that require disclosure to State licensing boards, it is the medical center Director's responsibility to ensure that the procedures detailed in M-2, Part I, Chapter 34, "Release of Information Concerning Health Care Professionals to State Licensing Boards and to Prospective Employers," are carefully followed.

l. Facilities are required to file a report with the National Practitioner Data Bank (NPDB) when there is an adverse clinical privileges action (e.g., restriction, suspension, denial, revocation, etc.) taken against physicians and dentists that affect privileges for more than 30 days, including the surrender or restriction of clinical privileges when the action is related to professional competence or professional conduct.

35.12 RESPONSIBILITY

a. **Medical Center Director.** The medical center Director must:

(1) Ensure there is leadership at each service level that is responsible for governance, management, clinical and support activities. Responsibilities will include developing plans, and managing processes to assess and improve the quality of care provided. Patient care services will be designed and delivered through an integrated interdisciplinary process, and RM activities will be integrated into that process.

(2) Provide, in collaboration with other medical center management staff, the framework for planning, directing, coordinating, improving and providing health care services that are based on the facility's mission and are responsive to the population served.

(3) Develop and implement IRMP. This includes developing local policy that incorporates requirements of VHA guidance, JCAHO, Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), and Occupational Safety and Health Administration (OSHA).

(4) Assign program responsibility and designate an individual(s) responsible for monitoring, reporting, and analyzing risk management data. The Quality Manager or Risk Manager will oversee and coordinate activities to ensure that all the appropriate offices and personnel are included in RM activities.

(5) Ensure that education and training are provided for all employees, with special attention to those who have frequent contact with patients who are self-destructive, assaultive or cognitively impaired.
NOTE: *Since some incidents of patient abuse may result from insufficient employee education or understanding of patient behavior, continuing education should assist in the prevention of patient abuse.*

b. **Regional Director.** Regional Directors are responsible for providing reasonable assurance of the appropriate and effective implementation of IRMP and provide education at the facility level. Regional

Directors' field offices will review investigations and other documents to ensure that they have been appropriately conducted and that the corrective action or follow-up has occurred; they will grant extensions for completion of investigations as warranted. Regions have responsibility for closing investigations after review and appropriate follow-up is completed. The region will report all incidents to the appropriate VA Central Office program office, where applicable.

c. **Associate Deputy Chief Medical Director for Clinical Programs.** The Associate Deputy Chief Medical Director for Clinical Programs is responsible for ensuring clinical program offices carry out their assigned functions, as follows:

(1) **Director, MH&BSS.** The Director, MH&BSS, is responsible for collecting and compiling data, conducting pattern analyses, providing feedback to the field, developing education programs, and writing national policy relating to suicides and assaultive and/or violent behavior.

(2) **Director, Pharmacy Service.** The Director, Pharmacy Service is responsible for collecting and compiling data, and for conducting pattern analyses on reportable events that involve pharmaceuticals and on information reported through FDA's MedWatch Program along with providing feedback to the field, developing education programs, and writing national policy on issues related to pharmacy and therapeutics.

d. **Inspector General.** The Inspector General monitors and evaluates VA's quality assessment or improvement programs and the care provided in VA medical centers.

e. **Medical Inspector.** The Medical Inspector monitors and evaluates the quality of care provided at VA medical centers.

f. **Director, Police and Security.** The Director, Police and Security, maintains data on criminal activity, provides law enforcement training to police personnel, and issues departmental policy on deterring and handling criminal activity on VHA property, including homicides and assaults.

g. **Associate Chief Medical Director for Quality Management.** The Associate Chief Medical Director for Quality Management is responsible for providing roll-up data to the program offices, regions, medical centers, establishing and clarifying national policy, educating the field, and providing ongoing guidance on the development of RM Programs, and facilitating the distribution of information related to reportable events to VA Central Office program offices.

