

NATIONAL PRACTITIONER DATA BANK (NPDB) REPORTS

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook contains requirements for health care facilities' participation in Department of Veterans Affairs (VA)-mandated paid malpractice claim review process and the process for reporting information to the National Practitioner Data Bank (NPDB) regarding physicians, dentists, and other licensed health care professionals.

2. SUMMARY OF CONTENTS/MAJOR CHANGES. This Handbook specifies:

a. The required procedure for notification of practitioners involved in the care that led to the claim through clarification of this process.

b. The specific procedures for assembly of information by facilities for submission to the Office of Medical-Legal Affairs (11ML).

c. The requirement for timely submission of information required for the paid malpractice claim review process.

d. The criteria and process for reconsideration of the determination made by the Review Panel.

3. RELATED DIRECTIVES. VHA Directive 1100 (to be published).

4. RESPONSIBLE OFFICE. Office of Quality and Performance (10Q), the Office of Patient Care Services (11), and the Office of Medical-Legal Affairs (11ML) are responsible for the contents of this Handbook. Questions may be addressed to 919-474-3905.

5. RESCISSEMENTS. VHA Handbook 1100.17, dated November 13, 2002, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of December 2014.

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DISTRIBUTION: E-mailed to the VHA Publication Distribution List 12/28/09

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NATIONAL PRACTITIONER DATA BANK (NPDB) REPORTS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook specifies the requirements for health care facilities' participation in Department of Veterans Affairs (VA)-mandated paid malpractice claim review process and the process for reporting information to the National Practitioner Data Bank (NPDB) regarding physicians, dentists, and other licensed health care professionals.

NOTE: *This Handbook does not apply to individuals in training programs, other than licensed physician and dental residents (see subpars. 8b(2) and 8b(3)).*

2. BACKGROUND

a. Under the provisions of the Health Care Quality Improvement Act of 1986 (Public Law (Pub. L.) 99-660), which established the NPDB, and a Memorandum of Understanding (MOU) between VA and the Department of Health and Human Services (HHS), reports of certain malpractice payments and certain clinical privileges actions must be submitted to the NPDB and appropriate state licensing boards for VA practitioners. Regulations in Title 38 Code of Federal Regulations (CFR) Part 46 published in the Federal Register on April 23, 2002, set forth VA policy regarding participation in NPDB reporting requirements. These reporting requirements apply to all VHA physicians, dentists, and other licensed health care practitioners involved in patient care who are employed, appointed, or contracted for, under job titles listed in the NPDB document entitled "Occupation/Field of Licensure Codes" on a full-time (FT), part-time (PT), intermittent, consultant, attending, without compensation (WOC), on-station fee-basis, on-station contract, on-station scarce medical specialty, mutual use, or sharing agreement basis. Since the NPDB is unable to ensure the identity of any individual in the absence of a license number, individuals who do not have a license will not be reported, except in special circumstances as outlined in subparagraph 8i(5).

b. For purposes of this Handbook, a malpractice payment is a payment, by way of settlement or judgment, by the United States on a claim of medical malpractice as defined in 38 CFR Section 46.1(b).

c. For purposes of this Handbook, adverse action is defined as reduction, suspension, denial (other than initial), nonrenewal, or revocation of privileges for a period exceeding 30 calendar days.

3. SCOPE

VHA facilities must file a report with the NPDB in accordance with regulations in 45 CFR Part 60, Subpart B, as applicable, and 38 CFR Part 46 regarding:

a. Any payment for the benefit of a physician, dentist, or other licensed health care practitioner, which was made as the result of a settlement or judgment of a claim of medical malpractice, in accordance with the procedure outlined in 38 CFR Part 46.3(b), and

b. Adverse clinical privileges actions (e.g., restriction, suspension, revocation, etc.) taken against physicians and dentists that are final and affect privileges for more than 30 calendar days, as well as acceptance of the surrender of clinical privileges, or the restriction of clinical privileges of physicians and dentists, when the action is related to professional competence or professional conduct.

NOTE: *Malpractice payment reporting applies to all licensed health care professionals. Adverse action reporting applies only to physicians and dentists.*

4. RESPONSIBILITY OF THE REGIONAL COUNSEL

The Regional Counsel is responsible, by encrypted electronic mail, for:

a. Providing notification to the Directors of all involved medical centers, with copies to Chiefs of Staff and Quality Managers of all involved medical centers, the Veterans Integrated Service Network (VISN) Director, and VISN Chief Medical Officer that a medical malpractice claim has been filed under the Federal Tort Claims Act (FTCA). The notification to the Quality Managers of all involved medical centers needs to include a copy of Standard Form (SF) 95, Claim for Damage, Injury, or Death.

b. Providing notification to the Directors of all involved medical centers, with copies to Chiefs of Staff and Quality Managers of all involved medical centers, the VISN Director, and VISN Chief Medical Officer that a medical malpractice claim has been paid.

c. Providing, upon payment of a medical malpractice claim, pertinent documents including, but not limited to, the SF 95 and "VA Tort Claim Information System" printout to the Director, Office of Medical-Legal Affairs.

