

January 28, 2008

PEER REVIEW FOR QUALITY MANAGEMENT

1. PURPOSE: This Veterans Health Administration (VHA) Directive sets forth the requirements for initiating, conducting, and documenting protected peer review for quality management of care provided by an individual health care provider in VHA health care facilities.

NOTE: This Directive is intended to complement other Directives that address areas of quality management as patient safety improvement. Additionally, in this Directive the terms “quality management” and “quality assurance” are used interchangeably.

2. BACKGROUND

a. Authority for Protected Peer Reviews is found in Title 38 United States Code (U.S.C.) § 5705, entitled Confidentiality of Medical Quality-Assurance Records, and its implementing regulations. Only documents designated in advance as being developed consistent with 38 U.S.C. § 5705 are confidential. This type of advance designation specifying the protected activities must be contained in a Department of Veterans Affairs (VA) Central Office or Regional Office policy document or by an advance designation of the activity at the facility level.

b. When conducted systematically and credibly, peer review can result in both immediate and long-term improvements in patient care by revealing areas for improvement in individual providers’ practice. This ultimately contributes to organizational performance and optimal patient outcomes. Policy for peer review for quality management purposes must specify the circumstances under which the reviews need to be considered, including:

- (1) Mortality Review,
- (2) Major surgical morbidity,
- (3) All completed suicides and suicide attempts within 30 days of an encounter,
- (4) Unexpected or negative outcomes,
- (5) Executive concerns,
- (6) Concerns of other facility groups,
- (7) Occurrence Screens (possible), and
- (8) Pre-payment Tort Claims.

THIS VHA DIRECTIVE EXPIRES JANUARY 31, 2013

c. Protected Peer Review, as described in this Directive, is intended to promote confidential and systematic processes that contribute to quality management efforts at the individual provider

level, within a non-punitive context. It can also be conducted to assess resource utilization issues related to individual provider decisions. Although organizational issues are sometimes identified, the primary goal is overall improvement in the care provided to veterans through a review of individual provider decisions. Similar to the Root Cause Analysis (RCA) process (as described in VHA Handbook 1050.01, VHA National Safety Improvement Handbook), it is expected that protected peer review done for quality management and/or resource utilization purposes fosters a responsive environment where issues are identified, acted upon proactively, and in ways that continually contribute to the best possible outcomes and strong organizational performance. Peer review is intended to be an endeavor encompassing multiple disciplines requiring active involvement from physicians, nurses, and other licensed staff.

d. A common approach to peer review has been a single reviewer making a judgment about the quality of decisions associated with clinical interventions. This approach does not have well-documented inter-rater reliability. Published evaluations of peer review processes highlight the limitations of unstructured judgments by a single reviewer and justify consideration of alternative approaches, such as use of a committee, subcommittee, or multiple reviewers with discussion to consensus.

NOTE: In order to ensure complete and timely protected peer review, VHA will implement, by separate directive, a national oversight program of all VHA medical facilities protected peer review programs.

e. The process for peer review should be consistent, timely, fair, comprehensive, useful, and balanced.

f. In order for a document to be protected as a peer review document conducted for quality management purposes, the document must meet one of the following conditions, it:

(1) Identifies, either implicitly or explicitly, individual providers or other employees, patients, or reviewers.

(2) Contains discussions relating to the quality of VA patient care and/or the utilization of VA resources by health care providers during a review of quality assurance data.

g. Peer reviews for quality management cannot be used to take personnel actions such as reassignment, changes in privileges, and demotions.

h. Documents that are generated during many other forms of review conducted for purposes other than protected quality and/or resource utilization improvement are not confidential and privileged under 38 U.S.C. § 5705 and its implementing regulations

i. **Definitions**

(1) **Confidential Documents.** The term “confidential documents” includes all documents or parts of documents produced by, or for, VA in the process of conducting systematic health care reviews for the purpose of improving the quality of health care or improving the utilization of health care resources, which are considered privileged under 38 U.S.C. § 5705, and its implementing regulations.

(2) **Provider.** The term “provider” is defined as anyone credentialed, privileged, or working within a professional scope of practice. *NOTE: This Directive does not apply to health care profession trainees acting within the scope of their training program.*

(3) **Peer.** The term “peer” is defined as an individual of similar education, training, licensure, and clinical privileges or scope of practice.

(4) **Protected Peer Review.** The term “peer review” is defined to include critical reviews of care performed by a peer and/or group of peers. All peer review processes must be in accordance with all applicable laws, regulations, and current VHA policies. Peer review, as designated by the Secretary of Veterans Affairs (conducted for the purpose of improving the quality of health care and/or improving the utilization of health care resources), is protected by 38 U.S.C. § 5705, and its implementing regulations. Peer review is a traditional organizational function designed to contribute to improving the quality of care and/or the appropriate utilization of health care resources.

