

**Memorandum of Understanding (MOU) for the
VA Portland Health Care System between
Department of Veterans Affairs, Portland Healthcare System (VAPORHCS) and
American Federation of Government Employees (AFGE), AFL-CIO
National VA Council 53, AFGE Locals 2157 and 2583**

The following constitutes an agreement between the [parties] of the VA Portland Health Care System (VAPORHCS) [Portland/Vancouver Divisions] within VISN 20, and the American Federation of Government Employees (AFGE), AFL-CIO, National VA Council #53 (NVAC), AFGE Local 2157 & AFGE Local 2583, the parties have reviewed and agreed upon the appropriate arrangements and procedures regarding the MCM 00-29 Quality Safety & Management and Patient Safety Activities that can Generate Confidential Documents.

Both Management and the Union reserve the right to re-open bargaining in this MOU by providing a minimum of 30 days advance written notice requesting negotiation. The terms of this MOU will remain in place until any new updates are agreed upon.

Donald Fowler
NVAC 11th District Representative
Chief Negotiator, Labor

Donald L Fowler

Date: 1/9/2020

Joann Badget
Chief of Quality Safety & Management
Chief, Spokesperson for the Agency

Joann Badget

Date: 1/9/2020

Denise L. Lieb
President AFGE Local 2583

Denise L. Lieb

Date: 1/9/2020

Marcia Blaine
President AFGE Local 2157

Marcia Blaine

Date: 1-9-20

VA Portland Health Care System (VAPORHCS)
Portland Oregon

VAPORHCS Policy No. 00-29

August 2019

**QUALITY MANAGEMENT AND PATIENT SAFETY ACTIVITIES
THAT CAN GENERATE CONFIDENTIAL DOCUMENTS**

- I. **PURPOSE:** To list and describe Quality Management (QM) and Patient Safety activities that can generate confidential documents under Title 38 United States Code (U.S.C.) Section 5705 and its revised implementing regulations. This memorandum provides guidance for VA Portland Health Care Systems (VAPORHCS) implementing VHA regulations for creating and protecting confidential documents.
- II. **POLICY:** Documents that meet the requirements in 38 U.S.C. 5705, and its implementing regulations, will be confidential.
 - A. The activity that generated the information must have been conducted by or for the Department of Veterans Affairs to improve the quality of health care or the utilization of resources.
 - B. The activity that generated the document must have been previously designated in writing as a QM activity that can produce confidential documents. A list of core activities at all VA medical facilities that can generate protected records is found in Attachment A. VISN Directors and Medical Center Directors can supplement this list for facilities under their control.
 - C. The document must meet one of the following conditions:
 1. The document identifies either implicitly or explicitly, individual practitioners, patients, or reviewers; or
 2. The document 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.
 - D. The activity that generated the document must be performed by a staff member of the VA medical facility where the document was generated, or there must have been written designation of the role of individuals who are not staff at the facility in performing the review.
 - E. The description of a QM activity in this policy does not mean all documents resulting from the activity are confidential. It is necessary that the requirements are 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

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confidential. Consequently, most documents resulting from some activities described in this policy, such as process action teams, will not be confidential. A list of activities that do not generate confidential documents is found in Attachment B.

III. **RESPONSIBILITIES:**

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

1. Describing in advance, in writing, those QM activities which generate confidential records;
2. Ensuring patient representation programs cannot generate confidential documents. **NOTE:** *If a study or review on a patient complaint needs to be confidential, it has to be designated as focused review;*
3. 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 VHA Directive 2008-077 that describes additional QM activities that can generate confidential documents; and*
 - a. 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 shall not be disclosed to anyone without authorization as provided for by law or its regulations. The statute provides for fines up to \$20,000 for unauthorized disclosures;" and
 - b. 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 document which do not qualify as confidential.
4. Providing the level of protection reasonably necessary to ensure that access to and disclosure of documents protected by 38 U.S.C. occurs only as authorized by that statute and its implementing regulations.

B. All **managers and supervisors** are responsible for implementing the requirements in this MCM as applicable to their scope of activities.

- C. The **Chief, Quality, Safety & Value Service (QSV)** will revise this policy as needed and provide consultation and education to VAPORHCS staff regarding policies and procedures.
- D. **All individuals** who have access to confidential quality management and patient safety documents are responsible for maintaining the confidentiality of these documents. Individuals 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 the VA or after voluntary or involuntary termination of their relationship with the VA.

IV. **REFERENCES:**

- A. Title 38 USC 5705 (Confidentiality of Medical Quality-assurance Records)
- B. 38 CFR Part 17 (Confidentiality of Healthcare Quality Assurance Reviews)
- C. VHA Directive 2008-077, Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents

- V. **RESCISSION:** MCM 00-29, Quality Management (QM) Activities That Can Generate Confidential Documents, dated August 27, 2014.

- VI. **FOLLOW-UP RESPONSIBILITY:**
Director, Quality, Safety & Value Service
Review Date: August 31, 2024

- VII. This policy will remain in effect until rescinded.

