

March 6, 2009

## **CONFIDENTIALITY OF QUALITY MANAGEMENT RECORDS AND DOCUMENTS**

1. **PURPOSE:** To provide guidance regarding the confidentiality of specified documents resulting from Quality Management (QM) activities carried out by or for Lebanon Veterans Affairs (VA) Medical Center.

2. **POLICY:**

a. The medical center will appropriately maintain the confidentiality of QM documents. As a healthcare organization, we must be sensitive to the need to share data with our customers and other healthcare organizations. The intent of the confidentiality law is to enable clinicians to participate in quality improvement activities without fear of reprisal, not to keep VA facilities from sharing aggregate data with non-VA organizations.

b. This directive applies to QM documents initiated on or after January 23, 1995, the date on which the revised VA QM confidentiality regulations, published at 59 Federal Register 53354, became effective. Guidance regarding the confidentiality of QM documents initiated before January 23, 1995, can be found in the previous confidentiality regulations originally published on October 22, 1982, at 47 Federal Register 47004, and the previous Medical Center Memoranda history file for this topic. Documents covered under this policy may be retained in any storage medium; i.e., written, optical disk, electronic, photographic, etc.

c. Documents from the QM activities listed in paragraph 3a are, in general, confidential only if all of the following criteria are met:

(1) The activity is performed by or for the Department of VA to improve the quality of healthcare or the utilization of healthcare resources.

(2) The activity that generated the document must have been previously designated in writing as a QM activity that can produce confidential documents. The designation can be either by the Under Secretary for Health for all VA facilities, by a Veterans Integrated Service Network (VISN) Director for all VA facilities within that VISN, or by the facility Director.

(3) The document identifies either implicitly or explicitly individual practitioners, patients, or reviewers or contains discussion relating to the quality of medical care or utilization of VA resources which occurred during the course of a review of quality management information or data, or was produced in deliberating on healthcare review findings or prepared for use in such deliberations.

(4) The document does not meet any of the 15 exceptions listed in Attachment A.

(5) The activity was performed at this medical center by staff of this medical center, or there was prior written designation of the role of the individuals who are not staff of this facility in performing the review.

### 3. **PROCEDURES:**

a. The following QM activities may generate confidential documents if criteria in paragraph 2c above are met:

#### (1) **Monitoring and Evaluation Reviews**

(a) ***Tort Claim Peer Review.*** The review of the care provided in cases in which malpractice claims have been filed, to identify, evaluate, and, where appropriate, correct circumstances having the potential to adversely affect the delivery of care. Reviews conducted entirely for other purposes, such as representing the United States in tort claim litigation, are not included.

(b) ***Morbidity and Mortality Reviews*** (including psychological autopsies). Discussions among clinicians of the care provided to individual patients who died or experienced complications. These discussions are scheduled and usually labeled as Morbidity and Mortality Conferences. Activities that involve preliminary reviews of care to provide material for consideration at Morbidity and Mortality Conferences are also included. If non-VA practitioners from affiliated facilities attend Morbidity and Mortality Conferences, there needs to be prior written designation of the role of these individuals if documents from these conferences are to be confidential. In addition, Section 5701 bars access by non-VA personnel to VA medical records or other documents identifying individual VA patients unless the identifying information has been deleted.

(c) ***Occurrence Screening.*** The screening of cases against a list of criteria which are specified in advance in a policy document from the Under Secretary for Health, VISN Director, or medical center Director. Cases, which involve one or more of the occurrences, are reviewed to identify possible problems in patient care. Cases meeting the criteria may be entered into an ongoing occurrence screening database to be reviewed and analyzed regularly to identify patterns that may be problematic. The Under Secretary for Health, VISN Director, or medical center Director may delete criteria, which they have previously authorized in a policy document.

(d) ***Drug Usage Evaluation.*** Reviews to assess the safety, appropriateness, and effectiveness of drugs prescribed by physicians. The dose, route, and time schedule chosen are often reviewed as well as the drug selected. Adverse drug event reports are included.

(e) ***Utilization Review.*** Reviews to identify inappropriate, inefficient, or insufficient use of resources involved in clinical care; e.g., review of admission and continued hospitalization or review of diagnostic studies. A specific review may apply to all patients

or to a specific group of patients defined by diagnosis, performance of a procedure, or other patient characteristics. Reviews of rejected applications for care are also included.

