

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

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive lists Quality Management (QM) activities that can generate confidential records and documents under Title 38 United States Code (U.S.C.) § 5705 and its implementing regulations and describes related VHA responsibilities to ensure confidential records and documents are properly marked and secured in accordance with VHA policy.

2. SUMMARY OF MAJOR CHANGES: This directive:

a. Clarifies the criteria that must be met for documents to become confidential and privileged under 38 U.S.C. § 5705 and its implementing regulations;

b. Updates the list of some QM activities designated by the Under Secretary for Health; and

c. Updates the description of related responsibilities within VHA (see paragraph 5) to ensure confidential records and documents are properly marked and secured per VHA policy.

3. RELATED ISSUES: VHA Directive 1190, Peer Review for Quality Management, dated November 21, 2018; VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016; VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011; and VHA Directive 1907.08, Health Care Information Security Policy and Requirements, dated April 30, 2019.

4. RESPONSIBLE OFFICE: The Assistant Under Secretary for Health for Quality and Patient Safety (10E) is responsible for this VHA directive. Questions may be referred to the Clinical Risk Management Program Office at 202 643-1101.

5. RESCISSIONS: VHA Directive 2008-077, Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents, dated November 7, 2008, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of July 2020. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

July 10, 2020

VHA DIRECTIVE 1320

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Gerard R. Cox, M.D., MHA
Assistant Under Secretary for Health
for Quality and Patient Safety

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List July 10, 2020.

CONTENTS

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

1. PURPOSE..... 1

2. BACKGROUND 1

3. DEFINITIONS 1

4. POLICY 2

5. RESPONSIBILITIES 2

6. TRAINING 5

7. RECORDS MANAGEMENT..... 5

8. REFERENCES..... 5

APPENDIX A

CRITERIA FOR A QUALITY MANAGEMENT RECORD OR DOCUMENT TO BE
CONFIDENTIAL.....A-1

APPENDIX B

VHA QUALITY MANAGEMENT DOCUMENTS AND RECORDS THAT MEET
CRITERIA TO BE CONFIDENTIAL.....B-1

APPENDIX C

VHA QUALITY MANAGEMENT DOCUMENTS AND RECORDS THAT ARE NOT
CONFIDENTIAL..... C-1

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

1. PURPOSE

This Veterans Health Administration (VHA) directive lists Quality Management (QM) activities and relevant criteria that can generate confidential records and documents. This directive also describes related VHA responsibilities. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 5705, 7301(b); Title 38 Code of Federal Regulations (C.F.R.) § 17.500 - 17.511.

2. BACKGROUND

a. Records and documents created by the Department of Veterans Affairs (VA) as part of a medical quality-assurance program are confidential and privileged and must not be disclosed to any person or entity except under limited circumstances as authorized by 38 U.S.C. § 5705 and its implementing regulations. The regulations implementing Section 5705 require the Under Secretary for Health, Veterans Integrated Service Network (VISN) Director or VA medical facility Director to describe in advance and in writing those quality assurance activities that generate confidential records and documents under 38 U.S.C. § 5705 and its implementing regulations. **NOTE:** “VISN” and “VISN Director” in this directive are the equivalent of the terms “Regional” and “Regional Director” used in 38 C.F.R. § 17.500 through 17.511.

b. Multiple other requirements must also be met for a QM record or document to be confidential under 38 U.S.C. § 5705. Many of the requirements are described in 38 C.F.R. § 17.500, 17.501 (a), (b), (c) and (g), and are summarized in Appendix A.

3. DEFINITIONS

a. **Confidential Information.** Confidential information is information, in paper or electronic format, that is to be maintained as private by not sharing or divulging it to a third party unless that party is privileged or has the authority to be entrusted with the information.

b. **Focused Reviews.** Focused reviews are clinical reviews which address specific issues, specific incidents or specific quality of care concerns. These reviews must be designated by the responsible office at the outset of the review as confidential and privileged under 38 U.S.C. § 5705.

c. **Privileged Documents.** Privileged documents are a private record or communication that the law exempts a person from revealing to another party.

d. **Quality Assurance.** Quality assurance is any activity carried out as a systemic health care review activity designated by the Secretary of VA to be carried out for the purpose of improving the quality of medical care or improving the utilization of health care resources in VA health care facilities. The terms “quality management,” “quality improvement,” and “quality assurance” are used interchangeably in this directive and

may include patient safety activities. Quality assurance is used as a synonym for quality management in the 38 U.S.C. § 5705 implementing regulations.