5. RESPONSIBILITY OF THE DIRECTOR, OFFICE OF MEDICAL-LEGAL AFFAIRS

The Director, Office of Medical-Legal Affairs, is responsible for coordinating the paid malpractice claim review process. In this context, the Director:

a. Receives the Regional Counsel's notification of malpractice payment.

b. Requests Medical Center Director(s) to provide, in accordance with subparagraph 8d, all documentation pertinent to the episode of care that led to the claim. A copy of this request is sent to the VISN Director, VISN Chief Medical Officer, and the VA medical center Chiefs of Staff, the Quality Managers, and the Risk Managers.

c. Selects and appoints the members of the paid malpractice claim Review Panel.

d. Moderates and serves as advisor to the Review Panel.

e. Summarizes the episode of care that led to the claim and the rationale for the Review Panel's determination regarding the standard of care rendered. Provides this information to the Director(s) of the involved medical center(s), with copies to the VISN Director, the VISN Chief Medical Officer, and the Chiefs of Staff, Quality Managers, and NPDB coordinators of the involved medical center(s), along with certification of the panel's conclusions signed by all panel members.

f. Receives from the Medical Center Director, a copy of submitted NPDB report(s).

6. RESPONSIBILITY OF THE MEDICAL CENTER DIRECTOR

Each Medical Center Director is responsible for:

a. Receiving Regional Counsel notification of malpractice payment.

b. Reporting and providing a copy of a paid claim to the Director, Office of Medical-Legal Affairs, for any payment made by VISN Directors and Medical Center Directors for monetary claims for \$2,500 or less filed under FTCA. *NOTE: Nothing in this Handbook relieves the facility Director of responsibility from any other VHA requirements for the review of Tort Claims.*

c. Providing written notification to all involved practitioners, within 30 calendar days of notification by Regional Counsel, that a claim has been filed.

d. Providing, upon notification by Regional Counsel, notification to all involved practitioners, in accordance with subparagraph 8c(2), that a claim has been paid.

e. Ensuring that all documents pertinent to the episode of care that led to the claim are provided to the Director, Office of Medical-Legal Affairs, in accordance with the requirements stated in subparagraph 8d.

f. Reviewing the conclusions of the paid malpractice claim Review Panel for further action.

g. Notifying the involved practitioner(s) of the Review Panel's conclusions.

h. Filing a report with NPDB and appropriate State Licensing Boards (SLBs) in accordance with requirements outlined in this Handbook (see subpar. 8i).

i. Acting as the authorized representative for all submissions to the NPDB. Any delegation of authority for submission of reports to other facility officials must be documented in writing to include date of delegation and circumstances governing delegation. The authorized representative for purposes of making reports must be limited to a formally-designated Acting Director. Copies of reports to the NPDB and related documentation must be filed in the reported individual's Credentialing and Privileging Folder.

NOTE: Paragraph 8 addresses the review process for, and NPDB reports related to, malpractice payments. Paragraph 9 addresses reports related to clinical privileges actions, and includes guidelines for formal review procedures to be followed prior to initiating such reports.

j. Providing the Office of Medical-Legal Affairs, within 30 calendar days of notification, a copy of the submitted NPDB report.

k. Ensuring that the requirements of this Handbook are incorporated into appropriate medical center publications.

l. Ensuring that actions taken under these procedures are strictly followed and documented.

NOTE: VHA officials are expressly prohibited from entering into formal or implied agreements not to report an employee in return for a personnel action, such as in: resignation, retirement, accepting a reassignment, etc. VHA officials cannot enter into formal or implied agreements to restrict information that would otherwise be reported under the provisions of this Handbook.

7. RESPONSIBILITY OF THE CHIEF PATIENT CARE SERVICES OFFICER

The Chief Patient Care Services Officer is authorized to submit the report concerning a medical malpractice payment reviewed pursuant to paragraph 8i(6) to the NPDB and is responsible for providing copies to the Medical Center Director, the practitioner, and SLBs. This is done in cases where the Chief Patient Care Services Officer deems it appropriate to do so following the review panel's determination that a malpractice payment has been made for the benefit of a physician, dentist, or other licensed health care practitioner.

8. MALPRACTICE PAYMENTS

a. **Parameters for Reporting Licensed Practitioners.** All licensed health care practitioners must be reported according to the requirements of this Handbook.

b. **Parameters for Reporting Licensed Trainees.** All licensed health care trainees must be reported according to the requirements of this Handbook.

(1) Attending staff (including contract employees, such as scarce medical specialists) are responsible for actions of interns and residents assigned under their supervision.

(a) Where the actions of a licensed trainee warrant reporting (for substandard care, professional incompetence, or professional misconduct), but did not result from gross negligence or willful professional misconduct, the attending is to be reported without mention of an involved trainee, but with a notification that the attending is being reported in a supervisory capacity.

(b) In circumstances where the Review Panel concludes that the payment of a claim was related to substandard care, professional incompetence, or professional misconduct resulting from gross negligence or willful professional misconduct on the part of a licensed trainee in a

training or residency program, the trainee must be reported to the NPDB. **NOTE:** *In this instance, the attending is not reported unless the Review Panel concludes there was substandard care, professional incompetence, or professional misconduct on the part of the attending in the supervisory role.*

(2) Physician residents who function outside the scope of their training program, e.g., who are appointed as the Admitting Officer of the Day (AOD), are to be considered and reported, if appropriate, as attending physicians.

(3) Unlicensed trainees are not to be reported since the NPDB is unable to ensure the identity of any individual in the absence of a license number, except in special circumstances as outlined in subparagraph 8i(5).

c. Practitioner Notification

(1) Practitioner Notification Prior to Payment

(a) The Medical Center Director identifies all practitioners involved in the episode of care that led to the claim.

