Department of Veterans Affairs **VHA HANDBOOK 1100.18**
Veterans Health Administration **Transmittal Sheet**
Washington, DC 20420 **December 22, 2005**

REPORTING AND RESPONDING TO STATE LICENSING BOARDS

1. REASON FOR ISSUE. This revised Veterans Health Administration (VHA) Handbook contains requirements for health care facilities' procedures regarding reporting and responding to State Licensing Boards (SLBs).

2. SUMMARY OF MAJOR CHANGES. The major change is to provide for the review of non-sensitive evidence packages for compliance with information law requirements to be performed by Privacy Officers so designated by the Veterans Integrated Services Network (VISN) Director. Those cases determined to be sensitive in nature under this policy will continue to be submitted to the Deputy Under Secretary for Health for Operations and Management (10N), and for legal review by the Office of General Counsel (02).

3. RELATED ISSUES. None

4. RESPONSIBLE OFFICE. The Office of Quality and Performance (10Q) is responsible for the contents of this VHA Handbook. Questions may be addressed to 202-273-8936.

5. RESCISSIONS. VHA Handbook 1100.18, dated February 17, 2004, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for revision or recertification on or before the last working day of December 2010.

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Under Secretary for Health

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REPORTING AND RESPONDING TO STATE LICENSING BOARDS

1. PURPOSE

It is the Department of Veterans Affairs (VA) policy to cooperate with State Licensing Boards (SLBs) after VA initiates a report and whenever there is an inquiry from an SLB regarding a VA licensed health care professional, whenever possible. This Handbook sets forth policies and procedures to be carried out by Veterans Health Administration (VHA) for:

a. Reporting licensed health care professionals to SLBs as a VHA initiative;

b. Responding to SLB in response to inquiries regarding VHA licensed health care professionals.

NOTE: *Requirements for reporting to the National Practitioner Data Bank (NPDB) are outlined in the VHA Handbook 1100.17.*

2. AUTHORITY

a. VA has broad authority to report to SLBs those employed or separated health care professionals whose behavior or clinical practice so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients. The authority to report those professionals is derived from VA's long-standing statutory authority, contained in Title 38 United States Code (U.S.C.) §§ 501, 7401-7405, which authorizes the Under Secretary for Health, as head of VHA, to set the terms and conditions of initial appointment and continued employment of health care personnel as may be necessary for VHA to operate health care facilities. This authority includes requiring health care professionals to obtain and maintain a current license, registration, or certification in their health care field.

b. The Veterans Administration Health Care Amendments of 1985, Public Law 99-166, and Part B of Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986, are both Acts which authorize and require VHA to strengthen quality assurance and reporting systems to promote better health care. Pursuant to Section 204 of Public Law 99-166, VA established a comprehensive quality assurance program for reporting any licensed health care professional to SLBs who:

(1) Was fired or who resigned following the completion of a disciplinary action relating to such professional's clinical competence;

(2) Resigned after having had such professional's clinical privileges restricted or revoked; or

(3) Resigned after serious concerns about such professional's clinical competence had been raised, but not resolved.

c. The statutory provisions of 38 U.S.C. §§501, 7401-7405, augmented by Public Laws 99-166 and 99-660, provide VHA ample authority to make reports to SLBs when exercised consistent with Privacy Act requirements for release of information.

3. BACKGROUND

a. VA is responsible for ensuring that its patients receive appropriate and safe health care. Similarly, VA has an obligation to reasonably ensure that its health care staff meet or exceed generally-accepted professional standards for patient care and, as such, has the obligation to alert those entities charged with licensing health care professionals when there is serious concern with regard to a licensed health care professional's clinical practice. This obligation includes notifying SLBs of VA's concern with regard to the clinical practice of current or former professionals, and responding to inquiries from SLBs concerning the clinical practice of those professionals.

b. VA has a responsibility to protect the privacy rights of its current and former professionals in the reporting process. VA ensures such protection by conforming to the disclosure requirements of Federal information law, including the Privacy Act, when initiating disclosure or responding to inquiries from SLBs. However, the guiding principle is making patient safety the paramount consideration.

c. The rationale for reporting professionals under the continuing jurisdiction and supervisory control of VA, for deficiencies which might impact on the safety of patients in a board's jurisdiction, is as follows:

(1) Many licensed health care professionals who provide health care services to VA beneficiaries are not exclusively under the control of VA. These professionals may provide health care services to patients, other than VA beneficiaries, elsewhere under a board's jurisdiction. These professionals include part-time, intermittent, on- and off-station fee basis and full-time professionals who may be involved in health care activities outside their full-time VA employment.

(2) VA must avoid even the appearance of "sheltering" or "protecting" its professionals from reasonable reporting standards which apply in the non-VA health care community.

4. DEFINITIONS

a. **Generally-accepted Standards of Clinical Practice.** Generally-accepted standards of clinical practice are the level of ability and practice expected of competent professionals, as well as the moral and ethical behavior necessary to carry out those responsibilities.

b. **Reasonable Concern for the Safety of Patients.** Reasonable concern for the safety of patients is when, given all the circumstances, a reasonable person would be concerned for the safety of patients treated by the licensed health care professional.

c. **Licensed Health Care Professional.** A licensed health care professional is an individual appointed or utilized under 5 U.S.C. or 38 U.S.C. on a full-time, part-time, intermittent, off-station or on-station, fee basis; contract basis, or sharing agreement basis; either permanent or temporary, whether paid or without compensation, who is licensed, certified or registered in a health care profession (such as a physician, dentist, podiatrist, optometrist, chiropractor, nurse, physician assistant, expanded-function dental auxiliary,

physical therapist, practical or vocational nurse, pharmacist, social worker, occupational therapist, or certified or registered respiratory therapist). It includes licensed residents, consultants, and attendings. As used in this Handbook, the term "licensed health care professional" also refers to a licensed health care provider appointed to a position in an occupation where appointment in VA does not require licensure or certification (such as a speech pathologist, psychologist, dietitian, or audiologist). As used in this Handbook, it also refers to licensed individuals working outside their licensed occupation, such as a registered nurse appointed to a Title 5 U.S.C. position, in any organizational unit or section of VHA, including Network offices and Central Office.

d. **Licensure.** Licensure is the official or legal permission to practice in an occupation, as evidenced by documentation issued by a State in the form of a license and/or registration.

e. **Certification.** Certification is the documentation issued by a recognized health care organization or other established entity, such as a State attesting to minimum competence in a health care field.

f. **Separated Licensed Health Care Professional.** A separated licensed health care professional is any licensed health care professional no longer on VA rolls and who left VA for any reason. This includes both voluntary and involuntary reasons, including disability retirement.

g. **Currently Employed Licensed Health Care Professional.** A currently employed licensed health care professional is any licensed health care professional who is on VA rolls for the provision of health care services, regardless of the status of the professional, such as full-time, part-time, contract service, fee basis, or without compensation.

h. **Substantial Evidence**

(1) Substantial evidence is the degree of relevant evidence that permits a reasonable person to conclude that there is a solid, material basis for believing that the professional is engaged in a substandard act which created a reasonable concern for patient safety.

(2) Substantial evidence of wrongdoing is more than a mere suspicion, or uncorroborated hearsay or rumor.

(3) For SLB reporting purposes, this definition focuses more on the quality and believability of the evidence than the quantity of the evidence. Substantial evidence of wrongdoing can be present, however, even if all the evidence, taken together, would lead a reasonable person to conclude that, more likely than not, no wrongdoing occurred.

5. VA-INITIATED REPORTING OF HEALTH CARE PROFESSIONALS TO AN SLB

a. VHA facilities (and other components) must report on their own initiative (after determining, through a process defined in this Handbook, that the appropriate Privacy Act requirements have been met) each licensed health care professional whose behavior or clinical practice so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients.

b. This applies to all VHA professionals at all levels and organizational units whether or not the conduct is directly related to the provision of VA health care, and whether or not the conduct occurred while in a duty status. The report must be submitted to each SLB where the professional holds a license. The following are examples of substandard actions which would ordinarily provide a reasonable basis for a concern for the safety of patients, and as such, would be reported:

(1) Significant deficiencies in clinical practice, for example: lack of diagnostic or treatment capability; multiple errors in transcribing, administering, or documenting medications; inability to perform clinical procedures considered basic to the performance of one's occupation; or performing procedures not included in one's clinical privileges in other than emergency situations.

(2) Patient neglect or abandonment.

(3) Mental health impairment sufficient to cause the individual to: make judgment errors affecting patient safety, behave inappropriately in the patient care environment, or provide unsafe patient care.

(4) Physical health impairment sufficient to cause the individual to provide unsafe patient care.

(5) Substance abuse when it affects the individual's ability to perform appropriately as a health care provider or in the patient care environment.

(6) Falsification of credentials.

(7) Falsification of medical records or prescriptions.

(8) Theft of drugs.

(9) Inappropriate dispensing of drugs.

(10) Unethical behavior or moral turpitude (such as sexual misconduct toward any patient involved in VA health care).

(11) Patient abuse, including mental, physical, sexual, and verbal abuse, and including:

(a) Any action or behavior that conflicts with a patient's rights identified in Title 38, Code of Federal Regulations (CFR);

(b) Intentional omission of care;

(c) Willful violations of a patient's privacy; and/or

(d) Willful physical injury, or intimidation, harassment, or ridicule of a patient.

(12) Falsification of research findings, regardless of where the research was carried out or the funding source, as long as it was involved in some aspect of VA operations.

c. When a decision is reached to initiate SLB reporting regarding a currently employed professional, a decision may also be made to initiate appropriate disciplinary proceedings or to place the professional in a non-clinical environment. ***NOTE:*** *Reporting to an SLB is to allow the SLB to proceed on its own time schedule and independent of the time requirements of any other proceedings in order to avoid unacceptable delays.* Disciplinary actions are based on a preponderance of evidence process; in contrast, reporting to an SLB requires only a finding that there is substantial evidence that the reporting test was met.

NOTE: *Reporting to an SLB in accordance with this policy is a separate and distinct process from reports filed with SLBs submitted subsequent to reporting to the NPDB in accordance with other VHA policies. Reporting under the requirements of one policy does not relieve the facility from meeting its obligation under any other VHA policy, e.g., requirements to report to an SLB in accordance with VHA Handbook 1100.17.*

d. A VA-initiated report to an SLB (after a determination that the appropriate Privacy Act requirements have been met) is only notice to an SLB that there is a question of a professional's clinical practice or behavior. Reporting is not a VA action against a professional's license. The SLB may or may not, according to its standards, follow-up and obtain relevant portions of the VA SLB Reporting File, or ultimately, undertake formal proceedings against the license of the professional.

e. In the event there has been a court conviction, the public documents related to that conviction may be provided directly to appropriate SLB by the responsible organizational head without further review.