4. POLICY

It is VHA policy that only VHA documents which meet the requirements in 38 U.S.C. § 5705 and its implementing regulations are to be considered confidential and privileged QM documents (see Appendix B for these requirements). Records and documents that meet the requirement, must be protected and secured in accordance with VHA policies included in this directive.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Determining the designees permitted to make decisions consistent with criteria outlined in Appendix A regarding:

(a) Access to protected information within VHA; and

(b) Disclosure requests permitted by law to be made by the Under Secretary for Health or a designee.

b. **Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health is responsible for:

(1) Continuously reviewing compliance with this directive.

(2) Overseeing the designation process of the Assistant Under Secretary for Health for Operations related to VHA quality assurance activities.

(3) Ensuring that all VHA program offices determine which of their activities meet the QM criteria and are designated as protected.

(4) Ensuring that the required designations outlined in Appendix A are completed in advance of the activities.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Providing assistance to VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards and applicable regulations.

(4) Designating which VHA activities are to be included under the classes of health care quality assurance reviews, which are outlined in Appendix B.

d. **Assistant Under Secretary for Health for Quality and Patient Safety.** The Assistant Under Secretary for Health for Quality and Patient Safety is responsible for ensuring VHA program offices, VISNs and VA medical facilities receive guidance to comply with this directive. This includes:

(1) Providing guidance to VHA program offices, VISNs and VA medical facilities regarding:

(a) The status of national VHA program office QM activities;

(b) Consultation with the VHA Office of Quality and Patient Safety and the VA Office of General Counsel when proposing new QM activities to ensure that only activities meeting the legal criteria are designated as 38 U.S.C. § 5705-protected and to facilitate tracking of designated QM activities; and

(c) The protections required by VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016 and VHA Directive 1907.08, Health Care Information Security and Requirements, dated April 30, 2019 regarding storage, access and disclosure for information and protections for documents and related electronic data.

(2) Facilitating communication between the VHA Office of Quality and Patient Safety, VHA Privacy and Freedom of Information Act (FOIA) Offices and VA Office of General Counsel to ensure the proper application of statutory and regulatory protections for information generated by QM activities in VHA.

e. **Directors of VHA Program Offices.** The Directors of VHA program offices are responsible for determining which of their QM activities must be designated as protected and ensuring that the required designations outlined in Appendix A are completed in advance of the activities.

f. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Determining which VISN-specific QM activities are to be included in health care quality assurance reviews and designating them in writing prior to beginning the activity, as outlined in Appendix A.

(3) Ensuring that all VHA policies regarding designations of focused reviews at the outset of those reviews are followed, including completion, content and filing of those designations.

(4) Determining designees permitted to make decisions regarding authorized access to protected information within the VISN as well as disclosure requests permitted or required by law to be made by the VISN Director.

(5) Ensuring that the status of all QM activities has been communicated and appropriately implemented within the VISN, including the protections required by VHA Directive 1605.01 and VHA Directive 1907.08 regarding storage, access and disclosure of protected information.

(6) Ensuring that questions regarding the jurisdiction of VISN policies are consistent with statutory and regulatory protections for information generated by QM activities in VHA, this directive and any other national policy documents.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Determining which VA medical facility-specific QM activities are to be included under health care quality assurance reviews and designating them in writing prior to beginning the activity, as outlined in Appendix A.

(2) Ensuring that applicable VHA policies regarding designations of focused reviews at the outset of those reviews are followed, including the assigned staff responsible for completion, content and filing of those designations.

(3) Determining designees permitted to make decisions regarding authorized access to protected information within the VA medical facility and disclosure requests permitted or required by law to be made by the VA medical facility Director.

(4) Ensuring that the status of all QM activities has been communicated and appropriately implemented within the VA medical facility, including the protections required by VHA Directive 1605.01 and VHA Directive 1907.08 regarding storage, access and disclosure for protected information.

(5) Ensuring that relevant VA medical facility operations are consistent with statutory and regulatory requirements, this VHA directive and VHA Directive 1605.01 regarding storage, access and disclosure of protected information.

h. **Assigned VA Employees.** VA medical facility, VISN and VHA Central Office employees assigned to coordinate QM activities that may produce confidential documents are responsible for:

(1) Coordinating, managing, overseeing and ensuring completion of the project that is under their purview.