(b) The Medical Center Director provides written notification to all involved practitioners that a claim has been filed within 30 calendar days of notification by Regional Counsel.

(c) A practitioner may consult an attorney at the practitioner's own expense. Regional Counsel is not authorized to represent the practitioner in matters related to Data Bank reporting. **NOTE:** *It is VA policy that each Medical Center Director must provide written notification to all licensed practitioners, who were assigned to provide care to a patient, when such care results in a claim for medical malpractice, within 30 calendar days from the date that Regional Counsel notifies the Director that a claim for medical malpractice has been filed under FTCA.*

NOTE: *In the event of payment, the Medical Center Director must notify all involved practitioners of the opportunity to submit a written statement to the Review Panel. Therefore, it is recommended that the Medical Center Director maintain a current verified address for all practitioners involved in all filed claims. The Medical Center Director may wish to maintain contact with the Regional Counsel regarding the status of filed claims.*

(2) Practitioner Notification Post Payment

(a) The Medical Center Director is responsible for notifying all involved practitioners of the opportunity to provide a written statement concerning the care that led to the claim for consideration by the Review Panel.

(b) For each involved practitioner, the Medical Center Director's notification must be in writing and hand-delivered or sent to the practitioner's current verified business or home address. If the practitioner is deceased, this information must be forwarded to the Review Panel in place of a written statement.

(c) For each involved practitioner, the Medical Center Director's notification must state that VA is considering whether to report the practitioner to the NPDB because of a specified malpractice payment. Reporting to the NPDB is based on the finding by a Review Panel that there was substandard care, professional incompetence, or professional misconduct during an episode of care. Attending staff are responsible for actions of health professional trainees assigned to their supervision. When licensed residents in training are identified as providers of substandard care, professional incompetence, or professional misconduct, the attending physician may be reported in the supervisory capacity, without mention of the licensed trainee except where the trainee's care is described as gross negligence or willful professional misconduct. In this case, the licensed trainee is to be reported without mention of the attending.

(d) For each involved practitioner, the Medical Center Director's notification must state that the request for a statement does not imply blame or fault, but, rather, is the practitioner's opportunity to submit information for consideration by the Review Panel.

(e) For each involved practitioner, the Medical Center Director's notification must state that:

1. The practitioner has the opportunity to submit a written statement concerning the care that led to the claim.

2. The practitioner is allowed 60 calendar days from receipt of notification and access to the medical record to submit the statement to either the Medical Center Director or the Director, Office of Medical-Legal Affairs.

3. The written statement is the practitioner's only opportunity to submit information for consideration by the Review Panel.

(f) For each involved practitioner not submitting a statement, the Medical Center Director is responsible for documenting that the involved practitioner received notification of the opportunity to submit a written statement. Written acknowledgement of receipt from the practitioner must be obtained. A copy of the certified mail return receipt postcard signed by the practitioner is acceptable documentation of receipt as is a delivery service (e.g., FedEx, United Parcel Service (UPS)) tracking record signed by the practitioner. A copy of the letter of notification with the practitioner's dated signature verifying receipt is also acceptable documentation. If a receipt is not returned, is not signed, or is signed by someone other than the practitioner, follow-up with the practitioner is required to document that the practitioner, in fact, received the notification. Acceptable follow-up with the practitioner includes, but is not limited to, email, fax, and telephone with documentation of follow-up on VA Form 119, Report of Contact.

(g) If an involved practitioner cannot be located, the Medical Center Director must provide documentation of the comprehensive efforts made to locate and contact that practitioner. Information sources that may prove useful in locating a practitioner include, but are not limited to: Human Resources Departments, Credentialing Offices, SLBs, specialty certification boards, educational institutions attended by the practitioner, and Internet searches.

(h) The Medical Center Director is responsible for providing all involved practitioners access to substantially the same medical record as that submitted for panel review. **NOTE:** *The records provided for review may have personally identifying information redacted to comply with statutes governing release of health information.*

NOTE: *Health Insurance Portability and Accountability Act of 1996 (HIPAA) does not supersede the prerogative of the involved practitioner to access the medical record in preparation of a statement.*

NOTE: *If the medical record is no longer at the facility where the care that led to the claim occurred, it must be obtained.*

NOTE: *Without a routine use or written authorization permitting disclosure of the personally-identifying information of a living patient, practitioners who are no longer employed by VA or their attorneys may not access the relevant portion of the medical record, unless the data is de-identified in accordance with VHA Handbook 1605.1.*

(i) On a rare occasion, the Review Panel may identify an additional practitioner involved in the care that led to the claim. In this instance, the Medical Center Director must be informed by the Director, Office of Medical-Legal Affairs, and is responsible for notifying that practitioner as in accordance with subparagraphs 8c(2)(a)-(h). Submission of this required information must be in accordance with subparagraph 8d.

d. **Information Submitted For Panel Review.** The Medical Center Director is responsible for sending to the Director, Office of Medical-Legal Affairs, all information necessary for the Review Panel including, but not limited to:

(1) Medical records limited to records pertinent to the episode of care that led to the claim.

(2) Reports of Administrative Investigation Board(s) appointed to investigate the episode of care.

NOTE: *Records that are confidential and privileged under the provisions of Title 38 United States Code (U.S.C.) 5705 cannot be submitted.*

(3) A list of all involved practitioners with status (Attending, Resident, Registered Nurse (RN), Nurse Practitioner (NP), etc.).

