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PEER REVIEW FOR QUALITY MANAGEMENT

1. PURPOSE: This Veterans Health Administration (VHA) Directive sets forth the requirements for initiating, conducting, and documenting peer review for quality management of care provided by an individual provider in VHA health care facilities. *NOTE: In this Directive the terms “quality management,” “quality improvement,” and “quality assurance” are used interchangeably.*

2. BACKGROUND: The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) refers to a peer review as a “focused review.” A focused review involves members of the health care staff in activities to measure, assess, and improve performance on an organization-wide basis.

a. 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. *NOTE: This Directive is intended to complement other Directives that address areas of quality management as patient safety improvement.*

b. Authority for focused 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 directive 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.

c. Peer review, as described in this Directive, is intended to promote confidential and systematic processes that contribute to quality improvement 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 review of individual provider decisions. Similar to the Root Cause Analysis (RCA) process (as described in VHA Handbook 1050.1), it is hoped that protected peer review done for quality improvement and/or resource utilization purposes will foster a responsive environment where issues are identified and acted upon proactively and in ways that continually contribute to the best possible outcomes and strong organizational performance.

d. Peer review is intended to be an endeavor encompassing multiple disciplines. Physicians, nurses, and other licensed staff need to be actively involved in properly-functioning peer review processes.

e. A common approach to peer review has been a single reviewer making a judgment about the quality of decisions associated with clinical interventions. However, this approach does not

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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.

f. Criteria for effective and credible peer review processes include consistency, timeliness, fairness, balance, and usefulness.

g. **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 operating within a professional scope of practice.

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

(4) **Peer Review.** The term “peer review” is defined to include critical reviews of an episode 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, including protection under 38 U.S.C. 5705, and its implementing regulations. *NOTE: Peer reviews for quality improvement cannot be used to take personnel actions such as reassignment, changes in privileges, and demotions.*

(5) **Protected Peer Reviews**

(a) Essential elements of protected peer review include:

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

2. Evaluation of an episode of care, and

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

(b) Peer review, as designated by the Secretary, Department 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.

(c) Protected peer review documents for quality improvement 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 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 improvement 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).

1. Language mandating protection under 38 U.S.C. § 5705 (such as the language in following subpar. 2g(5)(c)2) must be clearly and visibly placed on every page of every document to be made confidential.

2. All documents associated with this activity 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.”

3. Information about protected peer review cases may not be disclosed and is to be conducted as part of a facility’s quality improvement program. For example, a peer review may be initiated when malpractice claims are filed, so long as the purpose of the peer 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 change identified.*

4. Peer review findings may be disclosed as long as they are aggregated and documented in a way that strictly protects 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.

5. 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 (while not

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directly or indirectly identifying individual providers or other employees, patients, or reviews) are not protected.

6. Protected peer review for quality improvement always starts with an “initial review,” which must be completed within 45 days. The initial peer reviewer uses the definitions presented in subparagraph 2g(6) to evaluate quality and/or resource issues related to the care given by an individual provider.

(6) Peer Review Levels

(a) The initial review results in determination of a Level 1, Level 2, or Level 3 (see following subpar. 2g(6)(b)1). Completed initial protected peer reviews for quality improvement 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, or designee. *NOTE: As appropriate, the Chief Nurse Executive, or other non-nursing Executives, or designees, will be asked to co-chair the Peer Review Committee.*

(b) The Peer Review Committee then reconsiders 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 (see following subpar. 2g(6)(b)1). Since the Peer Review Committee oversees all peer reviews, a sufficient and representative sample of Level 1 peer review cases (at least 30 per year or 20 percent per year, whichever is greater, or all Level 1s if the total number does not reach 30) need to be reviewed to ensure the validity and reliability of the findings and to evaluate the peer review process itself. *NOTE: If there are fewer than eight Level 1s per quarter, all Level 1s need to be reviewed on a quarterly basis.*

1. Peer review of quality improvement 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:

a. Level 1. Most experienced, competent practitioners would have managed the case similarly in all of the aspects listed in following subparagraph 2g(6)(b)1.c.

b. Level 2. Most experienced, competent practitioners might have managed the case differently in one or more of the aspects listed in following subparagraph 2g(6)(b)1.c.

c. Level 3. Most experienced, competent practitioners would have managed the case differently in one or more of the aspects listed:

- (1) Choice of diagnostic tests and timely ordering of 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 period of clinical deterioration.