35.13 TORT CLAIMS

a. There is a recognized need to analyze VA Tort Claims on a systemwide basis in order to identify medical malpractice trends and issues. This information can be used to initiate corrective action, to conduct risk analysis, and to improve quality care. The Offices of Quality Management and General Counsel have implemented a sharing agreement with the Armed Forces Institute of Pathology (AFIP) to analyze VA tort claims systemwide beginning October 1, 1992. AFIP collects VA medical malpractice claims data and extracts information from the medical records and associated documents. The purpose of this trend analysis of medical malpractice claims is to identify opportunities for improvement in the care of patients.

b. Each VA facility where a Tort Claim has been filed will participate in the tort claim analysis. The Office of Quality Management is the liaison with AFIP and will receive periodic and annual reports from AFIP regarding tort claim analysis. Information from these reports will be disseminated to the medical centers for appropriate follow-up. Relevant information will also be sent to VA Central Office program offices. The medical center will provide all necessary forms and information related to tort claims filed at their facilities to their District Counsels.

c. The medical center will continue that part of the Tort Claim Information System (TCIS) process they have been following with their respective District Counsel. Revised instructions from the District Counsels must be followed as well. Within 15 days of the filing of a tort claim, the Office of the District Counsel will

send a copy of the Standard Form 95, Claim for Damage, Injury, or Death, and a copy of the TCIS Printout to the AFIP and the medical facility. The District Counsel will send the TCIS Provider Information and Peer Review and Corrective Action Form to the facility.

d. Within 60 days of receipt of the TCIS information from the District Counsel, the medical center will conduct a peer review of the case by completing the TCIS Provider Information and Peer Review and Corrective Action Form, (see App. 35C). This peer review is protected under 38 U.S.C. 5705. The medical center will send one copy of the completed TCIS Provider Information and Peer Review and Corrective Action Form to the Office of the District Counsel, and one copy of the TCIS Printout, one copy of the TCIS Provider Information and Peer Review and Corrective Action Form, and one copy of the patient's medical record to AFIP located at the following address:

Department of Legal Medicine
Armed Forces Institute of Pathology
8403 Colesville Road, Suite 860
Silver Spring, Maryland 20910-9813

e. Any other information developed independently by the medical center relating to the Tort Claim should be sent to AFIP and District Counsel.

f. When a Tort Claim which resulted in payment by the VA is closed, the medical center must conduct another peer review to determine whether the practitioner (s) should be reported to NPDB.

g. AFIP's analysis of the data will be provided to the facility for appropriate follow-up and for integration into the medical center's overall RM and/or quality improvement process. This data is to be reviewed by the appropriate services and medical center management for appropriate actions and follow-up.

35.14 OTHER RISK MANAGEMENT ACTIVITIES

NOTE: *As the health care environment evolves, medical centers should assess and reduce the risk associated with these changes and incorporate this in the medical center's IRMP.*

Medical centers are encouraged to look at RM as a medical center responsibility that includes all medical center staff. RM includes all activities that have the potential for placing the medical center at risk for liability. Topics outlined in this paragraph are only some of the programs and activities that have the potential for liability, and although the primary responsibility for these programs and activities will not change, personnel involved in the management of these programs should be included in the medical center RM activities.

a. Safety and Health Program (previously Plant, Technology, and Safety Management)

(1) Each medical center must have a comprehensive Safety and Health Management Program designed to provide a physical environment free of hazards to patients, personnel, and visitors, and to manage staff activities to reduce the risk of human injury. Section 19 of the Occupational Safety and Health Act of 1970 (Pub. L. 91-596) and Executive Order 12196 require that elements of the program must be consistent with standards set out by the Occupational Safety and Health Administration (OSHA). VA has restated its requirement to comply with all occupational safety and health standards issued by OSHA in Article 24 of the Master Agreement between the VA and the American Federation of Government Employees (AFGE). Additionally, medical centers must comply with the latest safety management standards of JCAHO.

(2) Policy and procedures will be developed and will be distributed to facility personnel. Orientation and inservice education will be provided to inform each new employee about individual responsibilities and how to fulfill them within the organization or service. Required yearly inservice reviews of the effectiveness of training will be completed in a timely manner and documented. Required training will be based on facility policy, VHA policy, JCAHO standards, and applicable local, State, and Federal laws and regulations.

(3) Performance standards will be used to assess the impact the Safety and Health Program (Plant, Technology, and Safety Management Program) will have on patient care, visitors, and employees. Data collected on quality indicators, opportunities for improvement, action plans, and progress, will be done in a timely manner in instances involving threat to life, health, or property. The medical center will incorporate safety standards into their risk management activities referencing the most current standards of JCAHO.