(4) A copy of the Medical Center Director's letter of notification to each practitioner.

(5) A written statement from each practitioner or documentation of fulfillment of the required procedure for practitioner notification, in accordance with subparagraph 8c(2), if the practitioner has not submitted a statement.

(6) All other information associated with the episode of care that led to the claim.

(7) Other information or documents requested by the Director, Office of Medical-Legal Affairs.

e. **Organization of Information Submitted For Panel Review.** All information is to be organized as follows and sent in one package to Director, Office of Medical-Legal Affairs.

(1) All material must be legible, sectioned using letter size tabbed indexes, labeled as detailed in subparagraph 8e(2), and in chronological order (earliest date first) within each section.

(2) Information is to include, in the following order:

(a) Tab labeled “Practitioners:”

1. List of licensed practitioners involved in the episode of care that led to the claim, including profession and specialty and/or subspecialty, and the status of each practitioner at the time of the episode (i.e., Resident or Fellow), if applicable.

2. A copy of the Medical Center Director’s letter notifying each practitioner of the opportunity to submit a written statement.

3. A written statement from each practitioner.

4. For each practitioner not providing a statement, documentation of receipt of notification in accordance with subparagraph 8c(2).

(b) Tab labeled “Admissions,” with tabs for each admission pertinent to the episode of care that led to the claim, in chronological order (earliest date first); the following information must be included in the appropriate section tabbed accordingly:

1. Tab labeled “Discharge Summary” with date of admission and date of discharge.

2. Tab labeled “Emergency Department.” Include written information such as VA Form 10-10M, Medical Certificate, or other documents.

3. Tab labeled “Operative Reports.” Include physician’s dictated operative report, nurse intraoperative report, anesthesia intraoperative clinical report, and patient consent.

4. Tab labeled “Inpatient Progress Notes.”

5. Tab labeled “Consultation Reports.”

6. Tab labeled “Radiology Reports.” Include films and images with submitted information when pertinent to the episode of care that led to the claim.

7. Tab labeled “Laboratory Reports.”

8. Tab labeled “Pathology and Autopsy Reports.”

9. Tab labeled “Other.” Include information pertinent to the episode of care that led to the claim not included in any of the preceding subparagraphs.

NOTE: Repeat the preceding sequence for each admission pertinent to the episode of care that led to the claim.

(c) Tab labeled “Outpatient Information” includes all outpatient records pertinent to the episode of care that led to the claim, in chronological order (earliest date first). The following information must be included within the appropriate section demarcated by a tab:

1. Tab labeled “Outpatient Progress Notes.” Include primary care, consultations, and allied health progress notes.

2. Tab labeled “Radiology Reports.” Include films and images with submitted information when pertinent to the episode of care that led to the claim.

3. Tab labeled “Laboratory Reports.”

4. Tab labeled “Pathology Reports.”

5. Tab labeled “Other.” Include outpatient information pertinent to the episode of care that led to the claim not included in any of the preceding sections.

(d) Tab labeled “Administrative Board of Investigation Report.”

(e) Tab labeled “Office of Medical-Legal Affairs Checklist.” The checklist must be signed and dated by medical center Chief of Staff and packet preparer (see App. C).

f. **Timeliness of Information For Panel Review**

(1) The Director, Office of Medical-Legal Affairs must send a request to the Medical Center Director for information for submission to the Review Panel using encrypted email or other secure method of transmission.

(2) All information submitted for panel review needs to be sent by delivery service (such as FedEx, UPS, or United States Postal Service) with tracking capability.

(3) Materials not meeting the quality requirements as in accordance with subparagraphs 8c, 8d, and 8e are not appropriate for submission to the Review Panel and the complete submission will be returned in total to the Medical Center Director for revision and resubmission.

(4) The Office of Medical-Legal Affairs must receive all required materials in accordance with this Handbook no later than 75 calendar days from the date of Director, Office of Medical-Legal Affairs' request for submission of these materials.

g. **Panel Review Process**

(1) Upon receipt of the material from the Medical Center Director, the Director, Office of Medical-Legal Affairs, must assign a minimum of three healthcare professionals to be panelists. All panels must include a member of the same profession and specialty, as appropriate, of the individual whose practice is being reviewed. Other professionals are to be appointed as necessary. If the review of the episode of care requires specialty-specific knowledge, the panel may request a consultation from an appropriate specialist.

(2) Each panelist is assigned cases and is responsible for reviewing all materials pertinent to the care that led to the claim. The reviewing panelist prepares a summary of the review and presents it to the panel for discussion. The panel decides, by majority vote, if care that led to the claim constituted substandard care, professional incompetence, or professional misconduct and determines if the substandard care, professional incompetence, or professional misconduct for which the payment was made is attributed to a licensed practitioner. For care rendered by trainees, the criteria for reporting a trainee are gross negligence or willful professional misconduct.

(3) The non-voting Director, Office of Medical-Legal Affairs, or designee, must participate in person with the Review Panel to familiarize the panel members with VA policy and regulation and to provide direction.