(f) ***Surgical and Other Procedure Reviews.*** This review assesses the appropriateness (whether the procedure was needed) and effectiveness of surgical and other procedures. It includes the review of cases in which there is a major discrepancy between preoperative and postoperative (including pathologic) diagnoses and review of specific invasive procedures, regardless of whether tissue was removed during the procedure.

(g) ***Medical Records Review.*** The assessment of the adequacy of medical record documentation by clinical staff with regard to completeness, timeliness, and clinical pertinence.

(h) ***Blood Usage Review.*** A review of all aspects of blood services to determine whether blood and blood products are appropriately ordered and stored, delivered, and provided in a safe, timely, and therapeutic manner. Evaluation of transfusion errors and reactions is included.

(i) ***Adverse Event Reporting.*** The reporting, review, or analysis of unusual or unexpected incidents involving patients, which cause harm or have the potential for causing harm. Employees becoming aware of such incidents report them to medical center management by initiating a Special Incident Report. Current examples of adverse events, which require review and reporting, are included in Veterans Health Administration (VHA) Handbook 1051/1 "Patient Safety Improvement." VA Form 10-2633 (Report of Special Incident Involving a Beneficiary), or similar forms, and followup documents, unless developed during or as a result of a Board of Investigation are confidential and privileged. Confidential documents, such as Reports of Special Incidents, which lead to a Board of Investigation, retain their confidential status even though documents resulting from the Board of Investigation are not confidential.

(j) ***Infection Control Reviews.*** Surveillance activities to identify and monitor the rate of nosocomial infections.

(k) ***Program Monitoring including Multidisciplinary Monitoring.*** A process involving indicators used by clinical services and programs to monitor the quality of specific aspects of the care they provide. The data from these indicators are periodically evaluated to identify opportunities for improvement. This monitoring and evaluation is multidisciplinary when it involves several services reviewing the same care from their different perspectives.

(l) ***Autopsy Review.*** The comparison of pre-mortem diagnoses and diagnostic assessment procedures with post-mortem diagnoses and other autopsy findings to assess diagnostic accuracy. This review may be performed at a Morbidity and Mortality Conference or in other settings.

(m) **Process Action Teams or Blitz Teams.** Multidisciplinary teams established to perform in-depth study of the processes involved in providing clinical services. They are also known as quality improvement teams and are usually part of a facility's Quality Management Program.

(n) **Emergency Department Register.** The daily log of activity and general outcomes of the Emergency Department activity which are reviewed daily by care line leaders and administration.

(2) **Focused reviews, which address specific issues (usually of major consequences to patient care processes and outcomes) or specific incidents (usually involving a discrete episode of care) and are designated by the medical center Director at the outset as protected by 38 United States Code (U.S.C.) 5705 and its implementing regulations.** A focused review will be terminated by the facility Director if it appears that disciplinary action may be indicated, and a board of investigation will be initiated so that evidence independent of the focused review may be developed and this evidence and the findings can be the basis of such disciplinary actions. VHA Central Office or VISN-focused reviews may involve comparison of facilities relative to each other on key indicators of quality of care. They are:

(a) **Quality Improvement Checklist (QUIC)**— A data system comparing VA medical facilities on key clinical indicators. QUIC is in operation at some, but not all VA healthcare facilities.

(b) **National Comparative Performance Analyses**— Data analyses describing an individual facility's or VISN's performance on key indicators of care relative to other facilities or VISNs. The analyses are based on national administrative databases; such as, the Patient Treatment File (PTF) or data collected specifically for QM purposes. Programs generating such analyses include the Performance Measurement Program, National Surgical Quality Improvement Program (NSQIP), and the Minimum Data Set/ Resident Assessment Information (MDS/RAI) Quality Indicators. The NSQIP includes the Continuous Improvement Cardiac Surgical Program (CICSP). Other national comparative performance analyses concern mortality on medical and psychiatric units, decubitus ulcers, and functional assessment as measured by patient responses to the research questionnaire, Short Form 36 (SF 36). Reports generated under 38 U.S.C. 7311 involving system-wide surgical morbidity and mortality rates are not included.

(c) **Trending and Analysis**— VISN and VHA Central Office trending and analysis of facility QM documents and data; such as, adverse drug reaction reports, reports of adverse events, and close calls.