6. FIVE-DAY ALERT NOTICE AND EXPEDITED REVIEW PROCEDURE REQUIRED FOR STATISTICAL ASSOCIATION AND EGREGIOUS PERFORMANCE CASES

NOTE: *Egregious performance is defined as conduct by a licensed health care professional that causes the facility Director, or designee, to summarily remove the professional from clinical duties because of an immediate and urgent concern for the safety of patients.*

a. Special procedures are required when a statistically-significant association links a licensed health care professional to a series of unexpected events that have resulted in patient injuries or deaths, or when egregious performance by a licensed health care professional is found.

Statistical significance is established at the .05 level of confidence, using generally-accepted statistical methods.

b. When a determination is made of either a statistical association or egregious performance, two immediate actions are required.

(1) The facility Director must commence an SLB Reporting Program review, as outlined in this Handbook, on an expedited basis.

(2) Within 5 days of the determination, the facility Director must provide to each SLB where the professional is licensed, an alert of the statistical association or the egregious performance, and concurrently provide a copy of the alert to the Veterans Integrated Service Network (VISN) (10N___), the Deputy Under Secretary for Health for Operations and Management (10NC), the Office of the Medical Inspector (10MI), and the General Counsel (02).

c. The alert must be prepared in the same format as shown in Appendix D. It will:

(1) Identify only the occupational title of the professional, such as physician, nurse, or pharmacist.

(2) Describe either the unexpected events that are statistically linked to that professional or the egregious performance.

(3) Disclose that an expedited review is being conducted to determine if there is a non-statistical nexus between the professional and the unexpected events in a statistical case, or to develop additional information in an egregious performance case.

(4) Notify the Board, that upon completion of the review, it will be advised of whether substantial evidence does or does not exist to indicate that the professional failed to meet generally-accepted standards of clinical practice that have caused the concern for patient safety.

(5) Assure the Board that, while the professional will be reported by name consistent with Privacy Act requirements to each SLB (s) where the professional is licensed, if substantial evidence exists to establish a statistical linkage or substandard performance, it may nevertheless at any time during the review, obtain the name of the licensed professional and further information, by making a request consistent with subsection (b)(7) of the Privacy Act (see App. K for sample request letter). This provision is an exception to the paragraph 16 of this Handbook. Any information disclosed under a subsection (b)(7) of the Privacy Act request that identifies a specific professional must also be provided to that professional.

7. ENTERING AGREEMENTS THAT WOULD PROHIBIT OR RESTRICT DISCLOSURE

VHA Directors, heads, and other employees are not authorized to, and must not enter into any formal or implied agreement that would prohibit or interfere with the reporting of a licensed health care professional to an SLB, or destroy or remove any information needed in

the review process in return for a personnel action, such as resignation, retirement, or reassignment. Any such purported agreement is not binding upon VA and such an agreement forms the basis for administrative and/or disciplinary action.

8. RESPONSIBILITY

The head of each organizational component of VHA has overall responsibility for VA-initiated reporting to an SLB and responding to inquiries from an SLB. For example, VISN Directors are responsible at the VISN level and facility Directors at the facility level.

9. THE SLB REPORTING STAGES; CREATING AND FILING RELATED RECORDS

a. The SLB Reporting Program involves five stages:

(1) Initial Review Stage;

(2) Comprehensive Review Stage;

(3) Decision Stage;

(4) Concurrence Stage; and

(5) The Reporting Stage.

NOTE: *These five stages normally are completed in about 100 days. An overview of the tasks, records to be created, and procedures is provided in Appendix A with suggested timeframes.*

b. Guidelines for compiling and organizing the SLB reporting file are contained in Appendix B.

c. The records created or compiled in connection with this reporting, including any Stage, are to be filed and retrieved by the name of the licensed health care professional and are to be maintained in Privacy Act System of Records 77VA10Q, Health Care Provider Credentialing and Privileging Records – VA, regardless of whether the professional has a credentialing folder.

10. THE INITIAL REVIEW STAGE

The Director, or head, must ensure that within 7 calendar days of the date a licensed health care professional leaves VA employment, or, information is received suggesting that a current employee's clinical practice has met the reporting standard, an initial review of the individual's clinical practice is conducted to determine if there may be substantial evidence that the individual so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients. Usually this review is conducted and documented by first and second level supervisory officials. There must be reasonably-detailed documentation that this review was performed. ***NOTE:*** *When the initial review indicates that a professional has retired for disability reasons, a comprehensive review is always required and reporting of that professional is usually indicated.*

11. THE COMPREHENSIVE REVIEW STAGE

a. **Failure to Meet Accepted Standards.** When the initial review suggests that there may be substantial evidence that the licensed health care professional so failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients, the Director, or head, of the organizational component, is responsible for immediately initiating a comprehensive review to determine whether there is, in fact, substantial evidence that this reporting standard has been met. This involves the preparation of an SLB Reporting File. The objective of the comprehensive review is to present a balanced and complete picture in the file of the circumstances which formed the basis for the concern. Consistent with information law requirements, the Director, or head, must ensure that the reviewer advises the licensed health care professional, as soon into the comprehensive review as is practicable, of the purpose of the review and invite the professional to provide information. The information conveyed to the professional must include the information contained in Appendix E. If the Advisement Notice is sent by mail rather than delivered in person, Certified Mail, Return Receipt Requested must be used. The notification procedures must be followed in providing the Advisement Notice.

b. **Conflicting Evidence.** The reviewer needs to be advised to identify in the review any significant conflicting evidence, make reasonable effort to decide what the more believable conflicting evidence seems to be, and set out in the review, the rationale for believing one position over another.

(1) The comprehensive review may or may not conclude that there is substantial evidence that:

(a) There was substandard care; and

(b) That some or all of the substandard care creates a reasonable concern for the safety of patients regarding each concern.

(2) Prior to sending the Notice of Intent to Report and the evidence gathered is determined not to be substantial evidence that would support a charge in the Notice of Intent to Report, this evidence must be preserved and marked "Review Material – Not Substantial Evidence" and maintained as marked in 77VA10Q under the professional's name.

c. **SLB Reporting File.** The SLB Reporting File consists of three parts: Evidence File, Notice of Intent to Report, and the Response and Rebuttal Resolution Memorandum. The Evidence File must be prepared as required by this Handbook. All parts of the file must be compiled and organized in accordance with the instructions in Appendix B.

d. **Notice of Intent to Report.** When the Evidence File indicates that there is substantial evidence that the reporting standard has been met, a Notice of Intent to Report must be provided by the reviewer to the licensed health care professional. A notice assists in satisfying information law requirements that reasonable efforts be made to ensure that the Evidence File information is timely, accurate, relevant, and complete. Each licensed health care professional being considered for reporting to an SLB must be provided a notice or at least a reasonable attempt to provide a notice is to be made. The notice must list each charge, and provide a brief but reasonably detailed description of the facts giving rise to each charge.

The description must be sufficiently clear and precise so that the professional can understand exactly what circumstances are giving rise to each charge and what the exact wrongdoing was. A charge not contained in the notice may not be disclosed to an SLB. Accordingly, the Index of Charges from the Evidence File must be copied verbatim into the Notice of Intent to Report, except for tab page references, and patient identifiers, which must not be included. In order to meet information law requirements, the content of the Notice of Intent to Report must conform to the sample Notice of Intent to Report letter contained in Appendix F.

e. **First Notice of Intent to Report.** The Notice of Intent to Report requirement is satisfied by the use of a Certified Mail, Return Receipt Requested letter. A memorandum or other alternative notification method is acceptable, if all of the information contained in the Notice of Intent to Report letter (see App. F), is included in writing to the professional who acknowledges receipt or there is other proof of receipt. Proof of notice, such as a signed Certified Mail Return Receipt or a witness statement, must be added to the SLB Reporting File in the location indicated in Appendix B.

f. **Second Notice of Intent to Report.** A second Notice of Intent to Report must be sent, Certified Mail, Return Receipt Requested, should there be no written acknowledgment from the professional of the Notice of Intent to Report certified mail letter and the notice was not returned within 15 days of the mailing date. Reasonable effort must be made to determine the correct current address of the licensed health care professional if it is unknown, or if there is a question before sending a second notice. This includes contacting the SLB and professional organizations, and developing other leads that could include prospective employers and references. If the second Notice of Intent to Report is unsuccessful, the reviewer must proceed after documenting in the file the efforts to provide notice.

g. **Licensed Health Care Professional Request for Evidence File.** Should the professional ask for the evidence being used to make the determination, the evidence must be provided in a manner to ensure receipt and acknowledgment of delivery, such as by Certified Mail, Return Receipt Requested, using a consistent anonymous patient identification after patient identifiers have been redacted. The professional has an additional 14 days from the date of receipt to respond and must be so advised.

h. **Response of the Professional and Rebuttal Resolution Memorandum.** Whenever a licensed health care professional responds to, and contests, any of the charges, the reviewer must consider each contested, or rebutted, charge and address each in a Rebuttal Resolution Memorandum similar in format to the sample in Appendix G. The reviewer must consider the evidence on both sides of a contested point and make a decision on which to believe. Making this determination may involve obtaining additional evidence. It always requires at least an explanation as to how the reviewer has resolved the conflict. The resolution might, involve believing one person's word over another's; where that is the case, a short explanation of why one over another was believed needs to be entered in the Memorandum. For another example, if physical abuse is the charge, and the professional responded that the patient provoked the situation by striking first, the Memorandum addresses this argument by stating the employee's rebuttal point and resolving it with a statement to the effect that there is no acceptable reason to strike a patient. It is possible that a professional's response demonstrates that a particular charge is unfounded; in that case, the charge and the supporting evidence must be deleted from the Evidence File, Notice of Intent to Report, the

Response, and wherever else they may appear in the SLB Reporting File before it is forwarded for concurrence. In such instances, that evidence must be preserved and marked "Notice to Report – Not Substantial Evidence" and maintained as marked in 77VA10Q under the professional's name. The Response and Rebuttal Resolution Memorandum material must be added to the SLB Reporting File at the point indicated in the Guidelines in Appendix B. ***NOTE:*** *For some additional guidance see the discussion of Resolution of Conflict in the Unit of Evidence in Appendix B.*

NOTE: *It is the intent of this policy to make determinations based on all information reasonably and timely available. However, strict adherence to time limits must not be utilized to defeat this process. It is expected that VA would consider a late reply to a Notice of Intent to Report letter; similarly, late action by VA would not be a bar to further processing or to reporting.*

12. THE DECISION STAGE

a. Upon completion of the Comprehensive Review Stage, the Director, or head, must decide whether to report the licensed health care professional. The entire Evidence File, Notice of Intent to Report documentation, and any Response and Rebuttal Resolution Memorandum materials, must be considered in determining whether there is substantial evidence that, as to each charge in question, the professional so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients. The determination ordinarily needs to be made within 7 calendar days after the Response segment of the Comprehensive Review has been completed.

b. It should be noted that not infrequently three or four charges, taken together, may result in a sufficient basis to warrant reporting. On occasion, during the Comprehensive Review process, some or even all of the charges may be dropped. Where some, but not all, of the charges are dropped, the remaining charges may or may not be sufficient to warrant reporting.

c. The Director, or head, may wish to consult with and consider recommendations from appropriate clinical service chiefs as to whether the reporting standard has been met for each of the charges. When a decision is made not to report a professional, the file is to be appropriately noted and the professional so advised.

d. When the Director, or head, decides to report the licensed health care professional, that official must add a Decision Memorandum to the file following the format in Appendix H. The Decision Memorandum must contain the following information:

(1) A statement that the Director, or head, has made a decision based upon consideration of the entire SLB Reporting File to report a licensed health care professional, providing the name and professional title (M.D., R.N.) of the individual and the SLB to whom the report is to be made;

(2) **Intended Reporting Statement.** In accordance with Congressional intent to maintain appropriate confidentiality for the professional, the intended reporting statement is to be limited to a generic description of the clinical shortcomings involved, such as,

"Dr. Fictitious W. Jones so failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients when Dr. Jones repeatedly erred in the selection of appropriate medications."