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

(9) Other relevant aspects of care.

(c) In order for documents to be protected as peer review documents conducted for quality improvement purposes, the documents must meet one of the following conditions:

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 evaluators during a review of quality assurance data.

(7) Other than Protected Peer Reviews

(a) 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. In addition to management reviews (see following subpar. 2g(7)(c), examples of unprotected reviews include, but are not limited to:

1. Reviews conducted while considering clinical privileges,

2. Administrative investigations, and

3. Occupational Safety and Health Administration investigations.

NOTE: *Malpractice payment reviews undertaken pursuant to Title 38 Code of Federal Regulations (CFR) Part 46, "Policy Regarding Participation in the National Practitioner Data Bank," are not included within the scope of this Directive (see VHA Handbook 1100.17).*

(b) Findings from non-protected reviews may be disclosed.

(c) Management Review. The term "management review" is defined as any review that is conducted for purposes other than confidential quality improvement and/or resource utilization related to individual provider decisions. For example, administrative investigations are a type of management review. Neither management review processes nor any related documentation are protected by 38 U.S.C. § 5705, and its implementing regulations. The fact that management

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review findings are and can be disclosed needs to be clearly understood and communicated (verbally and in writing) from the onset of a management review. Management reviews and other non-confidential reviews must, by law, be kept separate from any protected reviews. Unprotected management review activities include, but are not limited to:

1. A review of activities of clinical staff to assess and attest to competency of professional staff for the purpose of considering an adverse clinical privileging action.
2. A review of activities performed for the purpose of an administrative investigation.
3. A review of activities performed for the purpose of assisting the United States in consideration of tort claims or defenses of litigation under the Federal Tort Claims Act, particularly if the review is done at the request of the Regional Counsel or the Assistant United States Attorney.
4. A review of activities related to Professional Standards Boards conducted for the purpose of potentially reducing or removing privileges.
5. Peer recommendation forms used for credentialing and privileging.

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 improvement 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 JCAHO.

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) Conducting periodic inspections 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 on a quarterly basis (see subpar.4c(6)).
- (4) Ensuring that Patient Safety Officers and Patient Safety Managers are not assigned oversight duties related to peer review for quality improvement and/or resource utilization purposes.

b. **Facility Director.** The facility Director, or designee, has ultimate responsibility for peer reviews for quality improvement that are protected and performed within the facility. The facility Director is responsible for ensuring that:

(1) A Peer Review Committee is established. The Peer Review Committee must be multidisciplinary (including non-physician members) and consist of senior members of key clinical disciplines. *NOTE: VISNs and facilities may wish to establish an independent committee or may choose to create a sub-committee of an existing group, such as the Medical Executive Committee. For example, the Executive Committee of the Medical Staff could fulfill this function. Legal counsel may serve as technical advisor as needed. Communication with Regional Counsel may also be appropriate.* Persons capable of serving as a “peer” of the provider whose case is being reviewed need to be included as members of the Peer Review Committee. *NOTE: Flexible membership procedures are periodically needed, such as adding ad hoc members or ad hoc co-chairpersons, or asking another executive-level clinician to participate on the Peer Review Committee (when a subordinate is being reviewed), or requesting an executive from another discipline to be a temporary co-chairperson. For example, if the issue being reviewed directly involves nursing, then the Chief Nurse Executive, or designee, needs to be considered as an ad hoc co-chair.*

(a) If the activity which generated the document was performed at a VA facility, it must have been performed by that facility staff, or there must have been prior written designation of the role of those individuals who are not facility staff.

(b) No peer reviewer may have direct involvement with the care in question.