(2) Filing and storing a quality assurance designation memorandum or referring it to the appropriate QM staff member.

(3) Maintaining all records related to VA medical facility QM activities in accordance with the VA Records Control Schedule 10-1.

6. TRAINING

There are no mandatory training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be referred to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. 38 U.S.C. § 5705.
- b. 38 C.F.R. § 17.500 -17.511.
- c. VHA Directive 1190, Peer Review for Quality Management, dated November 21, 2018.
- d. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.
- e. VHA Directive 1907.08, Health Care Information Security and Requirements, dated April 30, 2019.
- f. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.
- g. The Council for Higher Education Accreditation Web site as a National Accrediting Body in a Health Profession, available at: <http://www.chea.org>.
- h. The Department of Education's Office of Postsecondary Education listing of "National Institutional and Specialized Accrediting Bodies," available at: http://www.ed.gov/admins/finaid/accred/accreditation_pg8.html.

**CRITERIA FOR A QUALITY MANAGEMENT RECORD OR DOCUMENT TO BE
CONFIDENTIAL**

1. The records or documents must have been produced by or for the Department of Veterans Affairs (VA) in the process of conducting systematic health care reviews for improving the quality of health care or the utilization of health care resources in VA medical facilities.

2. The individual(s) authorized to designate an activity as protected must do so in writing prior to beginning the activity. It is important to note that two different advance designations are required for many Quality Management (QM) activities:

a. **Designation required for all QM activities.** Prior to beginning QM activities, the Under Secretary for Health must describe in writing QM activities included under the four classes/categories of health care quality assurance reviews listed in Title 38 Code of Federal Regulations (C.F.R.) § 17.501(a), monitoring and evaluation reviews conducted by a facility, focused reviews that address specific issues or incidents, VA Central Office or Regional (VISN) program reviews and contracted external reviews of care. See Appendix B for further detail. This designation will be written by the Under Secretary for Health for any QM activity conducted within the Veterans Health Administration (VHA). Inclusion of the activity in this directive or in another VHA Central Office, Veterans Integrated Service Network (VISN) or VA medical facility policy satisfies this requirement that the category of activity must be designated. Documents generated by a QM activity designated as protected in VHA policy that has expired or been rescinded remain confidential and privileged.

b. **Additional designation required for many QM activities.** In addition to ensuring that the advance designation for the class or category of QM activity described in paragraph 2.a. of this appendix is in place, the reviewing office must also designate the following types of QM reviews at the outset and before conducting each individual review:

(1) VA medical facility, VHA Central Office or VISN focused reviews addressing specific issues or incidents and

(2) VHA Central Office or VISN general oversight reviews to assess VA medical facility compliance with VHA program office requirements.

NOTE: Designation documents themselves are not confidential. They must not contain any confidential details about the issue(s) or individuals that will be the subject of the review. The designation document is potentially discoverable; therefore, it should not identify the reviewers. The designation document must contain only a general statement explaining whether the activity is being done for improving the quality of medical care or improving the utilization of health care resources in VA medical facilities; and that the activity is being designated by the reviewing office at the outset of the review. The designation document(s) must be filed together with the QM

documents, so they are readily available to enable VA to validate the QM confidentiality of the document for any reason.

3. Contracted external reviews of care require an additional designation; the contract must specify that the reviews are protected by Title 38 United States Code (U.S.C.) § 5705 and the implementing regulations in 38 C.F.R. § 17.501 through 17.511.

4. A document or record must also meet at least one of the following conditions to be confidential and privileged:

a. The document or record identifies, either implicitly or explicitly, individual practitioners, patients or reviewers;

b. The document or record contains discussions relating to the quality of VHA medical care or to the utilization of VHA medical resources by health care evaluators during a review of quality assurance information or data even if they do not identify practitioners, patients or reviewers;

c. The document or record consists of individual committee, service or study team minutes, notes, reports, memoranda or other documents either produced by health care evaluators in deliberating on the findings of health care reviews or prepared for purposes of discussion or consideration by health care evaluators during a quality assurance review;

d. The document or record consists of memoranda, letters or other documents from the VA medical facility to the VISN Director or VHA which contain information generated by a quality assurance activity meeting the criteria in the regulations; or

e. The document or record consists of memoranda, letters or other documents produced by the VISN Director or VHA which either respond to or contain information generated by a quality assurance activity meeting the criteria in the regulations.