(a) Essential elements of protected peer review include:

1. Evaluation of the care provided by individual clinicians when care provided is of concern,

2. Determination of the necessity of specific actions recommended by the peer review process, and

3. Confidential communication back to appropriate providers regarding the results and any recommended actions to improve performance.

(b) Protected peer review documents for quality management include all reviews of patient care by an individual provider that are performed for the purpose of improving the quality of health care and/or improving the utilization of health care resources. In order for the documents generated by a peer review to be protected as confidential under 38 U.S.C. § 5705, and its implementing regulations, each peer review must be designated in writing as being conducted and/or prepared for quality management and/or resource utilization purposes prior to the initiation of the peer review. This designation can be issued by the Under Secretary for Health (for all VHA facilities), by a Veterans Integrated Services Network (VISN) Director (for VHA facilities within that VISN), and/or by the facility Director (for the individual facility).

***NOTE:** The activity that generates protected peer review records must be so designated in advance. Incorporation of the designation in the facility policy ensures protection for the protected peer review process and confidentiality of the information. This does not remove the requirement for designation in advance of other activities that generate protected information in accordance with VHA Directive 2004-051, Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents (e.g., focused reviews as identified in 38 C.F.R. 17.501(b), which must be designated in advance, prior to the initiation of the review).*

(c) Language mandating protection of this peer review process under 38 U.S.C. § 5705, and its implementing regulations must be clear and incorporated into the facility policy. Language detailing the protection may be placed on the document as additional identification (such as the language following paragraph 2.i.(4)(d).

(d) All documents associated with the protected peer review need to be treated as strictly confidential, unless determined otherwise after careful review (with documentation) by qualified VHA personnel. The following statement is recommended for required documentation:

“The documents, records, and other information contained herein, which resulted from _____(name of specific quality program or resource utilization activity)_____, are confidential and privileged under the provisions of 38 U.S.C. § 5705, and its implementing regulations. This material cannot be disclosed to anyone without authorization as provided for by that law or its regulations. The statute provides for fines up to \$20,000 for unauthorized disclosures.”

(e) A protected peer review is to be conducted as part of a facility’s quality management program and may not be disclosed outside of the quality management process. For example, a protected peer review may be initiated when a malpractice claim is filed, and will be a protected peer review so long as the purpose of the review is to identify, evaluate, and, where appropriate, correct circumstances having the potential to adversely effect the delivery of care.

***NOTE:** As long as confidentiality is maintained and appropriately documented, data from protected peer reviews can be aggregated and communicated to the organized professional staff so that trends are understood and opportunities for improvement identified.*

(f) Aggregated peer review findings may be disclosed, as long as they strictly protect the confidentiality of those involved and are communicated solely for the purposes of promoting organizational performance (including appropriate resource utilization) and optimal patient outcomes. Aggregated findings may not be released unless individual provider confidentiality is strictly protected.

(g) Title 38 U.S.C. § 5705 protection does not mean that all documents are confidential. Aggregated statistical information about multiple cases that does not implicitly or explicitly identify individual VA patients, VHA employees, or reviewers involved in quality assurance processes, is not protected. Similarly, summary documents which only identify study topics, the period of time covered by the study, criteria, norms, and/or general overall findings are not protected.

(5) Peer Review Levels

(a) The initial review results in determination of a Level of Care as a Level 1, Level 2, or Level 3 (see paragraph 3.i.(5)(b)). Completed initial protected peer reviews for quality management that were conducted by an individual reviewer must be sent to a multi-disciplinary Peer Review Committee or subcommittee (hereafter referred to as the Peer Review Committee) chaired by the Chief of Staff (COS).

(b) Peer review of quality management and/or resource utilization purposes is associated with the care provided by an individual licensed health care professional and includes use of the following definitions in assessing the decisions made by a provider:

1. Level 1. Level 1 is where most experienced, competent practitioners would have managed the case in a similar manner.

2. Level 2. Level 2 is where most experienced, competent practitioners might have managed the case differently.

3. Level 3. Level 3 is where most experienced, competent practitioners would have managed the case differently.

3. POLICY: It is VHA policy that each VISN and health care facility must establish and maintain a program of protected (confidential) peer review for quality management purposes (including resource utilization) relevant to the care provided by individual practitioners, in support of clinical care programs and professional services; and must comply with the requirements of those accrediting and oversight agencies that periodically review VHA health care facilities, including, but not limited to The Joint Commission.

4. ACTION

a. **VISN Director.** The VISN Director is responsible for:

(1) Establishing oversight processes for their health care facilities' peer review activities in order to ensure policy development, implementation, and follow-up on any action items formalized at the completion of a specific protected peer review.

(2) Ensuring an annual inspection of all VISN facilities to ensure that oversight, compliance, and follow-up procedures are implemented and functioning.