(d) **Root Cause Analysis (RCA)**

1 RCA is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse clinical events or close calls. An RCA

MCM 00-03, 03-06-09

investigates events and activities, gathers and manipulates data, and examines and reviews VHA care-delivery activities in order to:

a Identify the system elements or components that cause or contribute to the occurrence of an adverse clinical event or close call.

b Develop corrective actions and procedures for VHA to adopt both locally and nationally that will prevent the recurrence of similar events or close calls.

2 RCA usually involves:

a Gathering and examination of patient-specific and provider-specific data.

b Analysis and coordination between and among the facility, VISN, and national levels.

3 RCA may include reviews of several similar events (such as, medication errors) to derive common causal factors and solutions. These reviews are commonly referred to as aggregated reviews.

(e) ***Patient Safety Registry (PSR) and Patient Information System***

1 The PSR and Patient Information System is a central database that is used to report and monitor individual adverse events involving patients treated by VHA in VHA facilities. Facility, VISN, and national VHA components investigate, examine, and analyze an event reported to the database in order to:

a Identify basic or contributing causal factors that resulted in the adverse event.

b Develop protocols or procedures for VHA to adopt that will prevent a recurrence of the event.

2 The data usually involves:

a The gathering and examination of patient-specific data.

b Analysis and coordination of reported events at and between the facility, VISN, and national levels.

3 Analysis of data may involve a review of similar events from different facilities in order to derive common causal factors and solutions.

(3) **Contracted External Reviews of Care, specifically designated in the contract/agreement as protected by 38 U.S.C. 5705 and its implementing regulations**; i.e., External Peer Review Program (EPRP).

(4) Clinical Education Program Accreditation Reviews. The nationally recognized accreditation body, i.e., the Accreditation Council for Graduate Medical Education (ACGME), must accredit all education programs in VA or those organizations listed in the Department of Education's Office of Postsecondary Education listing of "National Institutional and Specialized Accreditation Bodies." These external review bodies have processes for initial and ongoing accreditation of their respective educational training program. Their review processes generate detailed reports addressing a wide range of program and institutional requirements. The reports may include information about specific VA training programs and resources (human and equipment) that would impact on the delivery of patient care; information about the training environment; and, critiques of the credentials and performance of individual faculty, physicians, and educators involved in the training program. The information is used to correct the identified shortcomings of VHA training programs and ensure that appropriate improvements are instituted.

b. The following statement will be used on documents considered confidential: **"The quality management portion of these documents or records (or information contained herein) which resulted from (name of specific QM program or activity), are deemed CONFIDENTIAL AND PRIVILEGED under the provisions of 38 U.S.C. 5705 which provides for fines up to \$20,000 for violations. This material shall not be disclosed or transmitted to ANYONE without proper consent or other authorization as provided by that law or its regulations."**

This statement will be helpful in retrospectively identifying confidential documents. **However, the statement, by itself, does not assure confidentiality of a document. Documents are confidential if they meet the requirements of 38 U.S.C. 5705 and its implementing regulations (as summarized in paragraph 2c above), even if no such statement is present; similarly, the use of this statement does not protect documents which do not qualify as being confidential.**

c. The filing and maintenance of confidential QM records will be accomplished by care line offices to ensure that access to and disclosure of all confidential information will occur only as authorized.

d. Those documents, which contain confidential material in one part, but not in others, such as Medical Executive Committee minutes, will be filed and maintained as if the entire document was protected.

e. Access to confidential QM records and documents within the medical center is restricted to VA employees (including consultants and contractors of VA) who have a need for such information to perform their government duties or contractual responsibilities. All individuals granted such access have been informed of the contents of this policy statement, including the penalties for unauthorized disclosure by the releasing official and individual signature on a confidentiality statement (Attachment B).

f. Confidential QM documents can be shown to the practitioner for educational or performance improvement purposes. To protect the integrity of the peer review process, the identities of the peer reviewers will not be disclosed to the provider, to the extent practicable.

g. Other VA employees (and consultants and contractors) may have access to confidential QM documents if they need the information to perform their government duties or contractual responsibilities. This includes staff of the Inspector General, Medical Inspector, and Regional Counsel.

h. Disclosure of confidential QM documents is authorized to the following non-VA requestors. [See paragraph 17.509 of the revised VA confidentiality regulations for details.]

(1) Department of Justice attorneys who are investigating a claim or potential claim against VA or who are preparing for litigation involving VA.