(c) The peer reviewers 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 reviewer is unable to conduct an objective, impartial, accurate, and informed review. *NOTE: In the event that there is no peer at the facility able or willing to serve as a peer reviewer, the Chief of Staff, or designee, consults with the VISN Chief Medical Officer to make arrangements to have the review conducted at another facility. The rationale for moving a peer review must be documented.*

3. Possess the relevant clinical expertise necessary to make accurate judgments about the decisions being reviewed. To accomplish this, relevant current standards of care must be considered. The basis for judgment, including use of clinical experience and opinion, needs to be explicitly documented.

4. Be formally trained regarding the peer review process, their responsibilities, and the organizations’ legal and ethical requirements. The peer reviewers must be clearly informed:

a. Of 38 U.S.C. § 5705, and its implementing regulations; and

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b. That the information they learn from their review is confidential and cannot be revealed to anyone outside the protected quality management process.

(2) A facility-level policy for protected peer review is developed and approved by the VISN Director by March 4, 2005. At a minimum, this policy must require that protected peer review (conducted for quality improvement purposes, including resource utilization) occur as described in this Directive. In addition, this policy must include provisions that state:

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

(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 and ad hoc co-chairs (to be dictated by the content to be reviewed).

(d) Time frames for 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.

(e) That issues related to patient safety, law enforcement, or potential administrative investigations determined during the peer review process are documented and referred to the appropriate management, professional, or law enforcement official in a timely manner utilizing existing routine-use exceptions involving those issues. For example, routine use 3 in patient medical records, system of records 24VA136 permits the referral of relevant records to the appropriate authorities when there is a violation of law, whether criminal, civil, or regulatory.

(f) The invited participation (during the review) by the individual(s) whose performance is being reviewed (see subpar. 4c(8)).

(g) The coordination of an outside protected peer review (conducted outside the facility), when needed.

(h) The formal education of peer reviewers, to include:

1. VHA quality improvement and patient safety activities can generate confidential documents under 38 U.S.C. § 5705, and its implementing regulations.

2. Protected peer review pertains to matters relevant to quality improvement and/or resource utilization and must be identified as confidential in writing at the beginning of the peer review process.

3. Policy for peer review for quality management purposes must specify the circumstances under which the reviews need to be considered, including the following:

a. Mortality Review. All deaths must be screened against death review criteria and exceptions to the death review criteria (see Att. A). Cases that meet the criteria must be referred for protected peer review for quality improvement. Mortalities and major morbidities 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 morbidity and mortality peer review.

b. Negative Outcomes. Negative Outcomes are events in which a patient has experienced a negative and/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.

c. Executive Concerns. 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.

d. Tort Claims. Initial notification of the filing of a tort claim may generate an immediate protected peer review for quality improvement to assess the extent of clinical staff involvement, review the patient's outcome, as well as to identify, evaluate and, when appropriate, correct circumstances having the potential to adversely effect the delivery of care and/or organizational performance. For this peer review to be protected by 38 U.S.C. § 5705, and its implementing regulations, it must be done for the preceding purpose (which is directly related to quality and/or resource utilization issues) and not for the purpose of assisting the United States in consideration of tort claims or defense of litigation under the Federal Tort Claims Act.

e. Concerns of other Facility Groups. Organizational groups or functions within the facility may submit a request for protected peer review for quality improvement purposes (including resource utilization). Facility groups interested in this type of peer review are typically interested in reviews of operative reports, invasive and non-invasive procedures, blood usage, medication usage, restraint and seclusion, resuscitation, care to high-risk populations, efficiency of clinical practice patterns, significant departures from established patterns of clinical practice, and completion of medical records. Conversely, facility groups may submit reports. On a quarterly basis, the committee or subcommittee responsible for protected peer review must review submitted reports from facility groups.

c. Peer Review Committee. The Peer Review Committee is responsible for:

(1) Meeting on a regularly scheduled basis, quarterly. A Chair or Co-Chair may call ad hoc meetings or add ad hoc members as needed.

(2) Reporting at least quarterly to the Executive Committee of the Medical Staff and (when appropriate) to the Chief Nurse and other key (non-nursing) Executives, as needed. **NOTE:** Executives from across disciplines need to be kept apprised of peer review activities related to their subordinates (see subpar. 4c(6)).