(3) Ensuring that there is an adequate review of the information provided, which includes reviewing data analysis information from facilities for variance and initiating appropriate actions, which might include a request for an external review, or a site visit to review the peer review process.

b. **VISN Chief Medical Officer (CMO)**. The VISN CMO is responsible for ensuring implementation of this Directive within all medical centers and Community-based Outpatient Clinics (CBOCs).

c. **VISN Quality Management Officer (QMO)**. The VISN QMO is responsible for the collection and analysis of data findings submitted by the facilities related to Protected Peer Review in collaboration with the CMO. The VISN QMO is also responsible for forwarding the Protected Peer Review data to the Office of Deputy Under Secretary for Health (DUSHOM) for national roll-up and analysis by the Office of Quality and Performance (OQP).

d. **Facility Director**. The facility Director has ultimate responsibility for peer reviews concerning quality management that are protected and performed within the facility. The facility Director is responsible for ensuring that:

(1) A Peer Review Committee is established. *NOTE: The organized medical staff should participate in the Protected Peer Review process and this participation should be required in the facility Medical Staff bylaws.*

(2) Appropriate education is provided. This includes:

(a) All clinical health care professionals are provided education on Protected Peer Review policy and processes. This must be completed within 6 months of publication of this directive.

(b) Participants in the Protected Peer Review process (reviewers and Peer Review Committee members), at a minimum, receive training on the following within 3 months of the date of this directive and prior to participating in a review with refresher training biennially (every 2 years)

1. VHA quality management and patient safety activities that can generate confidential documents under 38 U.S.C. § 5705, and its implementing regulations. This training will be available after March 31, 2008, and guidance provided through the Employee Education System (EES) Mandatory Training Website at <http://vaww.ees.lrn.va.gov/mandatorytraining>

2. Protected peer review pertaining to matters relevant to quality management and/or resource utilization, which must be identified as confidential in writing at the beginning of the peer review process. Users may access this satellite broadcast at http://vaww.sites.lrn.va.gov/vacatalog/cu_detail.asp?id=23518&search=true

(3) An Initial Peer Review is initiated, when appropriate. *NOTE: A Morbidity and Mortality Committee at the service level constituted as peers may serve as the initial peer review; however, full compliance with this Directive is required, including the review of its cases by the hospital Peer Review Committee. Other medical staff committees responsible for peer review, such as the Blood Use, Drug Use, or Operative and Invasive Review Committee may also apply when full compliance with the requirements of this Directive have been met.*

(a) **Qualifications**. A peer reviewer must:

1. Possess the relevant clinical expertise necessary to make accurate judgments about the decisions being reviewed. The term “Peer” is as an individual of similar education, licensure, training and clinical privileges or scope of practice.

2. Possess knowledge of relevant current standards of care.

3. Be formally trained regarding the peer review process, the responsibilities, and the facility's legal and ethical requirements.

***NOTE:** In the event that there is no peer at the facility qualified to serve as a Peer Reviewer, the COS coordinates arrangements for the review to be conducted at another facility.*

(b) Responsibilities

1. The initial peer reviewer uses the aspects for review of care presented in paragraph 4.e.(3)(b) to evaluate quality and/or resource issues related to the care given by an individual provider.

2. No peer reviewer may have direct involvement with the care in question.

3. Peer reviewers must:

a. Withdraw from a case if determined that the specialized knowledge required exceeds their expertise or when they feel uncomfortable about judging the care.

b. Abstain from review of cases in which there is a conflict of interest or, for any other reason, the reviewer is unable to conduct an objective, impartial, accurate, and informed review.

4. Completion of the initial protected peer review with assignment of Level of Care must be timely and consistent with facility policy which is not to exceed 45 days. On the rare occasion when the initial protected peer review is anticipated and cannot be completed within 45 days, a written request for an extension must be submitted to the COS prior to the due date.

***NOTE:** Documentation of the initial protected Peer Review must be reviewed by the multi-disciplinary Peer Review Committee chaired by the COS.*

5. If the matter being reviewed raises concerns about the possibility of substandard care, negligence, or any other competency issue that might impact safety or privileges immediate notification is to be given to the COS, the Nurse Executive, and other Executives as appropriate.

***NOTE:** Different types of reviews (e.g., protected and non-protected) can occur parallel to, or before or after, each other as long as protected and non-protected information and processes are kept separate.*

(c) Confidentiality. Information from the Peer Review is confidential and cannot be revealed to any one outside the protected Quality Management process except as provided in 38 U.S.C. § 5705(b), and 38 C.F.R. §§ 17.508 and 17.509.