(4) A prospective panelist is required to exclude himself or herself from participation in case consideration if either a provider or the claimant is:

(a) The panelist's spouse, minor child, or any relative with whom the panelist has a close personal relationship;

(b) A member of the panelist's household;

(c) A person with whom the panelist has a close personal relationship;

(d) A person for whom the panelist serves as a general partner, officer, director, trustee or employee;

(e) A person for whom within the last year the panelist has served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;

(f) A person for whom, to the panelist's knowledge, the panelist's spouse, parent, or any relative with whom there is a close personal relationship serves as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;

(g) A person with whom the panelist is seeking employment or with whom the panelist has an arrangement for future employment; or

(h) A person with whom the panelist has, or seeks, a contractual, business, or other financial relationship, other than an employment relationship described in the previous clause.

h. Panel Review Determination

(1) The Director, Office of Medical-Legal Affairs, prepares a memorandum that includes a narrative summary of the patient care and the rationale for the Review Panel's conclusion that is sent to the Directors of all involved medical centers, with copies to the VISN Director, the VISN Chief Medical Officer, and the Chiefs of Staff, Quality Managers, and NPDB Coordinators, identified by the medical center, of all involved medical centers, along with certification of the panel's conclusions signed by all panel members.

(2) At the discretion of the Director, Office of Medical-Legal Affairs, the Review Panel may be asked to reconsider its determination based on submission of substantive new or additional information not previously available. The reconsideration process does not obviate the requirement for the Medical Center Director to submit the report to the NPDB within 30 calendar days of notification in accordance with subparagraph 8i. If reconsideration determines that the original report to the NPDB is to be voided, the Director, Office of Medical-Legal Affairs, must notify the Medical Center Director and copy those who were notified of the original determination. The Medical Center Director must notify the appropriate entities in accordance with subparagraph 8i(7).

(3) Upon case completion, the Office of Medical-Legal Affairs must contact the medical center Risk Manager to determine disposition of records and carry out the medical center Risk Manager's recommendation for disposition of the record.

(4) The records provided for review may have personally identifying information redacted to comply with statutes governing release of health information.

i. Submission of NPDB Reports

(1) Payment will be considered to have been made for the benefit of a physician, dentist, or other licensed health care practitioner when the Director, Office of Medical-Legal Affairs, notifies, per subparagraph 8h(1), the Medical Center Director that the conclusion (of at least a majority) of the Review Panel is that payment was related to substandard care, professional incompetence, or professional misconduct on the part of the physician, dentist, or other licensed health care practitioner. In any case where professional incompetence or professional misconduct is involved, coordination with other relevant processes should occur (e.g., Professional Standards Board, Disciplinary Appeals Board, or administrative investigations). Any coordination is not intended to delay processes outlined in this Handbook. Prior to submitting the report to the NPDB, the Medical Center Director may notify the practitioner to be reported in order to provide an opportunity for discussion with appropriate facility officials, including the Director, before the report is submitted. This discussion may only encompass issues surrounding the accuracy of the report and is not to be considered as an appeal of the

merits of the determination that lead to the report. **NOTE:** *Review of content prior to submission could reduce later misunderstanding. The NPDB must send a copy of the computerized report to the facility and the practitioner with a limited comment period in which to make any changes in the facts of the report.*

(2) The Medical Center Director must file a report with the NPDB, on behalf of the VA medical facility, or any remote clinics operated by VA, regarding any medical malpractice payment that the review procedures established was related to substandard care, professional incompetence, or professional misconduct on the part of a physician, dentist, or other licensed health care professional.

(3) Malpractice payments made as the result of a settlement, or judgment, of a claim of medical malpractice and subsequent to the formal review process, outlined in the preceding are to be reported to the NPDB, as well as a copy of the report to the SLB(s) in all state(s) where practitioners hold licenses, and in the state where a reportable episode of care occurred.

(4) A copy of the NPDB report must also be sent by the Medical Center Director to the Director, Office of Medical-Legal Affairs, within 30 calendar days of receipt of notification that the NPDB report is to be filed.

(5) If it is determined that a practitioner or trainee, past or present, claims or claimed a license that was not held, but would be reportable under provisions of this policy if a license was held, the practitioner must be reported to NPDB. **NOTE:** *In these cases, the Medical Malpractice Payment Report for NPDB report would be completed by inserting the words "No License," and attaching a statement signed by the facility's authorized representative explaining why the report is being filed without a license number.*

(6) Medical Center Directors are responsible for filing the report to NPDB within 30 calendar days of receipt of notice from the Director, Office of Medical-Legal Affairs, of the determination by the Review Panel that report(s) is to be made due to a finding of substandard care, professional incompetence, or professional misconduct on the part of the practitioner. Reconsideration of the panel's determination, in accordance with subparagraph 8h(2), does not obviate the requirement to file the report with the NPDB within the required 30 calendar days. Reports not made within this period are subject to reporting by the Chief Patient Care Services Officer.

(7) Any corrections, revisions, additions, or voiding of previously submitted reports are to be submitted to the NPDB, all SLB(s) previously notified, and any VA offices which received copies of the initial report. Canceled or voided reports must be removed from the practitioner's credentialing and privileging file and filed elsewhere with voided reports. In accordance with the NPDB, once the NPDB report has been voided and the notice of the void distributed to the practitioner, the reporting entity, and those who queried the NPDB and received the now-voided report within the last 3 years, the NPDB must never again disclose the existence of the now-voided report or the filing of the report to anyone. **NOTE:** *The Medical Center Director is responsible for advising previous recipients of this information that the report to NPDB has been voided.*

(8) Payments made for claims of malpractice in which the review panel determines that the standard of care was met and there was no professional incompetence or professional misconduct, or which the panel determines are due solely to circumstances beyond the control of the practitioner (including, but not limited to: power failure, accidents unrelated to patient care, drugs mislabeled by the supplier, equipment malfunction, etc.) are not to be reported.