(4) The reporting and tracking requirement of the Safe Medical Device Act (SMDA) of 1990 (Pub. L. 101-629) will be integrated into the facility's Risk Management and/or Quality Improvement Performance Program. Information reported under the SMDA must not be generated from documents protected by 38 U.S.C. Section 5705.

(5) Each medical center will have a formal written policy for handling medical device hazards, recall and tracking, and will designate a point of contact for these activities. Facilities can minimize liability related to SMDA issues as follows:

- (a) Identifying laws, standards, or guidelines that set forth requirements for the use of medical devices.
- (b) Gathering information on medical device safety before purchasing.
- (c) Considering available safety options (for example, alarms, automatic shut off switches, guards) in light of the medical center's experiences with devices.
- (d) Considering user preferences, training and experience.
- (e) Ensuring that vendors provide appropriate training on all shifts.
- (f) Reviewing and applying Health Device Alerts or similar information services for reported hazards, recall, and other problems.
- (g) Reviewing and analyzing internal adverse event reports, service reports, and other documents that identify problems with devices or use of devices.
- (h) Ensuring that the decision-making process is documented and in particular, that any concerns on safety are addressed and documented, i. e., a favorable evaluation of the device in the publication "Health Device" showed that the brand selected was found to be safe and fit for its use by the facility.
- (i) Ensuring that practitioners have demonstrated competence with new or high-tech procedures before use.
- (j) Ensuring a comprehensive Equipment Management Program.

b. Measures for Identifying Customer Satisfaction and/or Dissatisfaction. The objectives of the Patient Feedback System, Patient Representatives, and Customer Satisfaction Surveys are to provide ongoing feedback about the VA health care experience. Data from these programs provide statistically valid and reliable, useful, operational and timely information to medical centers, and regional offices and VA Central Office. The programs are designed to be responsive to customer needs, wants and expectations and will target areas of care that could be improved. They can be used to identify sources of potential liabilities. Patient complaints data need to be analyzed to identify opportunities for improvement.

c. Infection Control

(1) Infection control is a hospital-wide system designed to reduce the number and frequency of nosocomial infections in the health care setting. There is to be a comprehensive hospital wide Infection Control Program with written policies and procedures for infection surveillance, prevention and control for all patient care services. The Infection Control Program must be monitored by a multidisciplinary

committee. Program elements must be consistent with VA policies, JCAHO, OSHA standards, and CDC guidelines.

(2) Patient care support services, such as central supply services, environmental services, and linen and laundry services, are involved in the prevention and control of infections and are to be provided orientation. Educational inservice training with sufficient scope and duration is to be provided to all employees regarding their responsibilities and how to fulfill them within the medical center. **NOTE:** *All inservice training and annual reviews are to be documented and completed in a timely manner.*

(3) Each medical center Director must ensure "Universal Precautions" are implemented throughout the medical center to reduce risk to occupation exposure and exposure of patients by preventing contact with potentially hazardous blood or blood products. Appropriate precautions need to be taken to reduce exposure of employees and patients to Tuberculosis (TB), and any materials contaminated by potentially infectious diseases. Some controls to minimize exposure include removing the hazard and/or isolating the worker from the hazard, and employing the use of protective devices.

d. **Credentialing and Privileging**

(1) Credentialing is the systematic process of verifying and reviewing an individual's qualifications and health status. This process ensures the possession of the required education, training, experience, physical and mental health, and skill to fulfill the requirements of the position and to support the requested clinical privileges. This process includes verification, through the appropriate primary sources, of the individual's:

- (a) Professional education,
- (b) Training,
- (c) Licensure,
- (d) Certifications and review of health status,
- (e) Previous experience including any gaps in employment,
- (f) Clinical privileges,
- (g) Professional references,
- (h) Malpractice history, and
- (i) Adverse actions.

(2) Privileging is defined as the process by which a practitioner is granted permission by the institution to provide medical or other patient care services within well-defined limits, based on an individual's clinical competence as determined by peer references, professional experience, health status, education, training, licensure, and registration.

(3) Medical center staff credentialing and privileging shall be carried out in accordance with VA Central Office policy and medical center by-laws. Privileges will be based on the mission of the facility and current JCAHO standards. Failure to complete the appropriate assessment of staff can put patients at risk for adverse outcomes and can result in liability. A release of information needs to be obtained prior to requesting information about a practitioner. RM, quality improvement, and utilization review data will be used as part of the reprivileging process.