5. In general, if it is determined prior to or during the course of a 38 U.S.C. § 5705-protected QM activity that a non-QM management review that may result in any type of personnel action is indicated (e.g., a focused clinical care review, Administrative Investigation (AI), Focused Professional Practice Evaluation (FPPE)), terminate the QM activity. Individuals who participated in the QM activity must not participate in the management review to ensure that the confidentiality of the 38 U.S.C. § 5705-protected activity is appropriately maintained and that the perception of the integrity of the process is preserved. If a protected QM activity must be terminated and a management review initiated, the appropriate manager is to be informed only that a matter is being referred for management review. Only the initial report or summary of the occurrence can be communicated to ensure there is a distinct separation of the protected and non-protected processes. Any information gathered or used in relation to a management review, including use for any type of personnel action, must be obtained independent of

any QM review(s). VA must not use information generated as a result of a QM review for personnel purposes.

6. When confidential QM documents are disclosed by the VA medical facility Director, VISN Director, Under Secretary for Health or their designees as permitted by law to authorized individuals, whether within or outside VA, the regulations require that they 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 and its implementing regulations at C.F.R. § 17.500 through 17.511, which provide for fines up to \$20,000 for unauthorized disclosures thereof. This material shall not be disclosed to anyone without authorization as provided for by that law or the implementing regulations.” **NOTE:** *Routinely labeling confidential QM documents with this statement is encouraged, as it is helpful in retrospectively identifying them as protected and for alerting individuals that it is a protected QM document. However, documents that meet QM requirements are confidential even if no such statement is present. Similarly, the label does not protect documents that do not qualify for QM protection.*

**VHA QUALITY MANAGEMENT DOCUMENTS AND RECORDS THAT MEET
CRITERIA TO BE CONFIDENTIAL**

1. The activities listed below, as well as all other Veterans Health Administration (VHA) Quality Management (QM) activities determined to meet QM requirements, are included under the classes of health care quality assurance reviews that are confidential and privileged under Title 38 United States Code (U.S.C.) § 5705 and its implementing regulations. The following is not an exhaustive list; other quality assurance activities may have been or will be designated in other VHA policy documents and memoranda. An additional advance designation memorandum at the outset of the review is not required for the following monitoring and evaluation reviews under paragraph 1.a. of this Appendix.

a. **Monitoring and Evaluation Reviews.** Monitoring and evaluation reviews conducted by a Department of Veterans Affairs (VA) medical facility include, but are not limited to:

(1) **Tort Claim Peer Reviews.** The requirements for this QM activity are found in VHA Directive 1190, Peer Review for Quality Management, dated November 21, 2018. A Tort Claim Peer Review is a type of Peer Review for Quality Management conducted in cases in which a malpractice claim has been filed; VHA initiates these reviews for quality management to identify, evaluate, and, where appropriate, correct circumstances having the potential to adversely affect the delivery of care. **NOTE:** *Medical Advisory Opinions (MAOs) requested by Office of General Counsel staff to assist in the defense or consideration of settlement of a tort claim; reviews obtained for determining whether to grant or revoke privileges; and other reviews conducted entirely for purposes other than quality management are not covered by this designation. Other confidentiality protections may apply to MAOs and other management reviews, but they are not confidential under 38 U.S.C. § 5705.*

(2) **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 but may also have other names (e.g., “patient safety case conferences”). Activities which involve preliminary reviews of care to provide material for consideration at Morbidity and Mortality Conferences are included.

(3) **Occurrence Screening.** Occurrence Screening is the evaluation of episodes of care against a list of specified criteria. 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.

(4) **Drug Usage Evaluations.** Drug Usage Evaluations are reviews to assess the safety, appropriateness and effectiveness of drugs ordered for VA patients. The dose, route and time schedule chosen are often reviewed, as well as the drug selected. Adverse drug event reports are included.

(5) **Utilization Reviews.** Utilization Reviews 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.

(6) **Surgical Case/Invasive Procedure Reviews.** The Surgical Case/Invasive Procedure Reviews include but are not limited to reviews that assess 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.

(7) **Medical Records Reviews.** The Medical Records Review assesses the adequacy of medical record documentation by clinical staff regarding completeness, timeliness and clinical pertinence.

(8) **Blood Usage Reviews.** 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. Evaluations of transfusion errors and reactions are included.