(9) Claims that are closed without payment and compensation payments due to an award under the provisions of 38 U.S.C. 1151 are not reportable and are not to be referred to review panels.

j. **Exceptions to NPDB Reporting.** Examples of exceptions to NPDB reporting are:

(1) The practitioner, determined by the panel to be reportable, is a contractor or an employee of a contractor (or subcontractor or employee of a subcontractor) on behalf of whom a payment has been made in the case and who has been reported to the NPDB by a different entity.

(2) The practitioner, determined by the panel to be reportable, is an employee of another Federal agency. **NOTE:** *The Director, Office of Medical-Legal Affairs, informs the appropriate Federal agency.*

(3) The case arises from a Patient Alert based upon product recalls or similar institutional corrections not implicating an individual practitioner, at the discretion of the Director, Office of Medical-Legal Affairs, in consultation with the Assistant General Counsel (021).

k. **NPDB Report Forms.** Reports to the NPDB are to be submitted electronically using software provided by the NPDB. These include:

(1) **The Medical Malpractice Payment Report.** Submission of an initial report or correction, revision, addition, or voiding of a previously submitted report must be in accordance with instructions on the NPDB website at: www.npdb-hipdb.hrsa.gov.

(2) **Any Additional Information.** Completion of information regarding any medical malpractice payment report for which the initial reporting form does not allow adequate space to provide all relevant information must be in accordance with instructions on the NPDB website at: www.npdb-hipdb.hrsa.gov.

9. ADVERSE ACTIONS

a. **Parameters for Reporting Adverse Actions**

(1) When the Medical Center Director renders a final determination based on a clinical professional review, relating to possible incompetence or improper professional conduct, that adversely affects the clinical privileges of a physician or dentist by reducing, restricting, suspending, revoking, or failing to renew such privileges for a period longer than 30 days, such action must be reported.

(2) The acceptance of the surrender of clinical privileges, or any restriction of such privileges, by a physician or dentist while such physician or dentist is under investigation by the health care entity for possible incompetence or improper professional conduct, or in return for not conducting such an investigation or proceeding, whether or not the individual remains in VA service, is reported in accordance with NPDB policy. At the time a physician or dentist surrenders, or voluntarily accepts restriction of clinical privileges, resigns, or retires from the medical position in VA while under investigation for possible professional incompetence or improper professional conduct, the physician must be formally notified that reporting to the NPDB is required. The physician must be offered due process (as outlined in VHA Handbook 1100.19) regarding reduction and revocation of privileges. Individuals who choose not to avail themselves of the due process procedures waive their right to due process and must be reported.

NOTE: *It is intended that the report be filed within 15 calendar days of the date the action is made final by signature of the VA Medical Center Director.*

b. Provisions for Reporting Adverse Actions

(1) Final Actions related to professional competence or conduct that adversely affect clinical privileges of a physician or dentist for a period longer than 30 calendar days must be reported to the NPDB and a copy of this report must be sent to the SLB in the state in which the facility is located and the SLB in all states where the practitioner holds licenses. This report is called an "Adverse Action Report" by the NPDB. **NOTE:** *For purposes of this Handbook, adverse action is defined as reduction, suspension, denial (other than initial), nonrenewal, or revocation of privileges for a period exceeding 30 calendar days.*

(a) Prior to reporting to any SLB or NPDB, appropriate internal VA medical center due process procedures, pursuant to the provisions of VHA Handbook 1100.19 regarding reduction and revocation of privileges, must be completed.

(b) Action taken to restore clinical privileges of physicians or dentists previously reported as restricted is to be reported in the same manner as the original report with copies to all recipients of the original report.

(c) Any corrections, revisions, additions, or voiding of previously submitted reports are to be submitted to the NPDB and SLB(s) in the same manner as the original report with copies to all recipients of the initial report.

NOTE: *Actions to restore privileges previously reduced, suspended, or revoked are not considered a void. Voided reports must be removed from the practitioner's credentialing and privileging file and filed elsewhere with voided reports. The Medical Center Director is responsible for advising previous recipients of this information, that the report to the NPDB has been voided.*

(2) Summary suspension of clinical privileges pending review by the executive committee of the medical staff or other review panel is not reportable. If final action related to professional

competence or conduct is taken by the Medical Center Director following the review, both the summary suspension and final action that adversely affect privileges for a period longer than 30 calendar days are reportable. **NOTE:** *For information on Summary Suspension of clinical privileges see VHA Handbook 1100.19.*

(3) The acceptance of the surrender of clinical privileges, including the surrender of clinical privileges inherent in resignation or retirement, or any restriction of clinical privileges by a physician or dentist either while under investigation by the facility for possible incompetence or improper professional conduct, or in return for not conducting such an investigation or proceeding whether or not the individual remains in VA service, must be reported to the NPDB. A copy of this report must be sent to the SLB in the state in which the facility is located and to the SLB in all states where the practitioner holds licenses.

