

November 7, 2008

QUALITY MANAGEMENT (QM) AND PATIENT SAFETY ACTIVITIES THAT CAN GENERATE CONFIDENTIAL DOCUMENTS

1. PURPOSE: This Veterans Health Administration (VHA) Directive lists and describes Quality Management (QM) activities which can generate confidential documents under Title 38 United States Code (U.S.C.) Section 5705, and its implementing regulations.

2. BACKGROUND

a. The confidentiality regulations state that the Under Secretary for Health, Veterans Integrated Service Network (VISN) Director, or facility Director must describe in advance, in writing, those quality assurance activities which generate confidential records under 38 U.S.C. 5705, and its implementing regulations. *NOTE: The terms "quality management," "quality improvement," and "quality assurance" are used interchangeably in this Directive; quality assurance is used as a synonym for quality management in the implementing regulations.*

b. The requirements for a QM document to be confidential are described in Title 38 Code of Federal Regulations (CFR) Sections 17.501 (a), (b), (c), and (g) of the confidentiality regulations. These requirements can be briefly summarized as follows: *NOTE: See 38 CFR 17.501 for a more precise and detailed description.*

(1) The activity that generated the information must have been conducted by or for the Department of Veterans Affairs (VA) to improve the quality of health care or the utilization of health care resources.

(2) The activity which generated the document must have been previously designated in writing as a QM activity which can produce confidential documents. The designation can be either by the Under Secretary for Health and applied to VHA facilities, or by a VISN Director to apply to all VHA facilities within that VISN, or by the facility Director to apply only to that facility.

(3) The document must meet one of the following conditions:

(a) It identifies, either implicitly or explicitly, individual practitioners, patients, or reviewers; or

(b) It contains discussions relating to the quality of VA medical care, or to the utilization of VA medical resources by health care evaluators during a review of quality assurance data.

(4) If the activity which generated the document was performed at a VA medical treatment facility, it must have been performed by staff of that facility or there must have been prior written designation of the role of individuals who were not staff at the facility in performing the review.

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c. The list of core activities at all VHA medical facilities that can generate records protected by 38 U.S.C. 5705, and the implementing regulations, can be expanded under the following circumstances:

(1) VISN and facility Directors can supplement this list for facilities under their control by describing additional QM activities that can generate confidential documents in policy directives or QM Plans.

(2) The description of a QM activity in this Directive, or in a similar document signed by a VISN or facility Director, does not mean that all documents resulting from the activity are confidential. It is necessary that the other requirements (referred to in subparagraphs 2b and 2c) must be met. In particular, aggregate statistical information that does not implicitly or explicitly identify individual VA patients, VA employees, or individuals involved in the quality assurance process is not confidential. Similarly, summary documents which only identify study topics, the period of time covered by the study, criteria, norms, or major overall findings, and do not identify individual health care practitioners even by implication, are not confidential. Consequently, most documents resulting from some activities described in this Directive, such as process action teams, will not be confidential.

3. POLICY: It is VHA policy that only VHA documents which meet the requirements in 38 U.S.C. 5705 and its implementing regulations are confidential.

4. ACTION: The facility Director is responsible for:

a. Ensuring that the criteria referred to in subparagraphs 2b and 2c are met and that documents from the following quality assurance activities are confidential:

(1) **Monitoring and Evaluation Reviews.** Monitoring and evaluation reviews conducted by a facility include:

(a) Tort Claim Peer Review. A Tort Claim Peer Review is 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. **NOTE:** *Reviews conducted entirely for other purposes, such as assisting the United States in consideration of tort claims or in defense of litigation under the Federal Tort Claims Act, are not included.*

(b) Morbidity and Mortality Reviews (including psychological autopsies). Morbidity and Mortality Reviews are 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 which involve preliminary reviews of care to provide material for consideration at Morbidity and Mortality Conferences are 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, 38 U.S.C. 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. Occurrence Screening is the screening of cases against a list of criteria that are specified, in advance, in a policy document from the Under Secretary for Health, VISN Director, or facility Director. Cases that 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 facility Director may delete criteria that they have previously authorized in a policy document.

(d) Drug Usage Evaluation. Drug Usage Evaluations are 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. The Utilization Review identifies 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 Usage Evaluation. The Surgical and Other Procedure Usage Evaluation is a review that 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 the review of specific invasive procedures, regardless of whether tissue was removed during the procedure.

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

(h) Blood Usage Review. The Blood Usage Review is 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 and Close Call Reporting. Adverse Event and Close Call Reporting is the reporting, review, or analysis of incidents involving patients that cause harm or have the potential for causing harm. Employees becoming aware of such incidents report them to the medical center. *NOTE: Current examples of adverse events, which require review and reporting, are included in VHA Handbook 1051.01.* VA Form 10-2633, Report of Special Incident Involving a Beneficiary, or similar forms, and follow-up documents, unless developed during or as a result of a Board of Investigation, are confidential and privileged. Confidential

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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. Infection Control Reviews are surveillance activities to identify and monitor the rate of nosocomial infections.