(4) A facility-level policy for protected peer review is implemented and in place. Policy for peer review for quality management purposes must specify the circumstances under which the reviews need to be considered, including the:

- (a) Mortality Review,
- (b) Major surgical morbidity,
- (c) All completed suicides,
- (d) Suicide attempts within 30 days of an encounter,
- (e) Unexpected or negative outcomes,
- (f) Executive concerns,
- (g) Concerns of other facility groups,
- (h) Occurrence screens (possible), and
- (i) Pre-payment Tort Claims.

NOTE: Mandatory occurrence screening program will be implemented by separate directive.

(5) The Facility policy is current for the conduct of protected peer review for quality management purposes, including resource utilization, and that, at a minimum, addresses the following:

(a) Criteria and definition(s) for those circumstances requiring protected peer review for quality management.

(b) Specification of the participants to be involved in the peer review process, including incorporation of the definition of the term “peer” as defined in this Directive.

(c) Method(s) for selecting ad hoc reviewers for protected peer reviews.

(d) Timeframes for completion of protected peer review activities, including when reviews are to be conducted and when results are to be reported to all parties concerned, including the providers whose care is under review and VISN leadership. Time begins with the date that the determination of Protected Peer Review is necessary.

1. Screen for Need for Protected Peer Review. This must be completed within 3 business days of identification or discovery of the event.

2. Initial Review Completed. This must be completed within 45 calendar days from determination to conduct Protected Peer Review is identified.

3. Final Review Completed. This must be completed within 120 calendar days from determination to conduct Protected Peer Review is identified.

(e) Issues related to patient safety, law enforcement, or potential administrative investigations determined during the peer review process must be documented and referred to the appropriate management, professional, or law enforcement official in a timely manner utilizing existing routine-use exceptions involving those issues.

(f) Provide an opportunity to participate in the review to the individual(s) whose performance is being reviewed.

(g) Coordination of an outside protected peer review when needed.

(h) Process for formal education for Peer Reviewers.

(i) Data management and analysis. **NOTE:** *In those instances where protected peer review is accomplished in conjunction with the affiliated institution or program, the facility policy must ensure that a Business Associate Agreement between the facility and the educational institution or program is established and maintained in order to ensure the sharing of review data, findings, recommendations, and actions are shared with the VHA facility. In these instances, the protected peer review process conducted at the Affiliate is part of the VHA facility's Protected Peer Review Program and information shall be shared with the VHA facility.*

(6) The following is forwarded to the VISN:

(a) The aggregate peer review data to include:

1. The number of peer reviews;

2. The number of deaths peer reviewed;

3. The assigned levels by the initial reviewer and the Peer Review Committee; and

4. The numbers of assignments of levels moved to a higher level (i.e., Level 2 to Level 3) or moved to a lower level, and the delinquency rate for the timeliness of reviews.

(b) A Summary of the Peer Review Committee's analysis is sent quarterly to the VISN for review (see Attachment D for required data). **NOTE:** *VISNs may choose to require additional data elements be reported.*

(7) Attention is paid to the Indicators for Protected Peer Review. The following need to be considered for a Protected Peer Review:

(a) Mortality Review. All deaths must be screened against death review criteria and exceptions to the death review criteria (see Attachment A). Cases that meet the criteria must be referred for protected peer review for quality management. Mortalities associated with any surgical procedure (elective or not) or any mortality later during the same hospitalization (or related to readmission for the same condition within 30 days) need to undergo peer review.

NOTE: The diagnosis of a "terminal" illness, the existence of an advanced directive, or a Do Not Resuscitate status is not considered an exception from Protected Peer Review.

(b) Major Morbidities associated with Surgical Procedures.

(c) All Suicide Attempts and Completed Suicides Within 30 days of any Encounter with a health care provider. This includes telephone visit, telemedicine, etc.

(d) Unexpected or Negative Occurrences. These occurrences include events in which a patient has experienced a negative or unexpected outcome that may be related to the care provided and for which facility management considers peer review the best method for determining if the care was appropriate (see Attachment C for sample of possible Occurrence Screens).

(e) Executive Concerns. These concerns about quality management issues from members of leadership or service and/or department chiefs may be requested when specifically related to the provision of patient care by a provider under the charge of the executive. Each facility must establish a process for initiation of peer review based on executive concerns.

(f) Concerns of Other Facility Groups. These concerns are from established organizational groups within the facility, which may submit a request for Protected Peer Review for quality management purposes.

(g) Tort Claims. Initial notification of the filing of a tort claim may generate an immediate Protected Peer Review for quality management.

NOTE: For this review to be protected by 38 U.S.C. § 5705, and its implementing regulations, it must be directly related to quality of health care delivered and/or utilization of health care resources and not entirely for the purpose of assisting the United States in consideration of the tort claim or defense of litigation under the Federal Tort Claims Act.

e. Facility Chief of Staff (COS). The Facility Chief of Staff is responsible for Chairing the Peer Review Committee and having oversight of the Peer Review Program.