(3) A statement that all portions of the SLB Reporting File have been compiled and organized as required in Appendix B, and in particular: the Advisement Notice procedure, the Notice of Intent to Report procedure, and the Rebuttal Resolution Memorandum procedure have been met and at what tab or page number in the file that documentation can be found.

(4) Confirmation that the SLB Reporting File is maintained in VA's Privacy Act System of Records 77VA10Q, Health Care Provider Credentialing and Privileging Records - VA, and that this disclosure is authorized under the SLB routine use contained in that system.

(5) A statement indicating all unsubstantiated or irrelevant information has been removed from the file. To enable review, only the records proposed to be disclosed should be submitted. Redactions or withholdings should include: charges and related information for which substantial evidence was lacking or harmful, personal information irrelevant to the sustained charges, and personal identifiers of patients.

(6) Any narrative or other material considered desirable to clarify, draw attention to, or otherwise augment the SLB Reporting File.

(7) A statement indicating that a copy of the file, as proposed, is being provided to the SLB and in an unredacted fashion, and must be maintained.

(8) A request for general review of the file, Decision Memorandum, and concurrence or comments based on the review by either a Privacy Officer in the VISN, or the Office of General Counsel as appropriate, and determined in accordance with guidance outlined in subparagraph 13a.

13. THE CONCURRENCE STAGE

a. Within 5 calendar days of deciding to report, the facility Director, or head, must decide if the case review is a non-sensitive or sensitive case. A case is determined to be sensitive if it indicates one of the following scenarios:

(1) A previous history of licensure action;

(2) Death of a patient;

(3) The professional who is the subject of the review has retained legal counsel in anticipation of litigation;

(4) There has been media attention associated with some aspect of the incident or subject of the review; or

(5) The professional who is the subject of the review has a clinical diagnosis or is under

the care of a physician, and that this information is part of the review or rebuttal process.

b. If the case is determined to be non-sensitive, the Decision Memorandum is forwarded to the VISN Director for concurrence and assignment to a Privacy Officer in a different facility within the VISN for determination as to whether VA has met its obligations under all disclosure authorities in connection with the decision to report.

(1) The VISN Director forwards to the designated facility Privacy Officer the complete SLB Reporting File consisting of the: Evidence File, Notice of Intent to Report documents, any Response and Rebuttal Resolution Memorandum materials, and the Decision Memorandum. A copy of the VISN Director's concurrence and the assignment memorandum is forwarded to the Deputy Under Secretary for Health for Operations and Management (10NC).

(2) Within 60 calendar days, the designated facility Privacy Officer must review the SLB Reporting File and evaluate whether:

(a) There is legal authority under Federal laws and regulations for the proposed reporting, and efforts have been made to ensure that the file is reasonably accurate, relevant, and complete.

(b) The licensed professional has been provided adequate notice of the proposal to report and has had the opportunity to submit information for consideration, as indicated by an Advisement Notice, a Notice of Intent to Report, any response of the professional, and a Rebuttal Resolution Memorandum, if applicable.

(c) The Reporting File does not contain information inappropriate for disclosure to the SLB, for example, quality assurance information protected under 38 U.S.C. 5705, records governed by 38 U.S.C. 7332 , and information gathered but insufficient to support a charge in the Notice of Intent to Report.

(d) The file is consistent with the guidelines of Appendix B of this Handbook, as follows:

1. The Decision Memorandum conforms to the requirements of this Handbook.

2. The Evidence File contains: an Advisement Notice, Index of Charges, evidence set off in a separate unit of evidence for each charge and organized in order corresponding to the Index, and adequate documentary support for each charge, including information regarding standards breached, harm to patients, and resolution of any conflicting evidence.

3. The Notice of Intent to Report document is present in the correct form and location in the file.

4. Any Response and Rebuttal Resolution Memorandum materials are included in the correct location in the file.

(3) A Reporting File that does not conform to the guidelines discussed in this Handbook must be returned by the facility Privacy Officer through the VISN Office to the facility Director for the file to be supplemented with additional information, or revised and resubmitted for further review.

(4) If the review by the Facility Privacy Officer determines that there is disclosure authority under Federal laws and regulations, the SLB Reporting File and Memorandum must be returned to the facility with the Privacy Officer's concurrence with the proposed reporting. The Privacy Officer's memorandum (see App. I) must contain information on actions taken and any other guidance necessary to complete the preparation of the file for submission to the SLB. The facility Privacy Officer completing the review forwards a copy of the memorandum of concurrence and the proposed reporting memorandum to the Deputy Under Secretary for Health for Operations and Management (10NC).

(5) If the facility Privacy Officer determines that the case is a sensitive case that requires legal review under preceding subparagraph 13a, the file must be returned to the VISN Director to be transferred through Deputy Under Secretary for Health for Operations and Management (10NC) to General Counsel (024). The VISN Director must then follow the procedures outlined in subparagraph 13.c. below.

c. If the case is determined to be sensitive, the Decision Memorandum must be addressed to General Counsel (024), through the Deputy Under Secretary for Health for Operations and Management (10NC) and forwarded through the VISN Director for concurrence. ***NOTE:*** *Do not submit the SLB reporting file directly to General Counsel.*

(1) Within 5 calendar days of the receipt of the SLB Reporting File, and before forwarding the file to General Counsel, the Deputy Under Secretary for Health for Operations and Management (10NC) must review the package to ensure that the file is consistent with the guidelines of Appendix B of this Handbook, as follows:

(a) The Reporting File does not contain information inappropriate for disclosure to the SLB, for example, quality assurance information protected under 38 U.S.C. 5705, records governed by 38 U.S.C. 7332 , and information gathered but insufficient to support a charge in the Notice of Intent to Report.

(b) The Decision Memorandum conforms to the requirements of this Handbook.

(c) The Evidence File contains: an Advisement Notice, Index of Charges, evidence set off in a separate unit of evidence for each charge and organized in order corresponding to the Index, and adequate documentary support for each charge, including information regarding standards breached, harm to patients, and resolution of any conflicting evidence.

(d) The Notice of Intent to Report document is present in the correct form and location in the file.

(e) Any Response and Rebuttal Resolution Memorandum materials must be included in the correct location in the file.

(2) A Reporting File that does not conform to the guidelines discussed in this Handbook may be held by the Deputy Under Secretary for Health for Operations and Management (10NC), or returned to the facility for the file to be supplemented with additional information, or revised and resubmitted for further review.

(3) If the complete evidence does not demonstrate that the individual so substantially failed to meet generally-accepted standards as to raise reasonable concern for the safety of patients, the file must be returned to the facility without forwarding to General Counsel for legal review.

(4) Upon receipt of the Reporting File from the Deputy Under Secretary for Health for Operations and Management (10NC), General Counsel (024) reviews the file and evaluates whether:

(a) There is legal authority under Federal laws and regulations for the proposed reporting, and efforts have been made to ensure that the file is reasonably accurate, relevant, and complete.

(b) The licensed professional has been provided adequate notice of the proposal to report and has had the opportunity to submit information for consideration, as indicated by an Advisement Notice, a Notice of Intent to Report, any response of the professional, and a Rebuttal Resolution Memorandum, if applicable.

(c) The Reporting File does not contain information inappropriate for disclosure to the SLB, for example, quality assurance information protected under 38 U.S.C. 5705, records governed by 38 U.S.C. 7332 , and information gathered, but insufficient to support a charge in the Notice of Intent to Report.

(d) The file is consistent with the guidelines of Appendix B of this Handbook, as follows:

1. The Decision Memorandum conforms to the requirements of this Handbook;

2. The Evidence File contains: an Advisement Notice, Index of Charges, evidence set off in a separate unit of evidence for each charge and organized in order corresponding to the Index, and adequate documentary support for each charge, including information regarding standards breached, harm to patients and resolution of any conflicting evidence;

3. The Notice of Intent to Report document is present in the correct form and location in the file; and

4. Any Response and Rebuttal Resolution Memorandum materials are included, in the correct location in the file.

(5) General Counsel (024), upon completion of its review, must return the complete SLB Reporting File to the Deputy Under Secretary for Health for Operations and Management (10NC) with its memorandum concurring or objecting to the proposed reporting based upon

information law requirements and the materials reviewed. Should the General Counsel memorandum concur in whole or in part with the proposed disclosure, it is anticipated that there may be recommendations consistent with confidentiality and reporting considerations, as to what information to report initially to the SLB and what information to subsequently disclose should the SLB request follow-up information. The Deputy Under Secretary for Health for Operations and Management (10NC) will return the SLB Reporting File to the originator with a cover memorandum authorizing or denying authority to report to the SLB.