(4) During the reprivileging process, a review of continuing education should ensure that practitioners have kept abreast of new developments for the privileges requested. Documentation of education and training should be provided for any new privileges requested. RM and/or Quality Improvement and

Utilization Review data from every level in which they practice, i.e., outpatient, inpatient, operating room, etc., need to be reviewed as part of the reprivileging process.

(5) The medical center is responsible for ensuring that practitioners have demonstrated competence in the use of new or high-tech procedures and equipment. Privileging for these high-tech procedures could include credentialing criteria and practice guidelines designed to encourage practitioners to stay abreast of changes in surgical intervention and technology.

e. Informed Consent

(1) Informed consent is a process by which a patient agrees to a procedure or treatment after complete disclosure is made. Courts have generally determined that informed consent must include:

(a) The nature, benefits, and risks of the proposed treatment or test; and

(b) The alternatives to the procedure, medication and other interventions and the prognosis if the proposed treatment is withheld.

(2) VHA regulations Title 38 Code of Federal Regulations (CFR) 17.34 and JCAHO standards require that informed consent be obtained. Failure to obtain the appropriate informed consent can result in liability. Each medical center is responsible for implementing the JCAHO standards on informed consent. The medical center needs to ensure procedures outlined in M-2, Part I, Chapter 23, Informed Consent, are followed, including those related to obtaining a telephonic consent and consents obtained from next of kin and/or significant others.

f. Utilization Review. Utilization Management (UM) is the medical center's overall program to increase the efficiency and appropriateness with which services are provided and resources are utilized. This includes Utilization Review (UR) activities, analysis of UR and other relevant data bases, corrective actions based upon these analyses and reviews of other resources such as time, equipment, space, money and staff. Each medical center will implement a UR Program based on current VA Central Office guidance. UR and UM are effective RM tools because issues identified in the review process can alert the risk manager and other staff to potential risks. Risk Management and Utilization Review can work together to improve processes and provide efficient, timely, quality care by sharing data on adverse events which may require admissions or extend the length of stay.

g. Peer Review

(1) Peer review can identify risk by identifying ineffective practice patterns and learning needs. The use of multiple independent reviewers or peer review committees allows for a wider range of expertise opinion and identification of system issues.

(2) An effective Peer Review Program can help reduce risk by improving provider performance through feedback and education, and by using practitioner-specific findings for educational purposes, for reprivileging, and for initiating administrative reviews when appropriate. Peer reviews are protected under 38 U.S.C. 5705, if they meet the requirements outlined in 38 CFR Part 17.

h. Contracts

(1) RM factors may be considered in awarding and administering contracts for health care resources. Currently VA can contract out its day-to-day health care operations to the extent that 38 U.S.C. explicitly authorizes. VA may only contract out health care services where specifically authorized, e.g., fee basis care (38 U.S.C. 1703), scarce medical specialist services (38 U.S.C. 7409) and sharing of specialized medical resources (38 U.S.C. 8153).

(2) Contracts entered by medical centers have the potential to have an impact on quality of care in a number of ways. Contracts for medical services, either on a shared resources or scarce medical specialist basis, that provide for non-VA employees to render medical treatment to VA patients will directly

affect patient care. Medical equipment, pharmaceuticals, devices and materials that could affect the outcome of care are acquired through contracts, as are servicing agreements to maintain equipment used in patient care. Aspects of the physical plant having a bearing on patient safety, such as elevator maintenance or other maintenance, are often the subjects of contracts.

(3) Contracting officers are expected to adhere to Federal and VA regulations applicable to contracts. Doing so is considered part of RM. For example, contracts for medical services require the contract physician to be covered by liability insurance in a specified amount, unless otherwise required by State law. Adherence to contracting regulations and policies will minimize the risk of a judgment against the Federal government for injuries to VA patients resulting from care by a contract physician or from the performance of contracts affecting equipment or physical plant. Adherence to any obligation to supervise or monitor the performance of contract employees helps ensure that the care provided is consistent with the highest regard for patient safety. Failure to adhere to the regulations and policies may result in wasted resources through contracts for goods or services that do not meet the VA standards.

i. **The Patient Self Determination Act of 1990.** Liability can result when a patient's and/or their family's wishes are not carried out by the health care team in the care of the patient. The Patient Self Determination Act of 1990 (PSDA) is a Federal law which requires that most hospitals, skilled nursing facilities, and home health agencies develop procedures and written policies on advance directives. Advance directives usually mean either a Living Will or Durable Power of Attorney for Health Care.