(k) Service and Program Monitoring including Multi-disciplinary Monitoring. Service and Program Monitoring are processes that involve 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. *NOTE: This monitoring and evaluation is multi-disciplinary when it involves several services reviewing the same care from their different perspectives.*

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

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

(2) **Focused Reviews.** Focused Reviews (including, but not limited to, Peer Review for Quality Management, National Surgical Quality Improvement Program (NSQIP), Continuous Improvement Cardiac Surgical Program (CICSP), Inpatient Evaluation Center (IPEC), or VHA Quality Improvement Program (VQuIP) focused reviews), and root cause analyses (RCAs), 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 which are designated by the responsible office at the outset of the review as protected by 38 U.S.C. 5705, and its implementing regulations, are considered confidential. Focused Reviews may be conducted by facilities, VISNs, or VHA Central Office. *NOTE: If it appears during a facility Focused Review that disciplinary action may be indicated, the medical center Director must determine if the Focused Review needs to be terminated and a Board of Investigation, whose findings can be the basis of disciplinary actions, initiated.* 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). QUIC is a data system comparing VA medical facilities on key clinical indicators. QUIC is in operation at some, but not all, VA health care facilities.

(b) National Comparative Performance Analyses. National Comparative Performance Analyses are 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 quality management purposes. Programs generating such analyses include the Performance Measurement Program and the NSQIP, CICSP, IPEC and VQuIP. **NOTE:** *Other national comparative performance analyses concern mortality on medical and psychiatric units, decubitus ulcers, and functional assessment of the patient. 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 quality management documents and data includes, but is not limited to: adverse drug reaction reports, reports of adverse events, and close calls.

(d) Root Cause Analysis (RCA). 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.

1. An RCA 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; and

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. The 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, and is commonly referred to as an aggregated review.

(e) Patient Safety Registry (PSR) and Patient Information System. The PSR and Patient Safety Information System is a central database that is used to report and monitor individual adverse events involving patients treated by VHA in VHA facilities.

1. 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; and

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

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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) **General Oversight Reviews.** VHA Central Office or VISN general oversight reviews to assess facility compliance with VA clinical program requirements, if the reviews are designated by the reviewing office at the outset of the review as protected by 38 U.S.C. 5705 and its implementing regulations.

(4) **External, Clinically-Oriented Reviews.** External, clinically-oriented reviews of care specifically designated in the contract or agreement as reviews protected by 38 U.S.C. 5705, and its implementing regulations (e.g., External Peer Review Program (EPRP)).

(5) **Clinical Education Program Accreditation Reviews.** All education programs conducted in VA must be accredited by the nationally-recognized accreditation body, i.e., the Accreditation Council for Graduate Medical Education (ACGME), or those organizations listed in the Department of Education's Office of Postsecondary Education listing of "National Institutional and Specialized Accrediting Bodies" (see Web site: www.ed.gov/admins/finaid/accred/accreditation_pg8.html). 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. Ensuring that patient representation programs cannot generate confidential documents.

NOTE: If a study or review following up a patient complaint needs to be confidential, it needs to be designated as a focused review.

c. Indicating on confidential QM documents created after the publication of the revised regulations that the document is confidential under 38 U.S.C. 5705, and its implementing regulations. The specific QM activity under which the document is included must be designated.

NOTE: The activity names used are to be from this Directive or from a VISN or facility policy document that describes additional QM activities that can generate confidential documents.

(1) The following statement is recommended, but not required for this purpose: “These documents or records, or information contained herein, which resulted from (name of specific QM program or activity), are confidential and privileged under the provisions of 38 U.S.C. 5705, and its implementing regulations. This material can not be disclosed to anyone without authorization as provided for by that law or its regulations. *NOTE: The statute provides for fines up to \$20,000 for unauthorized disclosures.*”

(2) The use of the disclosure, or a similar statement, is helpful in retrospectively identifying confidential documents. However, the statement by itself does not ensure confidentiality of a document. Documents which meet the requirements in 38 U.S.C. 5705, and its implementing regulations are confidential even if no such statement is present; similarly, the use of the disclosure statement does not protect documents which do not qualify under 38 U.S.C. 5705, and its implementing regulations.

d. Providing the level of protection reasonably necessary to ensure that access to and disclosure of documents, including electronic documents containing information protected by 38 U.S.C. 5705, occurs only as authorized by that statute and its implementing regulations. *NOTE: The manner in which this protection is to be provided is no longer specified by the confidentiality regulations.*

5. REFERENCES: Title 38 U.S.C. 5705.

6. FOLLOW-UP RESPONSIBILITIES: Chief, Office of Performance and Quality (10Q), is responsible for the contents of this Directive. Questions may be addressed to (202) 266-4533.

7. RESCISSION: VHA Directive 2004-051 is rescinded. This VHA Directive expires November 30, 2013.

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