14. THE REPORTING STAGE

The Director, or head, must send a reporting letter (sample in App. J) to the relevant SLB within 7 calendar days of receipt of a concurring legal review memorandum opinion from either the Privacy Officer who reviewed the evidence file or the General Counsel via the Deputy Under Secretary for Health for Operations and Management (10NC) following the format of the sample Reporting Letter to SLB in Appendix J. The letter to be released to the appropriate SLB should be limited, consisting only of the name and medical title of the professional and a generic description of the charges being reported, and it should be consistent with any guidance contained in the General Counsel memorandum. It needs to state what the SLB must do to obtain detailed information on the matter. A copy of the letter submitted to the SLB must be sent to the Deputy Under Secretary for Health for Operations and Management (10NC), the Office of the Medical Inspector (10MI) in VHA Central Office, and the professional. A letter from the SLB requesting follow-up information received by the facility must meet the Privacy Act, 5 U.S.C. § 552a, requirements identified in this Handbook to permit disclosure of the relevant portions of the SLB Reporting File (a sample request letter from a board is provided in App. K). All information to be released to the SLB is released only after patient identifiers have been deleted by redaction and replaced with consistent anonymous patient identifiers.

15. RESPONDING TO INQUIRIES FROM SLB

a. General

(1) As stated at the beginning of this Handbook, it is the policy of VA to cooperate whenever possible with an inquiry by an SLB. Accordingly, consistent with the procedures set out in this Handbook and applicable information law, VA health care facilities must provide reasonably complete, accurate, timely, and relevant information to an SLB in response to inquiries. Furthermore, while Federal Supremacy under the constitution could, under applicable circumstances, be invoked to prevent a State inquiry into the provision of care at a VA facility by a VA professional, consistent with the VA policy of cooperation with an SLB, the use of this doctrine to prevent such an inquiry will seldom, if ever, be authorized. For example, if a Director, or head, concludes, following a Comprehensive Review conducted in accordance with this Handbook, that the reporting standard has not been met and the VA inquiry is properly terminated, VA nevertheless will ordinarily cooperate with a subsequent inquiry initiated by an SLB, including making its SLB file available pursuant to a Privacy Act (b)(7) request and the health care oversight provisions of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.512(d)), rather than to raise a Constitutional Federal Supremacy objection. Such an objection may be raised only upon concurrence by the Deputy Under Secretary for Health for

Operations and Management (10NC) following consultation with General Counsel (023).

(2) Because of the Privacy Act, a standing request for information, such as a request for information to be provided each time there is a clinical practice concern, cannot be honored. The SLB needs to request specific information on a professional by a signed consent or Privacy Act law enforcement investigation letter similar to the sample Letter of Inquiry from SLB found in Appendix K. If the specific information on a professional includes any health information of a patient, authority for providing such information under the HIPAA Privacy Rule must be present. Reporting of information to the SLB and providing upon request additional information in regards to the case is authorized under the HIPAA Privacy Rule as a health care oversight activity (45 CFR 164.512(d)).

(3) Occasionally the Freedom of Information Act (FOIA) is cited by SLBs as authority to request information on professionals. Generally, FOIA does not permit disclosure about specific professionals. SLBs need to be advised to request the information with a signed consent from the individual in question or with a Privacy Act (b)(7) Law Enforcement Investigation Letter as outlined in subparagraph 15b.

b. **Signed Consent**

(1) A signed consent from the subject professional is sufficient to disclose information, covered by the Privacy Act, about a currently employed, or separated, VA health care professional, in response to a request from an SLB accompanied by the consent.

(2) When relying on the signed consent for disclosure authority, the consent must have been signed within the 6 months prior to the date of the disclosure. It must state the individual or organization to whom the information may be released and the type of information that may be released. It is suggested that all release of information be handled with the advice and consent of the local FOIA and/or Privacy Act Officer. Clarification may be sought from the Regional Counsel by that Officer in questionable cases, such as when VA receives a signed consent that specifies that VA may release any information "other than information that is derogatory," or, when the consent does not specify the type of information that VA may release.

c. **Privacy Act Subsection (b)(7), Law Enforcement Investigation Letter**

(1) Generally, information compiled to meet the requirements of this Handbook will be released if an SLB's request for that information meets the requirements of the Privacy Act, 5 U.S.C. 552a, subsection (b)(7), following essentially the format of the sample Privacy Act Subsection (b)(7), Law Enforcement Investigation Letter, in Appendix K. The request must:

(a) Be in writing on the SLB's letterhead stationery.

(b) Cite the State law giving the SLB authority to take action against professionals who hold such a license, certification, or registration.

(c) Identify, specifically, the individual about whom information is sought, the records desired, and the law enforcement activity for which the information is sought. ***NOTE:*** *This*

would usually indicate protection of the health of the State's citizens.

(d) Be signed by the head of the SLB or a person who has been designated to act for the head of the SLB. If a designee is to sign the request letter, to be effective:

1. The designee must be an official of sufficient rank to ensure that the request for records has been the subject of a high-level evaluation of the need for the information, even considering the privacy interests of the professional involved. Such an official would be at least at the supervisory level. ***NOTE:*** *Generally, a request signed by a line investigator is insufficient.*

2. The designation from the head of the SLB to the designee must accompany the request, and must state that the designee is authorized to make a request under the Privacy Act (b)(7).

3. Such a letter needs to be substantially similar to the sample Privacy Act (b)(7) letter contained in Appendix K. A copy of this sample law enforcement request letter needs to be provided to the SLB to assist them in complying with this disclosure requirement.

(2) If there is any doubt, the Director, or head, needs to consult with the local Privacy Act Officer, and as needed, Regional Counsel, to ensure that the SLB's law enforcement request complies with the Privacy Act requirements.

d. **Subpoena.** Occasionally, a SLB requests information pertaining to a professional by administrative or state court subpoena. VA does not believe that the Privacy Act permits disclosure by subpoena. The SLB needs to be advised that disclosure can be made with a signed consent or by a Privacy Act subsection (b)(7) law enforcement investigation letter (see App. K). Questions concerning subpoena requests need to be referred to Regional Counsel.

16. INTERIM RESPONSE TO A SLB INQUIRY WHEN VA IS CONSIDERING REPORTING ON ITS OWN INITIATIVE

When a request for information concerning a licensed health care professional is received from an SLB while a VA health care facility is considering reporting the individual, the facility needs to respond to the initial inquiry by stating that the SLB 's request is considered a serious matter; that a VA inquiry into this matter has been initiated; and that the request is being processed. The facility needs to expeditiously follow the five stages of procedures set forth regarding VA-initiated reporting (see App. A). Except when the statistical reporting procedures apply, the VA facility will not provide information to the SLB concerning the individual until after all procedures required for VA reporting have been met.

OVERVIEW OF THE FIVE STAGE STATE LICENSING BOARD REPORTING PROCESS

1. INITIAL REVIEW STAGE ***NOTE:*** *The suggested timeframe is 7 calendar days.*

a. Determine whether it initially appears that the behavior or clinical practice of a licensed health care professional so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients within 30 days of:

(1) An employee's departure from Department of Veterans Affairs (VA) rolls, or

(2) Receipt of information suggesting a current employee's provision of substandard care.

b. Proceed to the Comprehensive Review stage if serious concerns are raised that suggest that the preceding reporting standard may have been met, or file in Privacy Act System of Records 77VA10Q, Health Care Provider Credentialing and Privileging Records – VA, under the employee's name, a dated statement that an initial review determined no unresolved serious concerns regarding substandard clinical performance or behavior causing concern for patient safety.

2. COMPREHENSIVE REVIEW STAGE ***NOTE:*** *The suggested timeframe is 45 calendar days.*

a. Inform the licensed health care professional of concerns raised by the Advisement Notice and seek the professional's comments.

b. Commence the comprehensive review at the time the Advisement Notice is delivered or sent.

c. Review the licensed health care professional's response and note admissions, denials, or admissions with an explanation.

d. Develop additional facts as necessary to fully answer arguments or denials raised by the professional in order to resolve all contested issues.

e. Prepare an Index of Charges with each charge supported by an organized unit of evidence that includes the professional's response to each charge.

f. Remove and file in 77VA10Q "Review Material - Not Substantial Evidence," as appropriate.

g. Issue a Notice of Intent to Report that details each charge of substandard care or behavior by date and incident.

h. Deliver to, and secure written acknowledgment from, the licensed health care professional of the notice; or make reasonable efforts to a secure written acknowledgment of receipt when the initial delivery efforts fail.

i. Commence the Decision Stage after documentation of all additional reasonable efforts which were made to effect notification.

j. Remove the patient identifiers and provide a redacted copy of the Evidence File to the licensed health care professional upon request.

k. Prepare a Rebuttal Memorandum resolving all issues disputed by the licensed health care professional to the charges.

l. Remove and file in 77VA10Q "Notice of Intent to Report – Not Substantial Evidence," as appropriate.

3. DECISION STAGE ***NOTE:*** *The suggested timeframe is 7 calendar days.*

a. Determine whether substantial evidence exists to report each charge in the Notice of Intent to Report.

b. Determine whether reporting is indicated or appropriate considering the charges supported by substantial evidence.

c. Advise the licensed health care professional of a "total no report" decision and file the "no report" review materials in 77VA10Q.

d. Prepare a Decision Memorandum when there are charges to be reported include the intended summary reporting statement.

e. Remove or redact from the Evidence File all documentation not relevant to the charges to be reported.

f. Augment the Evidence File, as necessary, to promote clarity and understanding of technical medical procedures or terms.

4. CONCURRENCE STAGE ***NOTE:*** *The suggested timeframe is 35 calendar days, if the review is by a facility Privacy Officer.*

a. Forward the State Licensing Board (SLB) File to the Veterans Integrated Services Network (VISN) Director for review by a Privacy Officer or General Counsel (OGC), as appropriate. If it is considered appropriate for review by OGC, the SLB file must be forwarded through the Chief Network Officer.

b. For those files determined to be sensitive or require legal review, there must be a review by the Deputy Under Secretary for Health for Operations and Management (10NC) and OGC who prepares the transmittal memorandum either concurring in the proposed reporting, or indicating that the legal authority to report has not been met. For the files that are reviewed by a facility Privacy Officer, the memorandum concurring in the proposed reporting, or indicating the legal authority to report has not been met is prepared by the facility Privacy Officer performing the review.

5. REPORTING STAGE ***NOTE:*** *The suggested timeframe is 7 calendar days.*

a. For those cases reviewed by either the facility Privacy Officer or OGC, the staff at the reporting facility must prepare and send the Reporting Letter to the SLB with copy to the Deputy Under Secretary for Health for Operations and Management (10NC), the Medical Inspector (10MI), and the licensed health care professional.

b. File a copy of the reviewed "SLB Reporting File" under the employee's name in 77VA10Q.

c. Prepare and send the review materials properly requested by the SLB with the deletions and redactions, as indicated.