(1) Advance directives are verbal or written statements that allow patients, before they become too ill, to refuse or consent to treatment and direct the course of their care. It also allows patients to choose or appoint a family member or someone else to carry out those directions.

(2) Compliance with this law is required by health care agencies receiving Medicare and/or Medicaid. VA medical centers need to be aware of the law and its requirements. VA medical centers are required to comply with VHA Manual, M-2, Part 1, Chapter 31, "Withholding and Withdrawing of Life Sustaining Treatment," and JCAHO Patient Rights standards. The manual chapter and JCAHO standards are very similar to the requirements outlined in the law.

j. **Human Resources.** Medical centers generally have been concerned with medical professional liability. However, liability in dealing with all employees can pose a risk to the medical centers' resources.

(1) Examples of liability exposures that may arise within the medical center include issues relating to:

- (a) Hiring practices,
- (b) Privacy,
- (c) Willful misconduct,
- (d) Wrongful termination,
- (e) Benefit disputes,
- (f) Harassment,
- (g) Discrimination,
- (h) Defamation, and
- (i) Employee complaints.

(2) These activities generally fall under the jurisdiction of the Human Resources Management Service. Medical centers need to include the appropriate individual(s) from Human Resources Management Service in risk management activities.

k. **OWCP.** Another consideration for RM is the escalating costs of OWCP and the effect it has on an organization's ability to accomplish its mission. OWCP is a program that provides protection to workers who are injured while engaged in the business of its employer, and has the potential to pose a large financial burden on VA. VA's cost for OWCP during the period covering July 1, 1992, to June 30, 1993, was \$98 million for compensation and \$37 million for medical care, totaling \$135 million. In Fiscal Year 1994, VHA began decentralizing OWCP to each VA medical center. Medical centers can begin to minimize risks to employees through the implementation and monitoring of an Accident Prevention Program which would include hazard surveillance, reporting procedures, and continued education and training of staff.

GUIDANCE FOR REPORTING MANDATED RISK EVENTS BY SEVERITY LEVELS
VA Form 10-2633 required for all Risk Events

<u>EVENT</u>	<u>Notification to Region via phone or E-mail or FAX</u>	<u>Required Documents</u> VA Form 10-2633 for all
1. Suicide	Yes	Psychological autopsy Physical autopsy (where appropriate)
2. Suicide Attempts	Yes	Psychological and Autopsy
3. Patient Abuse (All levels)	Yes	Investigation or Fact finding if the employee admits
4. Missing Patient	Yes	
5. Homicide	Yes	
6. Assaults		
a. Sexual Assault (All Levels)	Yes	
b. Patient to Patient Assault (Level 2)	Yes	
c. Patient to Staff Assault (Level 2)	Yes	
7. Deaths	Yes	Morbidity and Mortality Committee
a. In Operating and or Recovery Room and/or During Induction of Anesthesia		
b. On medical center grounds		
c. Resulting from Failure to Treat		
d. Related to Misdiagnosis		
e. Due to equipment failure		
f. Medical Examiner cases		
g. Other specify		
8. Other - (can be defined locally based on an outcome of level 2 or level 3). Examples include:	Yes	
a. Medication error,		

- b. Falls
- c. Unexpected surgical or procedural outcomes,
- d. Severe injury obtained while involved in a VA recreational activity, and
- e. Transfusion reaction.

NOTE: *An investigation will be conducted in cases in which a preliminary review indicates a suspicion of patient abuse.*

NOTE: *All Boards of Investigation conducted that relate to the above risk event will be submitted to the region.*

**SAMPLE OF THE STATEMENT
OF EMPLOYEE RIGHTS AND OBLIGATIONS**

1. As a Department of Veterans Affairs (VA) employee, you are required to furnish all information or evidence in your possession and to testify freely and honestly concerning your knowledge of the matter under investigation. Any refusal on your part to testify, or any concealment of a material fact, or any inaccurate testimony knowingly and willingly given, may be grounds for disciplinary action against you personally.

2. You are not required, however, to give testimony against yourself in any matter in which there is an indication you were involved personally in a violation of the law and there is a possibility your testimony would be self-incriminating.