(9) **Adverse Event and Close Call Reporting.** Adverse Event and Close Call Reporting (also known as “event reports,” “safety reports,” “incident reports,” “electronic patient [incident] or [event] reports (e-PIR, e-PER),” “JPSR,” and by other names) 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 VA medical facility, as stated in VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011. Adverse Event and Close Call Reports also include Reports of Special Incidents and follow-up documents unless developed during or as a result of a Board of Investigation.

(10) **Infection Control Review and Surveillance.** Infection Control Review and Surveillance activities are conducted to prevent, identify and monitor the rate of health care associated infections.

(11) **Service and Program Monitoring Including Multi-Disciplinary Monitoring.** Service and Program Monitoring are processes used by clinical services and programs that involve indicators to monitor the quality of care. This may include monitoring performed by individual services or programs, several services or programs working

together or individuals from several services or programs working together as a team. The findings from these indicators are 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.*

(12) **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.

b. **Focused Reviews.** Focused Reviews which address specific issues or specific incidents, and which are designated by the responsible office at the outset of the review are confidential and privileged. An additional designation must be documented by the reviewing office at the outset of each individual or ongoing review for all the activities in this category. Focused Reviews may be conducted by assigned staff within VA medical facilities, VISNs or VHA Central Office. VHA Central Office or VISN Focused Reviews may involve comparison of facilities relative to each other on key indicators of quality of care. **NOTE:** *“Focused review” is the terminology used in implementing regulations. It should not be confused with other activities that may use the same name, but which are not conducted for QM purposes.* Focused reviews protected under 38 U.S.C. § 5705 include but are not limited to:

(1) **Peer Review for Quality Management.** The requirements for QM coverage of this activity are found in VHA Directive 1190. Peer Review for Quality Management is an organized process carried out by an individual health care provider or by an external contractor to evaluate the performance of other professionals for evaluating, monitoring and improving the quality of care. Peer Review for Quality Management must make a fair and credible assessment of the actions taken by the provider relative to the episode of care under review. The requirement for an additional designation by the reviewing office at the outset of the individual review must be satisfied by a designation memorandum completed by the VA medical facility Director or designee stating that the review is protected under 38 U.S.C. § 5705 and its implementing regulations; the designation may be combined with the document sent to the reviewer that directs the reviewer to conduct a Peer Review for Quality Management.

(2) **Other National Comparative Performance Analyses.** National comparative performance analyses are data analyses describing an individual VA medical facility's or VISN's performance on key indicators of care relative to other VA medical facilities or VISNs. The analyses are based on national administrative databases or data collected specifically for quality management purposes.

(3) **Trending and Analysis.** VHA and VISN trending and analysis of VA medical facility quality management documents and data include adverse drug reaction reports, reports of adverse events and close calls.

NOTE: *Purely statistical information that does not explicitly or implicitly identify an individual is not covered by 38 U.S.C. § 5705. See Appendix C.*

(4) **Root Cause Analysis.** Root cause analysis (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.

(a) An RCA investigates events and activities, gathers and manipulates data, and examines and reviews VHA care delivery activities in order to:

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

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

(b) RCA usually involves:

1. The gathering and examination of patient-specific and provider-specific data.

2. Analysis and coordination between and among the VA medical facility, VISN and VHA program offices.

(c) 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.

(5) **Patient Safety Registry and Patient Information System.** The Patient Safety Registry (PSR) and Patient Safety Information System is a central database that is used to report and monitor individual adverse events involving patients treated by health care providers in VA medical facilities.

(a) VA medical facility, VISN and VHA program office components investigate, examine and analyze an event reported to the database in order to:

1. Identify basic or contributing causal factors that resulted in the adverse event; and

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

(b) The data usually involves:

1. Gathering and examination of patient-specific data.

2. Analysis and coordination of reported events at and between the VA medical facility, VISN and national levels.

(c) Analysis of data may involve a review of similar events from different VA medical facilities in order to derive common causal factors and solutions.

c. **General Oversight Reviews.** VHA or VISN general oversight reviews to assess VA medical facility compliance with VHA clinical program requirements are confidential and privileged if the reviews are designated by the reviewing office at the outset of the review as protected. An additional designation must be documented by the reviewing office at the outset of each individual or ongoing review for all of the activities in this category.

d. **External, Clinically Oriented Reviews.** External, clinically oriented reviews of care must be specifically designated in the contract or agreement as reviews protected by 38 U.S.C. § 5705 and its implementing regulations. External, clinically oriented reviews of care include but are not limited to:

(1) **External Peer Review Program.** External Peer Review Program (EPRP) is a VHA-wide program administrated by VHA Central Office, designated to measure and report quality of care as specified by VHA and external accrediting organizations, such as The Joint Commission. De-identified and aggregated data is publicly reported for accreditation and informative purposes.