(1) **Composition and Qualifications of the Peer Review Committee**

(a) The Peer Review Committee must be multi-disciplinary (including non-physician members) and consist of senior members of key clinical disciplines.

NOTE: Facilities may wish to establish an independent committee or may choose to create a subcommittee of an existing group, such as the Medical Executive Committee. The Peer Review Committee may seek legal guidance and assistance from General/Regional Counsel as needed.

1. The Chair of the Committee must be the COS and the Nurse Executive must be a member.

2. A quorum must be defined in facility policy and consist of no less than three members of which one must be a “Peer.”

a. An individual capable of serving as a “peer” of the provider, whose case is being reviewed needs to be included as a member of the Peer Review Committee.

b. No Committee member may have direct involvement with the care in question.

c. Each committee member must complete training as identified in paragraph 4.d.(2) prior to assignment of a protected peer review.

(b) The Committee members must:

1. Withdraw from a case if determined that the specialized knowledge required exceeds their expertise or when they feel uncomfortable about judging the care.

2. Abstain from review of cases in which there is a conflict of interest or, for any other reason, the Committee member is unable to conduct an objective, impartial, accurate, and informed review.

(c) In the event there is no qualified “Peer” to serve on the Peer Review Committee, the COS must make arrangements for appropriate representation. This may be done using teleconferencing or referral to another facility or VISN.

NOTE: Complete training as identified in paragraph 4.d.(2) prior to participating in peer reviews, and on a biennially recurring basis (every 2 years).

(2) **Peer Review Committee Responsibilities.** Peer Review Committee is responsible for:

(a) Reconsidering all protected peer review cases within the facility completed by the individual initial peer reviewers when the level of review is determined to be a Level 2 or Level 3.

(b) Overseeing all peer reviews. A sufficient and representative sample of Level 1 peer review cases (at least ten per quarter or 15 percent, whichever is greater, or all Level 1s) need to

be reviewed to ensure the validity and reliability of the findings and to evaluate the peer review process itself.

NOTE: Level 1 cases selected for Peer Review Committee consideration should be those identified as "high risk" for their facility as defined by medical center policy.

(c) Meeting on a regularly scheduled basis, at least quarterly. *NOTE: The Chair may call ad hoc meetings or add ad hoc members as needed.*

(d) Reporting at least quarterly to the Executive Committee of the Medical Staff and other key Executives, as needed (see paragraph 4.e.(2)(k)).

NOTE: Executives from across disciplines must be kept apprised of peer review activities related to their subordinates.

(e) Coordinating the referral of significant information to appropriate leadership when the deficiency of care was not met due to a system issue(s).

(f) Completing the final review of each case within 120 days from the determination that a peer review is necessary. The exception for a delay, or an extension beyond 120 days, needs to be requested in writing, and approved by the Director, who is responsible for monitoring and reviewing the number of extensions twice a year.

(g) Assigning, in writing, a final Level, based on deliberations, along with any appropriate non-punitive, non-disciplinary actions to improve the quality of health care delivered or utilization of health care resources to the appropriate supervisor. The supervisor is responsible for initiating appropriate action and follow-up.

1. It is expected that the supervisor of the individual(s) that was assigned the Level 2 or Level 3 will communicate with the individual(s) in their service and ensure that appropriate non-disciplinary, non-punitive action is implemented.

2. Feedback of action must be accomplished by the supervisor's written notification to the Peer Review Committee upon completion of the action.

(h) Ensuring that, in most circumstances, health care profession trainees are acting within the scope of their training program, are not independent, and are under the supervision of a VA staff provider. If care delivered by a health care profession trainee is identified as Level 2 or Level 3, a decision must be made by the Peer Review Committee as to whether a failure of supervision contributed to the outcome.

1. If the supervision was deemed appropriate, a Level of Care must still be assigned but will not be attributable to either the trainee or supervising practitioner. The Peer Review Committee's data will document the Level of Care without attribution. The Peer Review will be referred to the health care profession trainee's Chief of Service and/or Program Director for follow-up, which ever is appropriate.

2. If the supervision was deemed inappropriate, the Level of Care will be assigned to the supervising practitioner.

***NOTE:** In no case should the Level of Care be attributable to the trainee alone unless there is clear cut evidence of gross negligence or willful professional misconduct.*

(i) Documenting issues related to patient safety, law enforcement, or potential administrative investigations determined during the peer review process and referring these concerns to the appropriate management, professional, or law enforcement official in a timely manner utilizing existing Privacy Act routine-use exceptions involving those issues. The Peer Review Committee is responsible for monitoring follow-up action on these concerns and documenting closure.

***NOTE:** Only the initial report (“charging facts”) can be communicated when starting a non-protected review, which means that a new and separate investigation(s) must begin.*

(j) Tracking, quarterly, an analysis of data with findings and recommendations, and forwarding this information to the facility Medical Executive Committee.