DARWIN G. GOODSPEED, FACHE
Director

Attachments: 2

A: Designated Quality Management and Patient Safety Activities that can Generate Records Protected by 38 USC 5705 and its Implementing Regulations

B: Quality Management and Patient Safety Documents that are NOT Confidential

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Attachment A

Designated Quality Management and Patient Safety Activities that can Generate Records Protected by 38 USC 5705 and its Implementing Regulations

A. Definition of Activities Designated by the Under Secretary for Health for all VA Facilities	
Monitoring and Evaluation Reviews	
a. Tort Claim Peer Reviews	This is the review of care provided in cases when malpractice claims have been filed to identify, evaluate and, where appropriate, correct circumstances having potential to adversely affect the delivery of care. [Note: Peer reviews conducted entirely for other purposes, such as representing 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).	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. There needs to be prior written designation of the role of non-VA practitioners from affiliated facilities who attend Morbidity and Mortality conferences if documents from these conferences are to be confidential. 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 that is specified in advance in a policy document from the Under Secretary of Health, VISN Director or facility Director. Cases that involve one or more occurrences are reviewed to identify possible problems in patient care. Cases meeting the criteria may be entered into ongoing occurrence screening database to be reviewed and analyzed regularly to identify patterns that may be problematic.
d. Drug Usage Evaluation (Including Adverse Drug Event Reports).	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

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	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	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 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. Evaluations of transfusion errors and reactions are included.
i. Adverse Event and Close Call Reporting	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 QSV Service by initiating a Special Incident Report. Examples of adverse events that require review and reporting are included in VHA Handbook 1050.1, VHA National Patient Safety Improvement Handbook. VA Form 10-2633, Report of Special Incident Involving a Beneficiary, or similar forms and follow-up documents (Root Cause Analysis, Focused Review) are confidential or privileged unless developed during or as a result of a Board of Investigation. Confidential documents, such as Reports of Special Incidents, RCAs, and/or focused review that lead to a Board of Investigation retain their confidential status even though documents resulting from Board of Investigations are not confidential.
j. Infection Control Reviews	Surveillance activities to identify and monitor the rate of nosocomial infections.
k. Service and 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

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	services reviewing the same care from their different perspectives.
I. Autopsy Review	The comparison of pre-mortem diagnosis and diagnostic assessment procedures with post-mortem diagnosis and other autopsy findings to assess diagnostic accuracy. This review may be performed at a Morbidity and Mortality Conference or in other settings.
m. Performance Improvement Teams	Multidisciplinary teams established to perform in-depth study of the processes involved in providing clinical services. They are also known as process action teams and are usually part of the facility's QM program.
Focused Reviews of Specific Issues or Incidents	
Focused Review (Peer Review for quality management, VA Surgical Quality Improvement Program (VASQIP), Inpatient Evaluation Center (IPEC), and Root Cause Analysis (RCA), etc.)	<p>Focused Reviews are designated, at the outset of the review, as protected by 38 U.S.C. 5705 and its implementing regulations. These reviews address specific issues, usually of major consequences to patient care processes and outcomes, or specific incidents (usually involving a discrete episode of care). Facilities, VISNs, or VHA Headquarters may conduct Focused Reviews.</p> <p>NOTE: The Director must determine if a focused review should be terminated and a Board of Investigation (BOI) initiated if it appears during a Focused Review that disciplinary action may be indicated. BOI findings can be the basis for disciplinary actions.</p>
VHA Headquarters or VISN Focused Reviews Involving Comparisons of Facilities and/or VISNs to each Other on Key Indicators of Quality Care. These are:	
b. National Comparative Performance Analysis	<p>Data analyses describing an individual facility's or VISN's performance on key indicators of care relative to other facilities. Analyses are based on national administrative databases, such as the Patient Treatment File (PTF) or data collected specifically for quality management purposes.</p> <ol style="list-style-type: none"> 1. Performance measurement system. 2. VASQIP 3. IPEC (Inpatient Evaluation Centers). 4. Occurrence of Decubitus Ulcers
c. VISN & VHA Headquarters trending & analysis of facility QM documents and data.	<p>These include:</p> <ol style="list-style-type: none"> 1. Patient incident and safety reports, tracking documents, trending databases, aggregated reports, etc. 2. Reports of patient abuse events.

<p>d. Root Cause Analysis (RCA)</p>	<p>A process for identifying the basic or contributing factors that underlie variation in performance associated with adverse clinical events or close calls. RCA may include reviews of several similar events such as medication errors to derive common causal factors and solutions. Also called an aggregated review. Facilities, VISNs, or VHA Headquarters may conduct RCAs.</p> <p>NOTE: The Director should determine if an RCA should be terminated and a Board of Investigation (BOI) initiated if it appears during a RCA that disciplinary action may be indicated. BOI findings can be the basis for disciplinary actions.</p>
<p>e. Patient Safety Registry and Patient Information System</p>	<p>A central database that is used to report and monitor individual adverse events involving patients treated by VA facilities. There may be facility, VISN and national components.</p>

VHA Headquarters or VISN General Oversight Reviews

These reviews are conducted to assess facility compliance with VA clinical program Requirements.

NOTE: These reviews will be considered confidential & protected if they are designated by the reviewing office at the time of the onset of the review as protected by 38 U.S.C. 5705 and its implementing regulations.

External, Clinically Oriented Reviews of Care

<p>External Peer Review Program (EPRP)</p>	<p>Specifically designated in the contract or agreement as reviews protected by 38 U.S.C. 5705 and its implementing regulations.</p>
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Clinical Education Program Accreditation Reviews

<p>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 website: www.ed.gov/admins/finaid/accred/accreditation_pg8.html)</p>	<p>The information in education program accreditation review reports is used to correct any identified shortcomings of VHA training programs and ensures that appropriate improvements are instituted.</p>
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Follow-up Reviews (Focused Reviews) of a Patient Complaint

Patient Representative Programs cannot generate confidential documents, and should not be included among the designated list of QM activities that can generate confidential documents in a facility or VISN policy document. However, if a study or review based on a patient complaint needs to be confidential it should be designated as a "focused review" on the documents under 38 U.S.C. 5705 and its implementing regulations.

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