3. Your right to refuse to answer a question on the grounds that your response might tend to incriminate you is a personal right. You do not have the right to refuse to answer a question on the grounds that your response might incriminate a person other than yourself.

4. You have the right to representation. If at any time during questioning you feel that your rights as an employee are being violated, you may request that questioning be suspended to afford you an opportunity to seek advice from your personal representative in accordance with rules and regulations of the Department of Veterans Affairs.

5. A copy of your own personal testimony will be provided to you upon your written request. You will be given an opportunity to read and sign your testimony or affidavit if and when it is transcribed and to make additions or corrections thereto before signing.

I HAVE READ OR HAVE HAD READ TO ME THE RIGHTS AND OBLIGATIONS OF A DEPARTMENT OF VETERANS AFFAIRS (VA) EMPLOYEE AS OUTLINED ABOVE AND FULLY UNDERSTAND THEM.

(Print or Type Name of Employee)

(Signature of Employee)

(Date)

(Print or Type Name of Witness)

(Signature of Witness)

(Date)

**TORT CLAIM INFORMATION SYSTEM PROVIDER INFORMATION,
 PEER REVIEW AND CORRECTIVE ACTION FORM**

The Provider Information and Peer Review section of this form must be completed by a Department of Veterans Affairs (VA) health care practitioner with training similar to that of the primary health care provided in the case. For example, if the primary provider is a cardiologist, then a cardiologist should be the peer reviewer. If a registered nurse is the primary provider involved in the case, then a registered nurse should be the peer reviewer. The reviewing practitioner at your facility who has been selected to do a peer review of this case should focusing specifically on the issues surrounding the tort claim. The Risk Manager or Quality Manager at your facility or other appropriate individual should complete sections d (Quality Improvement Risk Management Issues) and section e (Corrective Action). The information on this form is considered confidential and privileged by virtue of 38 United States Code (U.S.C.) 5705. Use an extra sheet of paper if more space is needed.

1. **PROVIDER INFORMATION.** Any health care provider can be named here. Data concerning the primary provider involved in the case should be given in item a. Data concerning other involved providers should be given in items b and c. If a resident or fellow is named, the appropriate attending physician should also be listed as one of the providers. In the Position block provide year of residency (e.g., PGY1, PGY2), staff status, C&A, on-station fee basis, on-station contract, on-station sharing agreement, without compensation, etc.

a. Name: _____	Position* _____
Service: _____	Specialty: _____
b. Name: _____	Position:* _____
Service: _____	Specialty: _____
c. Name: _____	Position:* _____
Service: _____	Specialty: _____

* **NOTE:** *The following are abbreviations which may be used to identify the position:*

- | | |
|--|---|
| PGY-1 = <i>First Year Training Post Medical School</i> | MS = <i>Medical Student</i> |
| PGY-2 = <i>Second Year Training Post Medical School</i> | HN = <i>Head Nurse</i> |
| PGY-3 = <i>Third Year Training Post Medical School</i> | SN = <i>Staff Nurse</i> |
| PGY-4 = <i>Fourth Year Training Post Medical School</i> | TC = <i>Technician</i> |
| PGY-5 = <i>Fifth Year Training Post Medical School</i> | AHP = <i>Allied Health Professional</i> |
| PGY-6 = <i>Sixth Year Training Post Medical School</i> | STF = <i>Credentialed Privileged Staff</i> |
| | OSS = <i>Other Support Staff</i> |

2. PEER REVIEW

a. **General Information.** Patient's Name _____

Social Security Number _____ Age _____ Admission date _____

Discharge date _____

In the following space provide a brief summary of the salient features of this case which are pertinent to the issues surrounding the tort claim.

b. Components of Care:

(1) Was the correct diagnosis made? (Circle answer and write in Diagnosis or International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) Code.)