(k) Tracking, quarterly, peer review activity. This includes the following:

1. The number of reviews;

2. The outcome by Level 1, Level 2, and Level 3; and

3. The number of changes from one level to another during the review process (e.g., the initial reviewer determines a Level 2, but it is changed to a Level 1 by the Committee).

(l) Reporting Peer Review Activity data on a quarterly basis using Attachment D, or available electronic reporting methods to the VISN QMO for VISN analysis. In collaboration with the VISN CMO, outlier data will be identified and follow-up action documented to the VISN Director and the medical center Director. Necessary actions will be documented to closure.

(m) Ensuring that the VISN QMO reports medical facility specific Peer Review Activity data on a quarterly basis to the OQP using Attachment D or available electronic reporting method. The OQP will analyze data, identifying outliers, and request VISN follow-up action plans as indicated. Necessary actions will be monitored to closure.

(n) Ensuring that formal discussions about peer review (e.g., occurring during peer review committee meetings) are recorded in formal meeting minutes. Documentation relevant to protected peer reviews must be kept by a Peer Review Committee official in a folder(s) that is not identifiable by provider; the folder must be stored in a secure location.

(o) Inviting the provider whose care is under review by the Peer Review Committee (only Level 2 and Level 3) to submit written comments on issues raised during the review process and

to provide additional substantive documentation if a Level 2 or Level 3 is assigned following the initial review. When a Level 2 or Level 3 has been determined, providers must be allowed, if they choose, to appear before the Peer Review Committee before a final Committee decision is reached. The responsible Peer Review Committee official must fully document all discussions held with a provider.

NOTE: The provider whose care is under review has the option to appeal based on local policies.

(p) Ensuring that the initial peer review (conducted by an individual) is accomplished within 45 days. Extensions may be granted in writing only by the COS.

NOTE: The number and reasons for extensions must be tracked and documented by the COS.

(q) Seeking, as necessary, peer reviewers from outside the facility or VISN. If external assistance is required, outside assistance may be sought from another facility or VISN CMO.

(r) Conducting each review through an explicit application of current standards of care based on accepted practice and analysis of reviewed professional literature published within the United States health care community.

(s) Providing a quarterly roll-up of the data, data analysis, and recommendations to the Executive Committee of the Medical Staff for any necessary actions, to include recommended data elements for review and analysis as:

1. The number of completed peer reviews and number of deaths referred to peer review tracked and trended by the provider under review, patient identifier, level of care, and service.

2. The number of peer reviews not in compliance with the timelines defined in the local facility policy, tracked and trended by service.

3. The number of changes from one level to another by the protected Peer Review Committee tracked and trended by service.

4. Tracking and trending the aspect of care (see paragraph. 4.e.(3)(b)) for those protected peer reviews that are determined to be a Level 2 or Level 3.

5. Systems issues identified and actions completed.

6. Tracking of actions completed by service.

(3) **Peer Review Process.** The Peer Review Process consists of an initial review conducted by an individual clinical peer reviewer followed by a secondary review by the facility Peer Review Committee (see Attachment B). This review results in the determination of a Level 1, Level 2, or Level 3 provision of care.

(a) Level of Provisions of Care

1. Level 1. Level 1 is where most experienced, competent practitioners would have managed the case similarly in all of the aspects listed in paragraph 4.e.(3)(b).

2. Level 2. Level 2 is where most experienced, competent practitioners might have managed the case differently in one or more of the listed aspects of care in paragraph 4.e.(3)(b).

3. Level 3. Level 3 is where most experienced, competent practitioners would have managed the case differently in one or more of the listed aspects of care in paragraph 4.e.(3)(b).

(b) Aspects for Review of Care

1. Choice of diagnostic tests and timely ordering of those diagnostic tests.

2. Performance of a procedure and/or treatment.

3. Addressing abnormal results of diagnostic tests.

4. Timeliness of diagnosis and appropriateness of diagnosis.

5. Timing of treatment initiation and appropriateness of treatment.

6. Adequacy of technique during procedures.

7. Recognition and communication of critical clues to patient's condition during the period of clinical deterioration.

8. Timely initiation of appropriate actions during periods of clinical deterioration.

9. Medical record documentation.

10. Supervision of health profession trainees.

11. Other relevant aspects of care.

f. **Medical Executive Committee.** The Medical Executive Committee, in its deliberations, must utilize the data analysis information from the Peer Review Committee to determine the need for further action. Criteria which may engender further action are:

(a) A lower number of peer reviews.

(b) Overwhelming majority of Level 1 assignments.

(c) Absence of Level 3 assignments.