(2) A committee or subcommittee of either house of Congress if the document pertains to any matter within the assigned jurisdiction of the committee; e.g., House/Senate Veterans Affairs Committee, etc.

(3) Accreditation agencies requested by VA to assess the quality of patient care; e.g., the Joint Commission, College of American Pathologists (CAP), Commission on Cancer, etc.

(4) The General Accounting Office, if the document pertains to any matter within its jurisdiction.

(5) Federal agencies charged with protecting the public health and welfare, Federal and private agencies which engage in various monitoring and quality control activities, agencies responsible for licensure of individual healthcare facilities or programs, and similar organizations [See subparagraph j below].

(6) A Federal agency or provider of healthcare participating with VA in a healthcare program, if disclosure of the document is necessary for VA to participate in the program [See subparagraph j below].

(7) A criminal or civil law enforcement governmental agency chartered under applicable law with protecting public health or safety, if a qualified representative makes a qualifying written request for the record [See subparagraph j below].

(8) Qualified persons or organizations, which are participating with VA in a healthcare program, if disclosure of the document is necessary for VA to participate in the program [See subparagraph j below].

(9) Healthcare personnel to the extent necessary to meet a medical emergency affecting the health or safety of any individual.

i. QM documents, whether confidential or not, will not be disclosed to a requestor outside VA until a determination has been made as to the applicability of all other applicable confidentiality statutes; i.e., the Privacy Act, 5 U.S.C. 552a, and VA's own confidentiality statutes, 38 U.S.C. 7332 [drug and alcohol abuse, Sickle Cell Anemia, Human Immunodeficiency Virus (HIV) Infection] and 38 U.S.C. 5701 (Veterans' names and addresses) as well as the Freedom of Information Act. This will require a collaborative review with the facility Freedom of Information Act Officer.

**j. A request for confidential QM documents listed under paragraph 3h(5) through (8) above must:**

- (1) Be made in writing on agency letterhead and signed by the requestor;**
- (2) Specify the nature and content of the information requested;**
- (3) Specify to whom the information should be transmitted or disclosed;**
- (4) Specify the purpose for which the information requested will be used; and**
- (5) Specify, to the extent possible, the beginning and final dates of the period for which disclosure or access are requested.**

k. The disclosure of confidential and privileged records and documents will always be by copies, abstracts, summaries, or similar records or documents. The original records and documents will not be removed from the medical center unless otherwise legally required. The only exception is that documents may be removed to the site where General Counsel/Regional Counsel, or any attorneys with the Office of General Counsel/Regional Counsel or the Department of Justice is conducting an investigation or preparing for litigation. 38 U.S.C. 5705 protected documents which are disclosed to authorized individuals will bear the following statement: **"These documents or records (or information contained herein) are confidential and privileged under the provisions of 38 U.S.C. 5705, which provide for fines of up to \$20,000 for unauthorized disclosure thereof, and the implementing regulations. This material shall not be disclosed to anyone without authorization as provided for by that law or these regulations."** The name of, and other identifying information, regarding any individual VA patient, employee, or other individual associated with VA shall be deleted before any disclosure, if disclosure would constitute a clearly unwarranted invasion of personal privacy, except in the case where documents are being released to the Office of General Counsel/Regional Counsel or any attorneys with the Office of General Counsel/Regional Counsel or the Department of Justice in conjunction with the investigation of a tort claim and/or representation of the government/VA in litigation.

l. When a request for QM documents is denied in whole or in part by the medical center, the requestor will be notified in writing of the right to appeal this decision to the General Counsel of the Department of Veterans Affairs within 60 days of the date of the denial letter.

m. Confidential QM documents will be maintained for 3 years.

n. Providing the level of protection reasonably necessary to ensure that access to and disclosure of electronic documents containing information protected by 38 U.S.C. 5705, occurs only as authorized by that statute and its implemented regulations.