Definitely Yes Probably Yes Probably No Definitely No N/A

Diagnosis of Provider

Suggested Diagnosis of Reviewer

(2) Was the correct diagnosis made in a timely manner? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

If Definitely No or Probably No, briefly describe, in the following space, what was done and what in your opinion should have been done:

(3) Was proper therapy and/or treatment selected? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

If Definitely No or Probably No, briefly describe, in the following space, what was done and what in your opinion should have been done:

(4) Was the proper therapy/treatment executed in a timely manner? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

If Definitely No or Probably No, briefly describe, in the following space, what was done and what in your opinion should have been done:

(5) Was the treatment technique performed correctly? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

If Definitely No or Probably No, briefly describe, in the following space, what was done and what in your opinion should have been done:

(6) Was the patient's condition properly monitored by the physician? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

If Definitely No or Probably No, briefly describe, in the following space, what was done and what in your opinion should have been done:

(7) Was the patient's condition properly monitored by the nursing staff? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

If Definitely No or Probably No, briefly describe, in the following space, what was done and what in your opinion should have been done:

(8) Was the patient injured as a result of any of the above components of care? (Circle answer.)

Definitely Yes Probably Yes Probably No Definitely No N/A

(9) If the patient was injured, in the following space briefly describe the injury:

c. **Summary Judgment of Standard of Care.** The summary judgment need not reflect the prior answers. Extenuating circumstances, such as lack of consensus about correct therapy or diagnosis (even among experts), complexity of the case or the degree of emergency in the case, etc., can be considered in making a determination of standard of care.

(1) The following is a list of aspects of care to be considered when making your summary judgment:

- (a) Choice of diagnostic test,
- (b) Timely ordering of diagnostic tests,
- (c) Addressing abnormal results of diagnostic tests,
- (d) Timeliness of diagnosis,
- (e) Appropriateness of diagnosis to evidence,
- (f) Timing of treatment initiation,
- (g) Appropriateness of treatment to condition,
- (h) Adequacy of technique during procedures,

(i) Recognition and communication of critical clues to patient's condition during a period of clinical deterioration,

- (j) Timely initiation of appropriate actions during a period of clinical deterioration,
- (k) Issues related to resident supervision,
- (l) Appropriate/complete medical record documentation, and
- (m) Other relevant aspects of care (specify).

(2) Circle Level 1, 2 ,or 3

(a) Level 1 - Most experienced, competent practitioners would have handled case similarly in all of the respects listed.

(b) Level 2 - Most experienced, competent practitioners might have handled case differently in one or more of the respects listed.

(c) Level 3 - Most experienced, competent practitioners would have handled case differently in one or more of the respects listed.

(3) Additional Comments: In the following space make any additional comments that you may wish pertinent to the issues surrounding this Tort Claim.

(4) Peer Reviewer Specialty:

(5) Date of Review:

(6) In the following order, Indicate other specialties that should review this case.

(a)

(b)

(c)

(d)

(e)

d. **Quality Improvement Risk Management Issues.** This information may be completed by any member of the Quality Improvement Staff. (Circle correct response.)

- | | | | |
|--|-----|----|----|
| (1) Was an autopsy requested? | Yes | No | NA |
| (2) Was an autopsy performed? | Yes | No | NA |
| (3) Was there a hospital acquired infection involved in this case | Yes | No | |
| (4) Was there a cardiac or respiratory arrest? | Yes | No | |
| (5) Was there a death (patient not terminal and not Do Not Resuscitate (DNR))? | Yes | No | |
| (6) Was there a re-admission within 10 days? | Yes | No | |
| (7) Was there an admission within 3 days following an unscheduled ambulatory care visit? | Yes | No | |
| (8) Was the patient transferred to a special care unit within 72 hours of being discharged from a special care unit? | Yes | No | |
| (9) Was there a return to the operating room on the same admission? | Yes | No | |
| (10) Was there a suicide attempt during the care or within 30 days of discharge? | Yes | No | |
| (11) Was there a transfusion reaction? | Yes | No | |
| (12) Did this patient have a fall in the hospital that resulted in a severe injury? | Yes | No | |
| (13) Was there equipment failure? | Yes | No | |
| (14) Did this case involve the use of advanced directives or DNR orders? | Yes | No | |
| (15) Did this claim involve a VA "system" problem? | Yes | No | |

(2) Was the subject matter of this tort claim reportable under the Integrated Risk Management Program (IRMP)?

(Circle) Yes No

(a) If so, was a VA Form 10-2633 completed, as required under the Integrated Risk Management Program?

(Circle) Yes No

(b) Were the appropriate review(s) outlined in the IRMP conducted on the event involved in this Tort Claim?

3. **NARRATIVE.** In the following space summarize any corrective actions taken as a result from this case.

(Signature)

(Date of Review)

Print or Type Name and Title)