- (d) Consistent absence of changes of levels.
- (e) Facility defined criteria that may define further review or action.
- (f) Consistent assignment of Level 3 for a provider.
- (g) All level changes result in a decrease in the assigned level (i.e., Level 3 to Level 2 or Level 1.)

g. **Chief Quality and Performance Officer (CQPO)**. Is responsible for the analysis of data findings by the VISN QMO related to protected peer review. CQPO is also responsible for reporting to the Under Secretary for Health on the protected peer review program activity within VHA, identifying potential outliers and corrective actions being taken, at a minimum, on a quarterly basis.

5. REFERENCES

- a. Title 38 U.S.C. § 5705.
- b. Title 38 CFR 17.500-17.511, “Confidentiality of Healthcare Quality Assurance Review Records.”
- c. VHA Handbook 1050.1, VHA National Patient Safety Improvement Handbook.
- d. VHA Directive 0700, Administrative Investigations.
- e. VA Handbook 0700, Administrative Investigations.
- f. VHA Handbook 1100.19, Credentialing and Privileging.
- g. VHA Record Control Schedule 10-1.
- h. VA System of Records, 24VA136.
- i. VHA Directive 2005-056, Mortality Assessment.
- j. VHA Directive 2004-051, Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents.

6. FOLLOW-UP RESPONSIBILITY: The Office of the Deputy Under Secretary for Health for Operations and Management (10N) and the Office of Quality and Performance (10Q) are responsible for the contents of this Directive. Questions may be referred to Director, Quality Standards, (919) 993-3035 Ext 236.

7. RECISSIONS: VHA Directive 2004-054, dated September 29, 2004, is rescinded. This VHA Directive expires January 31, 2013.

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Under Secretary for Health

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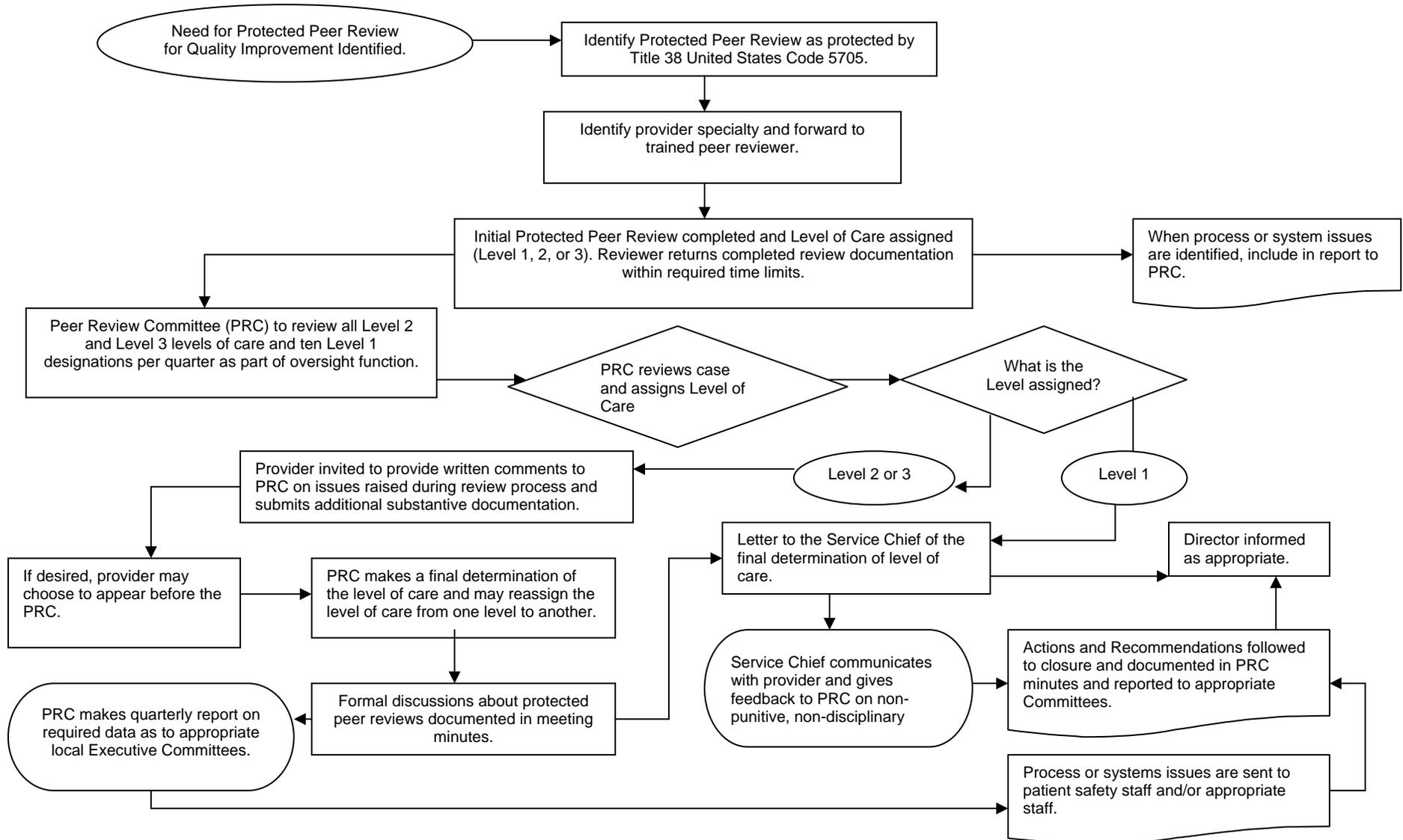
ATTACHMENT A**MANDATORY REVIEW SCREENING CRITERIA FOR PROTECTED PEER REVIEW**