GUIDELINES FOR COMPILING, ORGANIZING AND PREPARING THE STATE LICENSING BOARD REPORTING FILE AND DECISION MEMORANDUM

1. The Decision Memorandum and State Licensing Board (SLB) Reporting File. The SLB Reporting File consists of documentation that accurately establishes whether or not a licensed health care professional has so significantly failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients. The SLB Reporting File is filed and retrieved by the name of the licensed health care professional and is to be maintained in Department of Veterans Affairs (VA) Privacy Act System of Records 77VA10Q, Health Care Provider Credentialing and Privileging Records - VA. The Decision Memorandum and the components of the SLB Reporting File, are forwarded to the Veterans Integrated Services Network (VISN) Director and referred to either a facility Privacy Officer or General Counsel (OGC) through the Deputy Under Secretary for Health for Operations and Management (10NC), in the following order:

a. **The Decision Memorandum.** The Decision Memorandum is both a decision and transmittal document sending the file from the originating organizational head to the VISN Director who forwards the documentation to a facility Privacy Officer or OGC through the Deputy Under Secretary for Health for Operations and Management (10NC). ***NOTE:*** *A sample copy of a Decision Memorandum is included in Appendix H.*

b. **The Response and Rebuttal Resolution Memorandum.** The Response is any information provided by the licensed health care professional. The Rebuttal Resolution Memorandum consists of a detailed statement addressing any conflict created by the Response. ***NOTE:*** *A sample copy of a Rebuttal Resolution Memorandum is included in Appendix G.*

c. **The Notice of Intent to Report.** These materials consist of a copy of the notice, and documents showing either that the licensed health care professional received the notice, or that reasonable efforts were made to provide the licensed health care professional such notice. ***NOTE:*** *A sample copy of a Notice of Intent to Report is included in Appendix F.*

d. **The Evidence File.** The Evidence File consists of all relevant records for each charge of failure to meet the reporting standard. The Evidence File consists of three parts filed in the following order: Advisement Notice documentation, an Index of Charges, and Evidence Units supporting each charge. Each Evidence Unit includes any relevant information from the professional. Each charge which the reviewer determines is supported by substantial evidence needs to be listed on a document known as the Index of Charges. Each Unit of Evidence supporting each charge needs to be a separate component of the file, with such unit tabbed or otherwise marked to set it off from the other units of evidence for other charges. Units of evidence could include, but are not limited to: relevant portions of documents from administrative boards of investigation; reports of contact; police reports; patient record information (including, in cases involving controlled substances, all relevant prescription and administration control records); copies of facility policies and procedures that identify the standards or requirements breached; and relevant health information specific to the licensed health care professional; and signed statements from the charged licensed health care professional, staff, or patients. Each charge listed in the Index needs to be identified, by letter or number, the tab at which is located the Unit of Evidence supporting that charge.

2. Evidence Gathering Principles

a. **Overview.** When first commencing a review, exactly what happened and precisely what, if any, charges will end up being sent to an SLB often cannot be known. Hence, the reviewer may begin by interviewing the professional, some managers, other employees or patients, or gathering and reviewing records without having a particular focus. However, as the reviewer becomes educated in the facts surrounding the circumstances which gave rise to the concern about possible substandard care and harm to patients, the focus should become clearer. At that point, exactly what charges should be considered, which records should be obtained, from whom statements should be taken, and what questions should be answered in those statements becomes much more apparent. Collecting and organizing the relevant and important records and statements is the work of the reviewer. ***NOTE:*** *The purpose of the review is to obtain a fair and balanced portrayal of the events in question to enable the Director, or other decision maker, to make a properly informed decision on whether to report. Knowledge of a few basic principles concerning evidence in the SLB context may be useful in identifying the truly important evidence.*

(1) Relevant and Material Evidence. The primary limitation on the use of evidence in SLB proceedings is the requirement that evidence be relevant. Evidence is relevant when it relates to the charges of substandard care. Material evidence is that relevant evidence which is important to resolution of the issues in dispute. ***NOTE:*** *Material evidence is always relevant, but not all relevant evidence will be material.*

(2) Credible and Reliable Evidence. Relevant evidence is only persuasive when it is credible and reliable. Some factors to look at when weighing the credibility and reliability of evidence are the:

(a) Source of the evidence is known.

(b) Source is certain and positive concerning the evidence being offered.

(c) Evidence from the source corroborates (comports with or is consistent with) other evidence from other sources.

(d) Truthfulness of the source is not in doubt.

(e) Opinion-type evidence. If the source is competent and qualified to render the opinion (as an example, statements regarding a professional's physical or mental ability to perform the functions of the position).

(f) Source has no interest in the outcome of the concerns or has no bias against or hostility toward the parties.

(g) Source's testimony is based on personal knowledge rather than hearsay.

(h) Written or documentary evidence is legible, unaltered, and authentic.

(i) Source has made no prior inconsistent statements.

(3) Direct Evidence. Direct evidence needs to be collected; "indirect evidence" should be avoided as much as possible. Direct evidence demonstrates a fact (what occurred) itself, without passing through an intermediary. The records normally created in the provision of health care are direct evidence, since they are the record of what occurred, or at least, of what was entered. Thus, for example, in a situation where there is a question about the administration of medication, the usual records involved in medication administration provide direct evidence as to what was prescribed, copied, obtained, and administered. In a drug administration case, these records should always be collected to demonstrate shortcomings by the licensed health care professional as to each and every allegation of misadministration intended to be reported to the SLB.

(4) Indirect Evidence**.** A statement which is based not on the witness's own personal knowledge obtained through the witness' own senses, but rather on what the witness claims someone else said or wrote, is "indirect evidence" or hearsay. Although generally not admitted into evidence in courts, hearsay evidence is admissible in administrative proceedings, such as SLB reviews, provided it is relevant. However, hearsay, unless corroborated by direct evidence, may and often does have less credibility, and thus less value, than direct, non-hearsay since it is generally less reliable.

(5) Limited Value Evidence. Historically, reviewers in SLB cases have often collected considerable amounts of indirect evidence, often of a hearsay nature, which, at best, has limited value in establishing a basis for determining whether the reporting standard has been met. An example of indirect evidence records is the professional's performance evaluation. Such evaluations usually are written by one who is relying on activities witnessed by someone other than the writer. When a reviewer encounters indirect evidence related to a charge, a reasonable effort needs to be made to pursue that lead to direct evidence, to locate an actual witness to the event, and obtain a signed statement from that witness. The statement from the witness can then be used as direct evidence regarding that charge.

b. **Use of Records as Evidence**

(1) Patient's Medical Record. If some of a patient's medical record provides evidence for determining that the licensed health care professional so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients, then a copy of the portion of the medical record proving the failure(s) needs to be obtained and included as part of the Evidence File. Redactions are to be completed before a copy is sent to the professional and before the file is forwarded to the VISN Director and on to either a facility Privacy Officer or through the Deputy Under Secretary for Health for Operations and Management (10NC) to the OGC. This redaction must consist of deletion of the patient names and identifiers, which must be replaced with a consistent anonymous patient identifier.

(2) Licensed Health Care Professional's Fitness for Duty Record. If a licensed health care professional retires or is separated due to a disability, and the disability was evaluated as part of a fitness for duty evaluation and the evaluation suggests that the professional may be so unable to meet generally-accepted standards of clinical practice as to raise reasonable concern for the

safety of patients, a copy of the medical evaluation is to be included as a part of the Evidence File. ***NOTE:*** *Important in this type of case are statements by medical experts regarding the impact of the disability on the clinical practice ability of the professional, and any evidence of substandard care of risk to patients attributable to the disabling condition.*

(3) Use of Evidence or Case Record Developed for an Administrative Proceeding such as a Disciplinary Board or a Probationary Review Board. Generally, documents previously compiled for other purposes may be used in the Evidence File, but the use is limited to only those documents or portions of documents relevant to the charges in the proceedings outlined in this Handbook. The administrative investigation or other record may need to be reorganized, with portions deleted, to meet the compilation and organizational requirements of the Evidence File.

(4) Certain Records Prohibited from Use in Evidence File. Certain records may not be placed in the Evidence File; those records are the medical quality assurance records made confidential by law, i.e., Title 38 United States Code (U.S.C.), Section 5705, implementing regulations, VHA policy, and local issuances. One such document is a VA Form 10-2633, Patient Incident Report, created after January 23, 1995. A record covered by this protection may be examined by the reviewer and used to go to possible witnesses or treatment records to obtain includable direct evidence.

(5) A Brief Explanatory Note Helpful. Often, in a drug misadministration case, for example, the evidentiary value of the records may not be immediately apparent to a lay reviewer or an individual (such as an SLB official) not familiar with the facility's recordation system; or, possibly, the records may not be particularly legible. Accordingly, a good reviewer might include with the medication administration documents (or other evidentiary records) markings, notes, or brief explanations to help others understand what the record says and how it supports the particular charge.

c. **Use of Statements as Evidence**

(1) Witness Statements. In addition to records, the other main source of evidence is a signed statement of someone who actually saw or heard an action or event. A statement from health care professionals, patients, visitors, or staff that actually saw the alleged patient abuse, for example, should be sought. As with records, witness statements need to be of the direct evidence type. Whenever possible, they need to be written in the first person specifically describing what, when, and where an event happened, and who was present, e.g., "On June 19, 1998, around 6 p.m., while visiting my brother, Ronald Nelson in Room 404, I saw Nurse "A" slap Mr. Johnson, a patient and roommate of my brother." On the other hand, the statement, "I observed Dr. "Y" for 10 months and he was incapable of handling an emergency," is too vague and conclusory to be of much value. Indirect evidence and hearsay, such as "Nurse A told me that Dr. "W" frequently missed patient appointments," or an imprecise statement such as, "I don't remember exactly when, but Dr. "X" fell asleep during a procedure," generally will not suffice as evidence.

(2) Statement of the Professional. The law requires that the reviewer collect information to the greatest extent practicable directly from the licensed health care professional whose actions are in question. This means that the professional must be given the opportunity to provide a statement concerning the possible charges at the earliest practicable opportunity. The professional needs to be advised of the substance of relevant supporting evidence against them so that a knowledgeable reply can be made. The advisement needs to conform to Appendix E. If the health care professional admits to actions or shortcomings, effort should be made to obtain a signed admission statement containing specific details. ***NOTE:*** *It is recommended that the signing be witnessed.*

(3) Patient Statements. Reasonable effort should be made to obtain a signed statement from a patient when the patient can provide relevant information, such as when a patient states a medication was not received, but it is documented that it was administered, or when a patient witnessed or was a recipient of abuse. A separate statement stating that the patient was unable to provide such a statement needs to be provided in all cases where a statement from the patient would be expected. If the medical condition of the patient raises doubt as to the reliability of a statement, a statement from a professional familiar with the patient should accompany the patient's statement; it needs to indicate that person's familiarity with the patient and offer an opinion as to the reliability of the patient's comments. Besides the reliability considerations, before approaching the patient, the reviewer needs to ascertain whether the physical or mental health of the patient would be compromised if asked for a statement.