(4) Independent contractors and/or subcontractors acting on behalf of VA are subject to the VA policies on credentialing and privileging and NPDB reporting. In the following circumstances, VA must provide the contractor and/or subcontractor with appropriate internal VA medical center due process, pursuant to the provisions of VHA Credentialing and Privileging policy regarding reduction and revocation of privileges, prior to reporting the contractor and/or subcontractor to the NPDB and filing a copy of the report with the SLB(s) in the state(s) in which the contractor and/or subcontractor is licensed and in which the facility is located:

(a) When VA terminates a contract and/or subcontract for possible incompetence or improper professional conduct, thereby automatically revoking the medical staff appointment and clinical privileges of the contractor and/or subcontractor.

(b) When the contractor and/or subcontractor terminates the contract and/or subcontract, thereby surrendering clinical privileges, either while under investigation relating to possible incompetence or improper professional conduct, or in return for not conducting such an investigation or proceeding following appropriate due process procedures.

(c) When VA terminates the services (and associated medical staff appointment and clinical privileges) of a contractor employee or subcontractor employee under a continuing contract for possible incompetence or improper professional conduct.

c. Responsibility For Reporting Adverse Actions

(1) The Director of the VA medical center must file an adverse action report, on behalf of the VA medical facility and on behalf of any satellite clinics operated by them, within 15 calendar days of the date the action is made final by signature of the Medical Center Director, with the:

(a) NPDB,

(b) SLB in the state in which the facility is located (copy), and

(c) SLBs in all states in which the practitioner is licensed (copy).

(2) Prior to approving the report, the Medical Center Director must notify the practitioner to be reported and provide the practitioner an opportunity for discussion with appropriate facility officials, including the Medical Center Director, before the report is submitted. **NOTE:** *Review of content prior to submission reduces later misunderstanding. The NPDB must send a copy of NPDB's computerized report to the facility and the practitioner with a limited comment period in which to make any changes in the facts of the report.*

d. **Forms.** Reports to the NPDB must be submitted electronically using software provided by NPDB or on the appropriate form(s) provided by the NPDB. These include:

(1) **The Adverse Action Report.** The Adverse Action Report is used for submission of the initial report, correction, revision, addition, or voiding of a previously submitted report in accordance with instructions on the NPDB website at: www.npdb-hipdb.com.

(2) **Additional Information.** This is used for completing information regarding any Adverse Action Report for which the initial format does not allow adequate space to provide all relevant information in accordance with instructions on the NPDB website at: www.npdb-hipdb.com.

10. POST-NPDB REPORTING AND THE HHS DISPUTE PROCESS

a. Following the reporting by the facility to the NPDB, the NPDB must send a copy of the computerized report to the facility and to the practitioner (the Notification of a Report in the Data Bank(s)) with a limited comment period.

b. The practitioner can not submit changes to the report. If the practitioner believes the report contains factual inaccuracies, the practitioner must contact the reporting facility to request that it file a correction to the report in accordance with the NPDB's requirements. If the reporting facility declines to change the report, the provider may add a statement, initiate a dispute of the report in accordance with and through the NPDB dispute process, or both. **NOTE:** *HHS does have a dispute process for reports made to the NPDB. This process is external to VA and is initiated by the practitioner.*

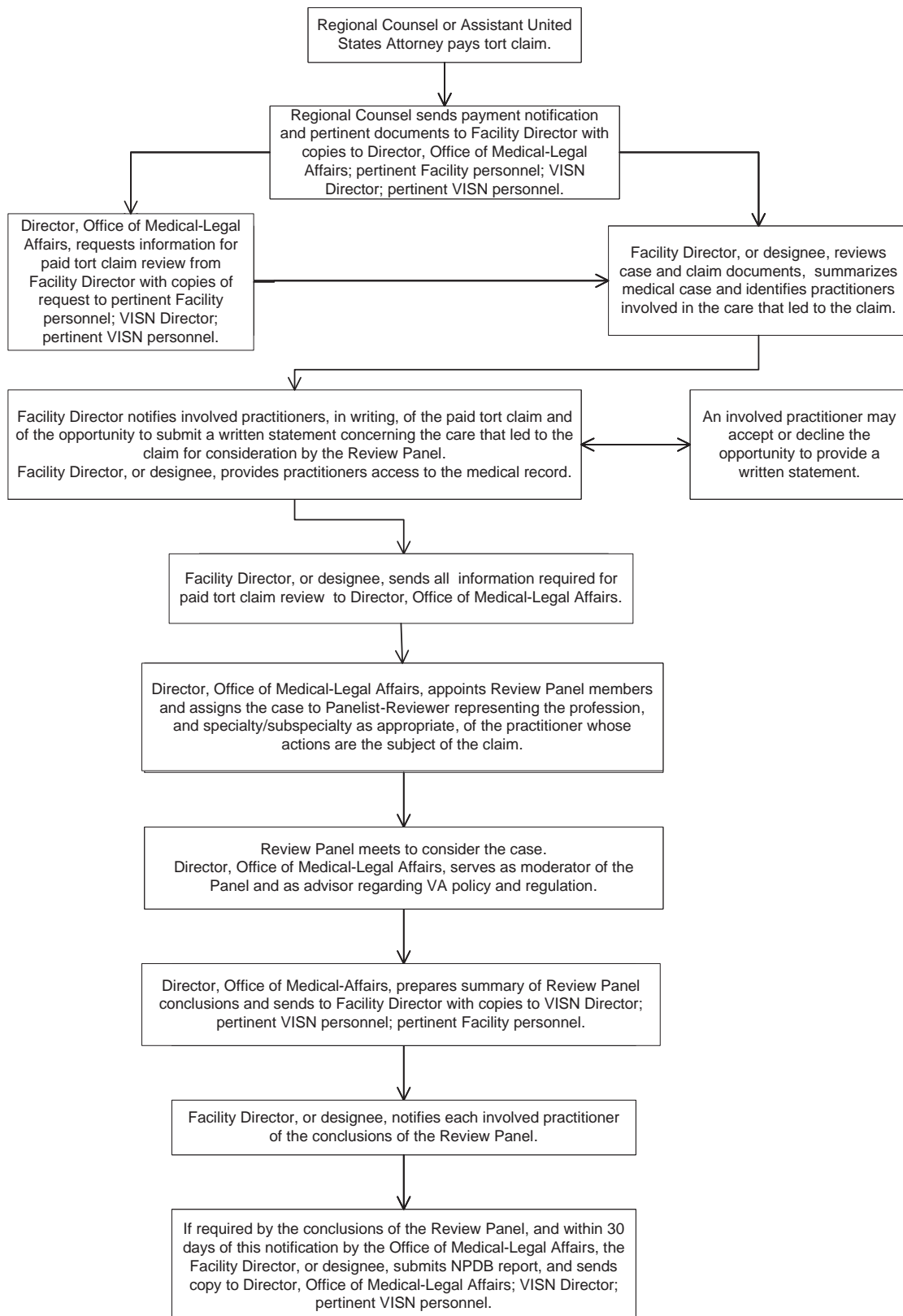
c. Practitioners who wish to add a statement to or dispute the factual accuracy of a report need to follow the instructions provided by the NPDB on the Notification of a Report in the Data Bank(s). The NPDB dispute process is not an avenue to protest a payment or to appeal the underlying reasons for reporting. Practitioners who wish to dispute the factual accuracy of the report or that the report was not submitted in accordance with NPDB reporting requirements may do so. Information on this process can be obtained from HHS through the NPDB.