If any of the following mortality criteria is present, Protective Peer Review is required.

1. Lack of documentation of patient's deterioration during 48 hours preceding death.
2. Change in patient's condition with no action taken during 48 hours preceding death.
3. Cardiac or pulmonary arrest that could have been avoided.
4. Lack of concordance between patient's pre-mortem and post-mortem diagnoses.
5. Signs of patient's deteriorating condition that should have been noted and/or communicated to the physician, but were not.
6. Death appears to be related to a failure to carry out orders.
7. Lack of documentation indicating explanation for the death.
8. Lack of documentation indicating that the patient's death was expected.
9. Death appears to be related to a hospital-incurred incident or a complication of treatment.
10. Death within 24 hours of admission (except in cases in which death is anticipated and clearly documented, such as transfer from hospice care).
11. Death within 72 hours of transfer out of a special care unit (unless the transfer was made because death was anticipated).
12. Death during or within 30 days of a surgical procedure or (if after 30 days) death is suspected to be related to the original procedure.
13. Death appears to be related to a medication error or a choice of medication.
14. Death appears to be associated with a lack of appropriate palliative care.
15. Reason to think death may have been preventable.
16. Suicide/suicide attempts within 30 days of an encounter with a health care professional.

ATTACHMENT B

PROTECTED PEER REVIEW FLOWCHART



ATTACHMENT C**SAMPLE OF POSSIBLE OCCURRENCE SCREENS****1. GENERAL OCCURRENCE SCREENS**

a. Admissions for adverse results, complications, and incomplete management or problems during a previous hospitalization, (within 10 days).

b. Unexpected transfer to a special care unit for complications, incomplete management prior to transfer, or premature discharge from the special care which resulted in transfer back to the unit.

c. Unplanned or partial removal, repair of organ or structure, or injury (laceration, perforation, tear or puncture) during an invasive procedure.

d. Unplanned return to surgery on current admission.

e. Cardiac arrest.

f. Post-op complications on current admission or within 30 days of surgery.

g. Neurological deficit not present on admission.

h. Acute Myocardial Infarction or Cerebral Vascular Accident within 48 hours of a surgical or invasive procedure.

i. Abnormal laboratory, x-ray, or other test result not addressed by a physician.

j. Staff supervision not documented in the medical record within 24 hours of patient admission.

k. Irregular discharges.

l. Non-completion of operative consent.

m. Patient and/or family issues and concerns that cannot be resolved.

n. Hospital incurred patient incident, such as:

(1) Falls.

(2) Medication errors.

(3) Alleged patient abuse.

- (4) Suicide attempts and suicide.
- (5) Assaults.
- (6) Missing patients.
- (7) Patient injury other than fall.
- (8) Death-unexpected or in conjunction with surgery.

2. AMBULATORY CARE OCCURRENCE SCREENS (in addition to the general occurrence screens).

- a. Admission within 3 days for adverse results, complications, or incomplete management of an ambulatory care visit.
- b. Subsequent visit to the Emergency Department (ED) or Triage for adverse results, incomplete management, or complications of previous hospitalization, out-patient care, and/or Nursing Home Care (NHC).
- c. Incomplete management in the ED or Acute Care (AC), during a visit.
- d. Inadequate documentation in the outpatient record.

ATTACHMENT D

MINIMUM QUARTERLY DATA REPORT

1. In accordance with paragraph 4.e.(2)(1) of the Directive, the facility leadership must forward, at a minimum, the following information and an analysis of the information in the following table.

Time Frame (Qtr/Yr)	VISN	Facility (Parent Station #)	Total # of Initial Peer Reviews	Total # of Initial Peer Reviews completed within 45 days	Total # of Peer Reviews Sent to Peer Review Committee	Total # of Peer Reviews completed by Peer Review Committee in 120 days	Total # of Death Peer Reviews	Initial Peer Review			Peer Review Committee Final Determination						
								Level 1	Level 2	Level 3	Level 1 to Level 2	Level 1 to Level 3	Level 2 to Level 1	Level 2 to Level 3	Level 3 to Level 1	Level 3 to Level 2	

2. Veterans Integrated Services Networks (VISNs) may require additional information.