#### 4. **RESPONSIBILITIES:**

a. The **Director** has the ultimate responsibility for applying the confidentiality law (38 U.S.C. 5705) and the implementing regulations.

b. The **Chief of Staff, Associate Director, and Associate Director for Patient Care Services** have the responsibility for implementing the confidentiality law and its revised regulations in the care lines under their span of control.

c. The **Director, Quality Management**, serves as QM Confidentiality Officer and is responsible for the day-to-day operation of the confidentiality program. The Director, Quality Management, working with the Release of Information Officer as appropriate, will coordinate all requests for the release of QM documents. The Director of Quality Management will work with and include the Medical Records Administrator, as necessary, in managing the confidentiality of electronic documents.

d. **Managers** are responsible for implementing the confidentiality law and its revised regulations within their areas.

e. **All employees who have access to confidential QM documents** will sign a confidentiality statement (Attachment B) and will not disclose these documents, or the information therein, to any person or organization, except as authorized by 38 U.S.C. 5705 and the implementing regulations, either while employed by VA or after voluntary or involuntary termination of their relationship with VA.

#### 5. **REFERENCES:**

The Joint Commission Manual for Hospitals

Title 38 U.S.C. 5705

VHA Directive 2004-051, September 28, 2004, Quality Management (QM) and Patient Safety Activities that can Generate Confidential Documents

6. **KEY WORDS:** Disclosure of QM documents, confidential document access, confidentiality statement.

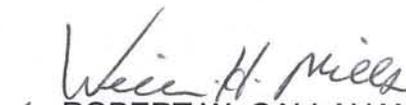
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7. **AUTHOR:** Performance Improvement Specialist

8. **RESCISSION:**

MCM 00-03, 11-18-04, same subject

9. **REISSUE DATE:** March 2012

  
for ROBERT W. CALLAHAN, JR.  
Director

Attachments: 2

Attachment A

**NON-CONFIDENTIAL QUALITY MANAGEMENT DOCUMENTS**

The following documents (and parts thereof) are NOT confidential UNDER 38 U.S.C. 5705:

- a. Statistical information regarding VA healthcare programs or activities that does not implicitly or explicitly identify individual VA patients, employees, and individuals involved in the Quality Management process.
- b. Summary documents or records, which only identify study topics, the period of time covered by the study, criteria, norms, and/or major overall findings, but which do not identify individual healthcare practitioners, even by implication.
- c. Contents of credential and privilege folders.
- d. Documents developed during or as a result of Boards of Investigations. [NOTE: Confidential documents ***protected by 38 U.S.C. 5705***, such as Reports of Special Incidents Involving a Beneficiary, which lead to an investigation, retain their confidential status even though documents resulting from the investigations are not confidential.]
- e. Completed patient satisfaction survey questionnaires and findings.
- f. Information concerning the number of cases treated and procedures performed by individual providers. [These documents will be used during the reprivilege process and filed in the credential and privilege folders.]
- g. Documents developed during or as a result of reviews performed to satisfy the requirements of a governmental body or a professional healthcare organization which is licensing practitioners or monitoring their professional performance; e.g., National Practitioner Data Bank (NPDB), Federation of State Medical Boards (FSMB), and National Council of State Boards of Nursing, etc.
- h. Office of the Medical Inspector's site-visit reports and documents, except to the extent that the documents and reports contain information that result from activities described as confidential ***under 38 U.S.C. 5705***.
- i. External reviews conducted by VHA Headquarters or the VISN Director other than those designated as being confidential ***under 38 U.S.C. 5705***.

j. Documents and reports of Professional Standards Boards, Credential and Privilege Review Board, and similar bodies, insofar as the documents relate to the credential and privilege process of practitioners.

k. Documents developed during data validation activities.

l. Documents developed during occupational health monitoring.

m. Documents developed during safety monitoring not directly related to the care of specified individual patients.

n. Documents developed during or as a result of Resource Management activities not directly related to the care of specified individual patients.

o. Reviews conducted at the request of a third-party payer.

Attachment B

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***TO BE REVIEWED AND SIGNED BY THE EMPLOYEE AND SUPERVISOR***

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**CONFIDENTIALITY STATEMENT**

I understand and agree that, in the performance of my duties as an employee of the Lebanon Veterans Affairs Medical Center, I may come into possession of information about patients concerning the services performed by healthcare personnel at this medical center, even though I may not take any direct part in or furnish the services performed for patients.

I have read and understand Medical Center Memorandum 00-03 (Confidentiality of Quality Management Records and Documents).

I understand and agree that I must hold medical and quality of care information in confidence during and after my employment.

I understand that willful disclosure of medical or quality of care information could subject me to a fine of not more than \$5,000 for the first offense and not more than \$20,000 for each subsequent offense.

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(Employee's signature)

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(Date)

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(Supervisor's signature)

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(Date)

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