3. Creating the Evidence File

a. Drafting the Charges

(1) At the outset of the review, there will probably be concern that certain specific actions or omissions constituting substandard care occurred. The review will initially focus on these, and indeed will often not need to go beyond these concerns to complete a competent inquiry. On other occasions, the inquiry might reveal that the initial concerns were "only the tip of the iceberg," or that the acts or omissions were somewhat misunderstood or mischaracterized when seen in the full light of the review. Any charges finally drawn up when the review is essentially complete may be somewhat different than the charges one might have expected to write up at the outset of the review.

(2) At any rate, once the circumstances are reasonably well understood and the evidence is in hand, the charges drafted must be drafted with care. Each substandard act or omission for which it appears there is substantial evidence needs to be identified in a charge. Each charge should describe one act or omission. The act or omission needs to be described with reasonable particularity, including the date, a description of the acts or omissions, the standard violated, a characterization of the shortcomings, e.g., diagnostic error, and if not apparent, why the act or omission creates a concern for the safety of patients. The patient is to be referred to in a consistent anonymous fashion, e. g., "Patient Z1234."

(3) A charge should not contain two or more shortcomings, nor should it consist of simply a broad reference to, for example, "numerous medication errors." Similarly, one cannot collect evidence on six or seven charges and then add another broad charge, such as "and numerous other such failings" to the list of charges. Further, as stated in the preceding, the charge should not merely describe an act or omission; rather, while the act or omission can and should be described, the charge must go further to state what standard was breached by the act or omission. For example, it is not sufficient to state that "On July 1, 1998, you reported wasting x amount of the controlled drug yz." The charge must then state what was wrong with that statement, such as "applicable administration rules require that such wasting be witnessed, but this was not done." The charge should also contain a characterization, and a reference to concern for patient safety, if necessary. For example, "This constituted a failure in the administration of controlled substances and raises serious concern that you cannot be trusted in administering controlled substances." Characterizing the type of shortcoming helps the licensed heath care provider understand how VA views the provider's actions. The professional's response could easily be different depending on the characterization. For example, if VA characterized the preceding report of unobserved wasting differently, such as a missing controlled substance situation or as "diversion of controlled substance for personal use," the response to this graver charge could be significantly different than if the professional understood the charge only as an administrative failure. ***NOTE:*** *Do not leave the licensed health care practitioner in doubt about what was wrong with the act or omission when drafting the charge.*

(4) Another example. "You saw patient Mr. X3456 on July 3, 1998. On that visit the patient complained of a sore throat, inability to swallow, and significant weight loss. You failed to order indicated tests and procedures to diagnose Mr. X's cancer of the throat. This constituted diagnostic and treatment error." In this example, the circumstances of the charge are described specifically, including the date and an anonymous patient identifier, and they are confined to the facts necessary to the specific act or omission for which reporting is being considered. The example also states that a standard existed and was breached. Finally, the act or omission is characterized as to the general type of shortcoming, e.g., diagnostic failure, treatment failure. A basis for a concern about patient harm is apparent.

(5) Every charge must identify a specific shortcoming and be supported by relevant evidence. A charge of diversion for personal use often is difficult to support without an eyewitness of the diversion and the personal use. Evidence of diversion, but not of use, should result in a charge only of diversion, which is a serious enough charge.

(6) In a drug administration or documentation case, it may be unnecessary to charge the professional with, and provide evidence of, a very large number of drug administration or documentation failures. If the failures are all of one type, e.g., failure to properly document, a representative number of relatively recent shortcomings can provide a sufficient basis to meet the reporting standard. For example, several failings of the same type over a reasonable period of time, especially when coupled with documented, but unsuccessful, remedial efforts, would ordinarily provide a sufficient basis for a Director to decide to report the professional for failure to properly administer or document drugs.

b. **Units of Evidence Supporting Charges**

(1) There should be a unit of evidence, i.e., a grouping of evidence, to support each charge. Each unit must demonstrate all of the following: the substandard event; the standard which should have been adhered to; the professional's knowledge of that standard if it is an unusual standard; an explanation of how the conduct or omission in question violated the standard, if not readily apparent; why the substandard care makes a reasonable person concerned for the safety of patients. Where a series of charges involve violation of the same standard, the standard need be set forth only in one unit of evidence. The units supporting the other similar charges need only refer to the standard set out in the earlier unit. Similarly, if an explanation of how the standard was breached or why the acts create concern for patients is the same as set forth in the earlier unit of evidence, subsequent units need only make a reference to the earlier unit.

(2) If a statement or record contains evidence supporting more than one charge, the statement or record ordinarily will be included in one unit of evidence only to the extent it supports that charge. Another portion of the statement or record, relevant to a different charge, must be included in the unit, supporting that charge, and so on. Alternatively, an entire statement or record can be included in each relevant unit, with the portion unrelated to that particular charge blanked out. If statements or documents have been compiled on some charges which ultimately do not appear appropriate for reporting, the portions of those records or statements which refer to such charges must be removed, blanked out or otherwise rendered illegible. Similarly, if evidence contains derogatory or personal information about the licensed health care professional which is not part of the charges being reported, that information needs to be edited out or otherwise removed from the file.

4. Resolution of Conflict in the Unit of Evidence. In the process of collecting evidence to support a likely charge, the reviewer may encounter conflicting evidence. It is the responsibility of the reviewer to identify and exercise reasonable effort to resolve the conflict, and to create a statement explaining the rationale of the reviewer in resolving the conflict. That statement should be included in the unit of evidence supporting the particular charge. For example, the licensed health care professional might deny, in a statement, being in the area of controlled substances on the night in question; however, two eyewitnesses might state that they saw that professional in that area at the relevant time. The reviewer must add a memo to the file identifying this conflict and resolving it, with rationale. In that instance the reviewer might believe, and therefore write, that she accepted the story of the two eyewitnesses because the professional's statement was self serving while she could find no reason why the two eyewitnesses would misstate the facts.

GUIDANCE FOR PRIVACY OFFICERS ON REPORTING FILE REVIEW

1. Background

a. To ensure that its health care professionals meet generally-accepted professional standards for patient care, the Department of Veterans Affairs (VA) notifies State Licensing Boards (SLB), charged with licensing health care professionals, when a professional's behavior or clinical practice so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients (see Veterans Health Administration (VHA) Handbook. 1100.18, pars. 1-5).

b. A facility reports a professional to the appropriate SLBs by submitting a Reporting File, which contains an Evidence File of documentation supporting the charges of substandard care. Records that may appear in an Evidence File include: patient medical records, including prescription and administration control records; documents of administrative boards of investigation; police reports; signed statements and reports of contact from the professional, staff, or patients; facility policies and procedures that identify the standards or requirements breached; and relevant health information specific to the licensed health care professional (see App. B, subpar. 1d).

2. Disclosure Authority

a. The Privacy Act permits VHA to release to an SLB the Evidence File concerning a health care professional pursuant to the professional's prior written consent or a qualifying request from the SLB (see Title 5 United States Code (U.S.C.) § 552a(b)(7) – the Privacy Act)). The routine use in the "Patient Medical Records – VA" system of records (24VA19) regarding disclosures to SLBs does not provide authority for the disclosure of the Evidence File. Under the routine use, VA may alert an SLB of incidents suggesting substandard care, without naming the licensed health care professional, and indicate that the Evidence File may be provided pursuant to a qualifying law enforcement request. The release of any more information, including the Evidence File, must be authorized by either a written consent of the professional or a law enforcement request that qualifies under section (b)(7) of the Privacy Act. ***NOTE:*** *For a sample letter that meets the requirements for a proper law enforcement request, see Appendix K.*

b. To the extent that the Evidence File contains individually-identifiable health information, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorizes VHA to disclose such materials in conducting its health care operations. The definition of health care operations includes: the review of the competence or qualifications of a health care professional, as well as accreditation, certification, licensing, and credentialing activities. Accordingly, VHA may provide the SLB with an Evidence File that contains individually-identifiable health information to conduct its health care operations (see Title 45 Code of Federal Regulations (CFR) §§ 164.501, and 164.506(c)(1)).

3. Categories of Records and Information

a. **Individual Identifiers.** Information that identifies individual patients, including names,

addresses, and social security numbers, must be redacted from all documents. Names of VA employees may generally remain in the Evidence File, although their home addresses, telephone numbers, and Social Security Numbers must be redacted. To assist the reviewer where more than one patient is involved, individual identifiers may be replaced anonymous patient identifiers, such as Patient W (see VHA Handbook. 1100.18, App. B, par. 2b(1)).

b. **Title 38 U.S.C. § 5705(a)§ 5705 Records (Medical quality assurance (QA) materials).** Medical quality assurance (QA) materials, such as monitoring and evaluation reviews and focused reviews, are confidential and privileged and may not be placed in an Evidence File (see 38 U.S.C. § 5705(a), 38 CFR § 17.501, VHA HB. 1100.18, par. 13b(5), and App. B, par. 2b(4)). If a document has been identified as quality assurance material, consult the facility's quality assurance plan to confirm. If a document that does not qualify as medical qualify assurance material is erroneously designated as a § 5705 document and included in an Evidence File, the error needs to be corrected by redacting the statement identifying the record as medical quality assurance material.

c. **Title 38 U.S.C. § 7332 Records and Similar Documents (that reveal the identity, diagnosis, prognosis, or treatment of individuals for drug abuse, alcoholism, Human Immunodeficiency Virus (HIV), or sickle cell anemia).** Records that reveal the identity, diagnosis, prognosis, or treatment of individuals for drug abuse, alcoholism, HIV, or sickle cell anemia may not be included in an Evidence File (see 38 U.S.C. § 7332(a); 42 U.S.C. § 290dd-2(a); 38 CFR § 1.461). such materials appear necessary to report (i.e., the file would lack sufficient evidence without such documents), the information must be made anonymous by redacting individual identifiers. To assist the reviewer where more than one patient is involved, individual identifiers may be replaced anonymous patient identifiers, such as Patient W (see App. B, par. 2b(1)).

d. **Employee Drugs Testing or Drug and Alcohol Abuse Records.** Records that contain the results of an employee's drug test or employee records maintained in connection with drug and alcohol abuse prevention, treatment, and rehabilitation programs and services may not be included in an Evidence File (see 5 U.S.C. § 7361(b), and 7362(b)). If such materials appear necessary to report (i.e., the file would lack sufficient evidence without such documents), the information must be made anonymous by redacting individual identifiers. ***NOTE:*** *If it is not possible to both remove this information and redact individual identifiers (e.g., the positive drug test results of a professional being reported for theft of narcotic medication), contact the VHA Privacy Officer, for guidance.*

4. <u>Sensitive Cases.</u> Cases that raise one or more of the following issues are deemed sensitive and are to be forwarded to the Veterans Integrated Services Network (VISN) Director, who refers the matters to the Office of General Counsel for special review:

a. Death of a patient;

b. Media attention associated with the underlying incident(s);

c. A professional who has obtained legal representation;

d. A professional who has a history of previous licensure actions (e.g., probation); or

e. A professional whose clinical diagnosis or treatment is relevant to, and included in, the reporting or rebuttal.