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(3) Coordinating the referral of significant information to appropriate personnel when the deficiency of care was not met due only to a system (i.e., organizational) issue(s). **NOTE:** *Different types of reviews (e.g., protected and non-protected) can occur parallel to, or before and/or after, each other as long as protected and non-protected information and processes are kept separate.*

(4) Completing the final review of each case within 120 days from the determination that a peer review is necessary (the initial reviews must to be completed within 45 days). The exception for a delay, or an extension beyond 120 days, needs to be documented and signed off by the Chief of Staff, who is responsible for monitoring and reviewing the number of extensions on a semi-annual basis.

(5) Notifying the Chief of Staff, or designee, and (as appropriate) the Chief Nurse Executive, or other non-nursing Executives, immediately 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.

(a) In consultation with other Executives, the Chief of Staff, or designee, determines what actions are needed to protect patients and whether or not a non-protected review is needed in addition to, or instead of, the protected review.

(b) Provided that information is kept confidential as required, the protected findings or any other protected information or documentation (which are the results of 38 U.S.C. § 5705-protected activities) generated by a peer review may also “trigger” a new investigation that is not 38 U.S.C. § 5705-protected, such as a management review; or it may trigger an additional protected review, such as an RCA. Although the protected findings may serve as the trigger for a non-protected review, these same findings are protected (confidential) and cannot be disclosed.

(c) 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.

(d) There are no restrictions on multiple reviews, as long as protected and non-protected information and processes are kept separate, and as long as only the initial reporting information is forwarded from those conducting a protected review to those conducting a non-protected review.

(6) Quarterly tracking of peer review activity. This includes the following:

(a) The number of reviews;

(b) The outcome by Level 1, Level 2, and Level 3;

(c) 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);

(d) Follow-up on action items; and

(e) Recommendations that result from completed peer reviews.

(7) 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 and stored in a secure location.

(8) 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 also 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 discussions held with a provider. **NOTE:** *The provider whose care is under review has the option to appeal based on local policies.*

(9) Ensuring that the initial peer review (conducted by an individual) is accomplished within 45 days. Extensions may be granted in writing only by the Chief of Staff, or designee. **NOTE:** *The number and reasons for extensions will be tracked and documented by the Chief of Staff.*

(10) Seeking, as necessary, peer reviewers from outside the facility or VISN. If multiple reviews are required for the same case (for example when the same case requires both a protected peer review as well as a non-protected review, such as an administrative investigation), outside assistance from another facility or VISN may be sought. **NOTE:** *These instances are relatively rare.*

(11) 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.

5. REFERENCES

a. Title 38 U.S.C. § 5705.

b. Title 38 CFR Part 46, "Policy Regarding Participation in the National Practitioner Data Bank."

c. Title 38 CFR 17.500-17.511, "Confidentiality of Healthcare Quality Assurance Review Records."

d. VHA Handbook 1050.1, VHA National Patient Safety Improvement Handbook.

e. VHA Directive 0700, Administrative Investigations.

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f. VA Handbook 0700, Administrative Investigations.

g. VHA Handbook 1100.19, Credentialing and Privileging.

h. VHA Handbook 1100.17, National Practitioner Data Bank Reports.

i. VHA Record Control Schedule 10-1.

j. VHA Directive 2004-036, Mortality Assessment.

k. VHA Directive 2004-051, Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents.

l. VA System of Records, 24VA136.

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 202-273-8953.

7. RECISSIONS: None. This VHA Directive expires July 31, 2009.

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ATTACHMENT A

DEATH REVIEW SCREENING CRITERIA

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

1. There is lack of documentation of patient's deterioration during 48 hours preceding death.
2. There was a change in patient's condition with no action taken during 48 hours preceding death.
3. If there was a cardiac or pulmonary arrest, could it have been avoided?
4. There was a lack of concordance between patient's pre-mortem and post-mortem diagnoses.
5. It appears there were 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. There is a lack of documentation indicating explanation for the death.
8. There is a 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 expected).
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. There is reason to think death may have been preventable.

ATTACHMENT B

PEER REVIEW FLOWCHART