(2) **External Peer Review Contract.** VHA Central Office, VHA Office of Quality and Patient Safety maintains a contract to provide external reviews. The protected external reviews provided under this contract include but are not limited to:

(a) Audit reviews, which are a secondary review of a national sample of completed Peer Reviews for Quality Management; and

(b) VA medical facility-requested reviews, which serve as initial review in a VA medical facility's Peer Review for Quality Management program.

NOTE: *The provisions of 38 U.S.C. § 5705 and its implementing regulations apply to the contractor in the same manner as they apply to VA employees and peer review data gathered by VA employees.*

e. **Clinical Education Program Accreditation Reviews.** Nearly all education programs conducted in VA must be accredited by a nationally recognized accreditation body, i.e., the Accreditation Council for Graduate Medical Education (ACGME) for graduate medical education. Other authorized education accrediting bodies may be found at the Department of Education's Office of Postsecondary Education listing of "National Institutional and Specialized Accrediting Bodies" (see website: http://www.ed.gov/admins/finaid/accred/accreditation_pg8.html) or are listed at the Council for Higher Education Accreditation website as a National Accrediting Body in a Health Profession (<http://www.chea.org>). Regional accrediting bodies are not sufficient for the clinical health professions in VHA. These external review bodies have processes for initial and ongoing accreditation of their respective educational training programs.

July 10, 2020

**VHA DIRECTIVE 1320
APPENDIX B**

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.

**VHA QUALITY MANAGEMENT DOCUMENTS AND RECORDS THAT ARE NOT
CONFIDENTIAL**

The following items are not confidential under Title 38 United States Code (U.S.C.) § 5705, even if they otherwise meet the criteria outlined in Appendix A:

- 1.** Statistical information regarding Department of Veterans Affairs (VA) health care programs or activities that does not implicitly or explicitly identify individual VA patients, VA employees or individuals involved in the quality assurance process;
- 2.** Summary documents or records which only identify study topics, the period of time covered by the study, criteria, norms or major overall findings but which do not identify individual health care practitioners even by implication;
- 3.** The contents of Credentialing and Privileging folders;
- 4.** Records and documents developed during or as a result of Boards of Investigations;
- 5.** Completed patient satisfaction survey questionnaires and findings from patient satisfaction surveys;
- 6.** Records and documents which only indicate the number of patients treated by a practitioner, either by diagnosis or in aggregate, or number of procedures performed by a practitioner, either by procedure or in aggregate;
- 7.** Records and documents developed during or as a result of reviews performed to satisfy the requirements of a governmental body or a professional health care organization which is licensing practitioners or monitoring their professional performance, e.g., National Practitioner Data Bank, Federation of State Medical Boards and National Council of State Boards of Nursing;
- 8.** Documents and reports developed during or as a result of site visits by the Office of the Medical Inspector except to the extent that the documents and reports contain 38 U.S.C. § 5705-protected information produced by or for VA;
- 9.** External reviews not designated by the reviewing office as confidential;
- 10.** Documents and reports of Professional Standards Boards, Credentialing Committees, Executive Committees of Medical Staff and similar bodies, insofar as the documents relate to the credentialing and privileging of practitioners;
- 11.** Documents and reports developed during or as a result of data validation activities;
- 12.** Documents and reports developed during or as a result of occupational health monitoring;

13. Documents and reports developed during or as a result of safety monitoring not directly related to the care of specified individual patients;

14. Documents and reports developed during or as a result of resource management activities not directly related to the care of specified individual patients; and

15. Information and records derived from patient medical records or facility administrative records, which are not protected by 38 U.S.C. § 5705 and the implementing regulations in 17.500 through 17.511, may be sent or communicated to a third party payor who has asked for this information in response to a VA request for reimbursement based on Public Law 99-272 and Public Law 101-508. Reviews conducted at the request of the third party payor do not generate records protected by 38 U.S.C. § 5705 and the implementing regulations in 17.500 through 17.511 since the reviews are not undertaken as part of the VA's quality assurance program. Patient Advocacy Program activities cannot generate confidential documents. However, a review conducted for quality management purposes after becoming aware of an issue identified as a result of a patient complaint or other non-QM activity may generate documents that meet the criteria for confidentiality.