5. Miscellaneous. For details on reviewing the Evidence File, see Appendix B. For further guidance, contact the VHA Privacy Officer.

SAMPLE SPECIAL REPORTING PROCEDURES ALERT LETTER TO STATE LICENSING BOARDS

NOTE: *For alerting a State Licensing Board of a statistical association or egregious performance by occupational title.*

(Date)

(Address of SLB in the State where the professional is licensed)

Dear _____:

In compliance with Department of Veterans Affairs (VA) authority, be advised that a (occupational title of the employee), who (is or was) a licensed health care professional of this facility, has been (*insert either (statistically linked with a series of unexpected patient events) or (involved in egregious performance)).* (*Describe the unexpected events that are statistically linked to the professional or describe the egregious performance).*

VA initiates a report to the State Licensing Board (SLB) when there is substantial evidence that the professional failed to meet generally-accepted standards of clinical practice so as to raise reasonable concern for the safety of patients. (*Insert either (Statistical association alone does not constitute substantial evidence since it fails to show what clinical standard was breached, how it was breached, when and where it was breached. Such association, however, creates a duty to investigate further to determine whether the reporting standard has been met) or (The egregious performance described above is only a preliminary finding, based solely on limited evidence. Such information, however, creates a duty to investigate further to determine whether the reporting standard has been met.))*

An accelerated review is being conducted to determine [*Insert either (if there is a non-statistical connection between the professional and the unexpected events) or (if the performance described above meets the reporting standard)]*. Upon completion of the review, you will be advised whether substantial evidence does or does not exist to indicate that the professional breached a care standard which would raise reasonable concern for the safety of patients. If such evidence exists, the professional will be reported consistent with Privacy Act requirements to each SLB where the professional is licensed.

Notwithstanding the above, you may at any time request the professional's name and further information by submitting a letter consistent with subsection (b)(7) of the Privacy Act, Title 5 United States Code §552a (b)(7). Questions may be addressed to _____, (title), at (telephone number).

(Signature)

Medical Facility Director

SAMPLE ADVISEMENT NOTICE TO LICENSED HEALTH CARE PROFESSIONAL
(Certified Mail, Return Receipt Requested)

John Doe, M.D.
123 East Main
Little Town, Big State 00123

Dear Dr. Doe:

This is a notice to advise you that we are making a review of the concerns raised regarding your behavior or clinical practice, specifically (State in summary form the general concerns such as (your care and treatment of patient W1234), (your relationship with patient L2345), (your handling of controlled substances), (your physical or mental ability to meet the demands of your position), (your actions and conduct on June 27, 19XX), (your clinical judgment involving treatment of patient 3456)). These concerns suggest that you may have so significantly failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients.

The Privacy Act requires that we attempt to collect information regarding these concerns to the greatest extent practicable directly from you. Our legal right to ask for information is Title 38 United States Code, Sections 501, 7401-7405 and their regulations. The information collected will be used to aid in making a determination whether to initiate a report to the appropriate State Licensing Boards (SLB), if there is substantial evidence that would support the above described concerns. Our review is intended to provide sufficient information to enable a full and fair decision in this matter. We will make the best decision possible on the basis of the information available to us, even if you decide not to provide any information. Any information you provide is voluntary and will be maintained in the Department of Veterans Affairs (VA) Privacy Act System of Records 77VA10Q, Health Care Provider Credentialing and Privileging Records – VA, which may be available to the SLB, similar licensing bodies, or to other types of law enforcement authorities under the Privacy Act routine use authority. Any information you desire to provide regarding the concerns should be addressed to _____at Department of Veterans Affairs Medical Center, 1234 Street, Anytown, Big State 12345, within 14 calendar days from your receipt of this notice, who may be reached at (123) 456-7899.

Should the review result in a tentative determination to make a report to the appropriate SLB, you will be further advised and provided an opportunity to address what is proposed to be reported.

Sincerely yours,

Jane Smith
Medical Center Director

NOTE: *The described concerns should be sufficient to enable the professional to understand what actions were involved and the nature of the concerns that have arisen from those actions.*

One requirement is that the Advisement is mailed Certified Mail, Return Receipt Requested, should the professional no longer be employed by the facility initiating this review. Otherwise, if currently employed, the Advisement may be hand delivered, but the professional needs to sign a copy of the Advisement as an acknowledgment of receipt or there should be other evidence of receipt.

SAMPLE NOTICE OF INTENT TO REPORT
LICENSED HEALTH CARE PROFESSIONAL
(Certified Mail, Return Receipt Requested)

(Date)

Dear _____:

It is the policy of the Department of Veterans Affairs (VA) to report to State Licensing Boards (SLB) licensed health care professionals whose clinical practice appears to have so significantly failed to meet generally-accepted standards of clinical practice so as to raise reasonable concern for the safety of patients. Our legal authority to make these reports is Title 38 United States Code, Sections 501, 7401-7405 and their regulations.

Based upon the following, we are considering whether, under these criteria, you should be reported to the SLB. Our records indicate **(*NOTE:* *Repeat verbatim the Index of Charges, except for Tab references--do not include patient names.)***

(SAMPLE INDEX OF CHARGES)

a. On December 13, 1997, you treated patient W2345 and wrote that the patient has "unsteady gait and slow speech." On December 14 and 15, 1997, you diagnosed the patient as having a sinus headache. Later, the patient was diagnosed as having a brain tumor. Your misdiagnosis resulted in the patient not receiving proper treatment for several days and constitutes treatment and diagnostic error.

b. Between approximately July 24 and September 23, 1997, you engaged in a sexual relationship with patient A2598, a member of your therapy group. Your conduct blurred the distinctions between the professional staff and patients and resulted in a relapse of the patient. Your conduct constitutes patient abuse.

c. On May 25, 1997, you prescribed ampicillin to patient E3456 even though her medical records stated that she was allergic to penicillin. The drug caused the patient to have an adverse reaction which resulted in the hospitalization of the patient. Your actions constitute treatment error.

d. On August 19, 1997, you went on leave for 2 weeks without transferring care of your patients. This lack of continuity of care resulted in an emergency situation involving patient S4956. His deteriorating condition was unattended for several hours while the nursing staff located a physician who was available and willing to intervene. This constituted patient abandonment.

e. On November 24, 1997, the Sure-Med cabinet recorded that between 0200 and 0600, you withdrew four 2mg tubex of Ativan, one each for patients B40963, G9547, Q4747, and M3419. The medical records for all four patients show that each patient received only 1 mg. While you

state that you wasted the unused 4 mg, the required procedures for documenting and witnessing controlled substances as contained in Medical Center Policy Document 123-ABC were not observed. This failure to properly account for controlled substances constitutes medication documentation error.

If you have information that you believe should be considered regarding whether VA should report you concerning these matters, please submit such information to the above address within 14 calendar days from the date of receipt of this letter, to the attention of (insert name), who may be contacted at (000) 123-4567.

Providing information in response to this letter is voluntary. If you do not provide information, a decision concerning whether to report you to the SLB will be made based on available information. Any information you provide will be maintained in VA system of record 77VA10Q, which may be available to the SLB, similar licensing bodies, or to other types of law enforcement authorities under the Privacy Act routine use authority.

(Signature)
Medical Center Director

SAMPLE REBUTTAL RESOLUTION MEMORANDUM
(From a Service Chief or Chief of Staff to an Organizational Head such as a VA Medical Center Director)

From: Service Chief for Ambulatory Care

Thru: Chief of Staff

To: Director

Subj: Rebuttal Resolution Regarding Proposed Reporting to State Licensing Boards (SLB) of Jane Doe, R.N.

1. By letter of November 10, 20xx, Ms. Doe was notified of our intent to report her to the appropriate State Licensing Boards (SLB) for five concerns which we believe meet the standard for reporting. By letter of December 14, 20xx, Ms. Doe replied to the Intent to Report letter and by letter of January 2, 20xx, an additional reply was received from her attorney. After consideration of that correspondence, I recommend that charge four be dropped as explained below and the other charges be reported as proposed. The adoption of this recommendation resolves all the contested and disputed issues raised in Ms. Doe's response to the Notice of Intent to Report letter.

2. Neither Ms. Doe nor her attorney challenged or rebutted the first three charges regarding multiple medication documentation and administration errors, and there is substantial evidence to support those charges. However, both Ms. Doe and her attorney challenge charges four and five regarding diversion of narcotics for personal use and patient mental abuse.

3. Ms. Doe denies the fourth charge alleging diversion of narcotics for personal use. The allegation is supported by the five documents under Charge Four: (1) the Sure-Med report that recorded Ms. Doe as the individual removing four Perocet pills on September 9 for patient W9754; (2) the patient's statement that the pills he received did not lessen his pain and those pills did not appear to him to be the usual ones he received; (3) Ms. Doe's documentation in his records that she gave him two pills each at 0100 and 0500; (4) the statement from Dr. Jones that patient W9754 was alert and able to record events accurately; and (5) the September 9 Report of Contact from James Brown that stated that he saw four pills (type unknown) on the night stand of patient W9754 when he first reported for duty at 0730, but the pills were not there after the shift change at 0800. She contends that she gave the medicine as charted, that the pills looked different because they came from a new supplier, and that the medicine observed may have been her own personal medicine that she took before leaving duty. The five documents relied upon do not present any reliable evidence of diversion of the four Perocet pills for personal use. Additionally, while I was able to confirm that we had a new supplier of Perocet pills that looked different, I was unable to confirm if the new pills were in use on the day in question. Under these circumstances, I do not believe that the charge of diversion for personal use can be sustained and that is the

reason for the recommendation that this charge be dropped from any reporting and that all references to the charge be deleted from any reports to be made to the SLB.

4. The fifth charge was that Ms. Doe mentally abused patient S3456 by her improper contact and conduct with him when she was a nurse on the psychiatric ward from May through August, 19xx. In her reply, Ms. Doe admits to improper contact and conduct with patient S3456 by her letters, telephone calls, and poems to him, but denies that her conduct constituted "patient mental abuse" as alleged in the Notice of Intent to Report letter. I do not find any merit in the distinctions made by her and her attorney. I believe that there is substantial evidence to report the patient abuse as alleged. Under Charge Five in the Evidence File is an August 15, 199x, letter of proposed removal that contains the same allegations that are in our Letter of Intent to Report. In her August 29, 199x, reply to her proposed removal, Ms. Doe admitted that she sent patient S3456 letters and poems that had romantic overtones and were suggestive of a personal relationship. However, she maintains that her letters and telephone calls were in response to his letters and calls to her. Her reply letter contained her apology for causing him "marital difficulty" and having his therapy team changed. Ms. Doe's admissions must be considered in the context that, during the time of the letters and telephone calls, patient S3456 had just been discharged from three months as an inpatient on the psychiatric ward and had just completed his first month as an outpatient in twice weekly therapy. Ms. Doe abused her professional relationship with patient S3456 and created harm in his personal life based upon the dependent relationship between therapist and patient, and Ms. Doe's knowledge that her telephone calls to patient S3456 at home caused his wife to complain to the Psychiatric Service Chief, which resulted in his reassignment to a new therapy team. Based on these facts, the characterization of Ms. Doe's interactions with patient S3456 as constituting mental patient abuse is reasonable, is supported by substantial evidence, and should not be changed because of Ms. Doe's rebuttal.

5. In reaching resolution of the issues raised by the response letter, I have consulted with the supervisory officials who were involved in the initiation of the charges in the Notice of Intent to Report and they are in agreement with my recommendations.

SAMPLE DECISION MEMORANDUM FROM AN ORGANIZATIONAL HEAD SUCH AS A VA MEDICAL CENTER DIRECTOR (00) TO GENERAL COUNSEL (024)

(Date)

From: Director, VAMC _____

To: General Counsel (024)

Thru: VISN (XXX)
Deputy Under Secretary for Health for Operations and Management (10NC)

Subj: Disclosure to SLB
Name: John Doe, M.D.
Date of Birth: 10/4/36
Occupation: Physician
SSN: 000-00-0000
Last Known Address:
Licensure: New York #00000
Maine #0000

1. In accordance with the authority contained in VHA Handbook 1100.18, I have decided, based upon a careful review of the attached State Licensing Board (SLB) Reporting File, that there is substantial evidence to make a report to the _____ and _____ SLB regarding John Doe, M.D. In accordance with the Handbook, the file is submitted for your review to determine if requirements of the Privacy Act and other information disclosure laws have been met so that I can report that:

> John Doe, M.D., so substantially failed to meet generally-accepted standards of clinical practice as to raise reasonable concern for the safety of patients, when during his clinical performance as a general staff surgeon, he made multiple diagnostic and treatment errors.

2. The sustained charge(s) of Dr. Doe's failures are contained in the Index of Charges at Tab(s) _____

3. The specific procedures were met as indicated:

a. Advisement Notice, Tab_____.

b. Notice of Intent to Report, Tab_____.

c. Response and Rebuttal Resolution Memorandum, Tab_____.

d. All instances of conflicting evidence have been identified and resolved in the specific Unit of Evidence where the charges appear.

4. All unsupported charges and unrelated evidence, and all information unrelated to the charges, have been removed from the attached File. The SLB Reporting File is maintained and retrieved by the name of the subject professional and is filed in Privacy Act System of Records 77VA10Q, Health Care Provider Credentialing and Privileging Records – VA.

5. The File has been edited appropriately, including redacting or blanking out or otherwise eliminating:

a. Charges and related information for which substantial evidence was lacking;

b. Harmful or personal information irrelevant to the sustained charges;

c. Personal identifiers of patients are highlighted or otherwise marked to indicate how they will be redacted once the concurrence stage is completed; and

d. Records not authorized for release.

6. A copy of the File, as provided to the SLB, will be maintained at the facility.

7. Should additional information be desired, please contact, _____ _____, who is familiar with this matter at (123) abc-1234, extension 456.

(Signature)
VA Healthcare Facility Director

Attachments

SAMPLE REPORTING FILE REVIEW MEMORANDUM FROM PRIVACY OFFICER

Privacy Officer, _____ *[VA MEDICAL CENTER]*

Disclosure to State Licensing Board – _____ *[NAME OF PROFESSIONAL]*

Director, _____ *[VA MEDICAL CENTER]*

1. The Evidence File associated with the proposal to report _____ *[NAME]* to the appropriate State Licensing Board (SLB) has been reviewed for compliance with applicable legal authorities.

2. In accordance with VHA Handbook 1100.18, the following actions have been taken to complete the preparation of the Evidence File for submission to the SLB(s): (check any or all)

□ a. Patient identifiers (e.g., names, social security numbers, and home addresses) have been redacted from _____ *[IDENTIFY DOCUMENTS]* at Tab(s) _____ . VHA Handbook. 1100.18, App. B, para. 2b(1).

□ b. Records not authorized for release (e.g., medical quality assurance materials confidential and privileged under Title 38 United States Code (U.S.C.) § 5705) have been removed from Tab(s) _____ . VHA Handbook. 1100.18.

□ c. Documents that reveal the identity, diagnosis, prognosis, or treatment of individuals for drug abuse, alcoholism, HIV, or sickle cell anemia under 38 U.S.C. § 7332 have been removed from Tab(s) _____ . VHA Handbook. 1100.18.

□ d. Employee records related to drug test results or education, training, treatment, rehabilitation, or research for drug or alcohol abuse have been removed from Tab(s) _____ . VHA Handbook 1100.18..

□ e. Information that pertains to another professional that is not relevant and material to the proposed reporting has been redacted or removed from _____ *[IDENTIFY DOCUMENTS]* at Tab(s) _____ . VHA Handbook 1100.18.

□ f. Other _____

_____

_____

3. The Reporting File may be released to an SLB pursuant to either _____ *[NAME]*'s prior written consent or a qualifying law enforcement request from the SLB(s) that meets the requirements described at Appendices J and K of VHA Handbook 1100.18.

_____ [Privacy Officer]

Attachment

SAMPLE REPORTING LETTER TO STATE LICENSING BOARD

(Copy of letter to be forwarded to the Deputy Under Secretary for Health for Operations and Management (10NC)

(Date)

(Address of SLB)

Dear _____:

In compliance with applicable authority be advised that there is substantial evidence that Jane Doe, R.N., so significantly failed to meet generally-accepted standards of clinical practice so as to raise reasonable concern for the safety of patients by *(Insert summary statement here)* .

SOME EXAMPLES OF SUMMARY STATEMENTS ARE:

1. Making repeated and significant medication errors in (transcription) (administration) (documentation);
2. Making repeated and significant treatment and diagnostic errors;
3. Being unable to meet the health standards for her position;
4. Having an intimate personal relationship with a patient;
5. Abusing her position by engaging in a (business) (financial) (sexual) relationship with a patient;
6. (Verbally) (physically) (emotionally) abusing patients;
7. Making repeated (transcription) (administration) (documentation) errors with controlled medications;
8. Engaging in _____

The following identifying data are submitted:

Date of Birth:	March 20, 19xx
Social Security Number:	000-00-0000
Last Known Address:	5555 Twin Valley Road
Massachusetts License Number:	000000, Expires 3-20-2002
New York License Number:	09394578599, Expires 3-38-2003

Questions in this regard may be referred to (insert name and title), at (telephone number).

If you wish to obtain the relevant information contained in the State Licensing Board Reporting File in this case, please submit a letter to the undersigned, which meets the requirements of subsection (b)(7) of the Privacy Act. A sample letter and instructions that will permit proper disclosure are enclosed.

(Signature)
Medical Center Director
Enclosure (The enclosure is Appendix K)

SAMPLE PRIVACY ACT SUBSECTION (b)(7) LAW ENFORCEMENT LETTER FROM STATE LICENSING BOARD (SLB) REQUESTING VA's SLB REPORTING FILE

(Official Letterhead Stationery)

(Date)

Director
VA Medical Center
One Veterans Drive
Minneapolis, MN 55417

RE: John Doe, M.D.

Dear Madame:

Thank you for your recent correspondence of December 1, 200x, regarding John Doe, M.D. A review of our records reflects that Dr. Doe holds an active unrestricted license in this jurisdiction. The Board requests that you submit the relevant portions of the SLB Reporting File to support your conclusion that Dr. Doe failed to conform to generally-accepted standards of clinical practice so as to raise reasonable concern for the safety of patients.

As you may know, whenever issues of a professional's competence or harm to patients is raised, the Board has law enforcement authority to review the concerns and take action as may be appropriate to protect the public's health. I understand that the requested information is contained in a system of records and its disclosure is governed by the Title 5 United States Code § 552a, subsection (b)(7) of the Privacy Act, which permits the disclosure of the requested information to a governmental agency for a law enforcement activity. This Board is authorized by the *(INSERT APPLICABLE AUTHORITY, SUCH AS: Physicians and Nurses Practice Act, found at Section 23.345 of the State Code)* to investigate Physicians, Dentists, and Nurses licensed by this State when information is received that substandard care may be occurring and for other purposes set forth in the cited Statute.

(The paragraph in brackets is to be used only when the letter is signed by a designee and not the Board head – See following note.) **[**The Board's head has delegated to me the power to request records covered by the Privacy Act, and a copy of that delegation is also enclosed.**]**

Should you have any questions or concerns, please contact me at (123) 345-6789. Thank you for your cooperation.

Sincerely,

(Signature)
Board head or designee, as appropriate

Enclosures

NOTE: *For VA to have Privacy Act disclosure authority, the letter must be signed by the head of the SLB or a person who has been designated to act for the head of the Board. A designee must be an official of sufficient rank to ensure that the request for records has been the subject of high level evaluation of the need for the information. If the request is signed by a designee, a copy of the designation of authority, specifically citing (b)(7) of the Privacy Act, must be enclosed. The text portion of a sample (b)(7) Privacy Act delegation from a SLB acceptable to VA follows*: I am the Executive Director and head of the _____ State Board of Nursing. The _____State Board of Nursing has authority under State Statute Section xx 1234 to investigate and monitor concerns about substandard health care practices. I understand that disclosure of information contained in a system of records is governed by the Privacy Act, 5 U.S.C. §552a. Subsection (b)(7) of the Privacy Act permits the disclosure of the requested information to a governmental agency for a law enforcement activity as set forth in State Statute ABC found at Section XX of the State Code.

To assist me in carrying out my duties under the Statute, I am delegating to the persons listed below my authority to request such information on behalf of the Board:

Deputy Executive Director
Associate Executive Director for Investigations
Associate Executive Director for Prosecution

This delegation is effective on _____, 200x. The current status of any person using the above titles may be verified by calling the Board's office at (123) 456-7898.

Sincerely yours,

Mary Jones Smith, RN, MS, Ds N.
Executive Director