11. REFERENCES

- a. Pub. L. 99-660 and its revisions (Pub. L. 100-177).
- b. Title 45 CFR Part 60.
- c. Title 38 CFR Part 46.

- d. Title 38 U.S.C. 7401 and 7405.
- e. MOU between HHS and VA, effective October 1, 1990.
- f. VA Handbook 5005.
- g. VA Handbook 5021, Part VI.
- h. Privacy Act System of Records Notice, 77VA10Q, Health Care Provider Credentialing and Privileging Records - VA.
- i. National Practitioner Data Bank Guidebook.
- j. VHA Handbook 1605.1

VHA PAID TORT CLAIM REVIEW PROCESS



SAMPLE FACILITY NOTIFICATION LETTER

Date: Month/Day/Year

From: Director, Office of Medical-Legal Affairs (11ML)

Subj: National Practitioner Data Bank Review Process

To: (Facility Director Name)
(Facility)

1. A payment has been made on a claim against the United States arising out of medical care provided at your facility in the case of:

Patient's Name:

Social Security Number (SSN):

2. The Office of Medical-Legal Affairs (OMLA) is required by Veterans Health Administration (VHA) regulation to conduct the Review Panel for this paid malpractice claim in accordance with the National Practitioner Data Bank (NPDB) reporting program. Your assistance in facilitating this review is required (Title 38 Code of Federal Regulations (CFR) Part 46 and VHA Handbook 1100.17). OMLA is to receive all required information for paid tort claim review no later than 75 calendar days from the date of this memorandum.

3. Practitioner Identification

a. Identify each practitioner involved in the episode of care which led to the claim and for which payment was made. ***NOTE:** If a resident is identified, the attending physician is also an involved practitioner.*

b. Inform each practitioner that the practitioner may be reported to the NPDB based on the conclusion of a Review Panel regarding the standard of care rendered.

4. Practitioner Statement

a. Offer each practitioner the opportunity to submit a written statement concerning the care that led to the claim. A request for a statement does not imply blame or fault. In accordance with VHA regulation, a practitioner is allowed 60 calendar days from receipt of notification and access to the medical record to submit a statement.

b. Notification of the opportunity to submit a statement is mandatory. The practitioner may accept or decline.

c. The practitioner must be provided access to substantially the same medical record as that submitted for panel review.

d. The written statement is the only opportunity in the review process for a practitioner to submit information for consideration by the Review Panel.

5. Practitioner Notification

a. For each involved practitioner, the Medical Center Director's notification must be in writing and hand-delivered or sent to the practitioner's current verified business or home address. If the practitioner is deceased, this information must be forwarded to the Review Panel in place of a written statement.

b. For each involved practitioner not submitting a statement, the Medical Center Director is responsible for documenting that the involved practitioner received notification of the opportunity to submit a written statement. Written acknowledgement of receipt from the practitioner must be obtained. A copy of the certified mail return receipt postcard signed by the practitioner is acceptable documentation of receipt as is a delivery service (e.g., FedEx, United Parcel Service (UPS)) tracking record signed by the practitioner. A copy of the letter of notification with the practitioner's dated signature verifying receipt is also acceptable documentation.

c. If the receipt is not returned, is not signed, or is signed by someone other than the practitioner, follow-up with the practitioner is required to document that the practitioner, in fact, received the notification. Acceptable follow-up with the practitioner includes, but is not limited to, email, fax, and telephone with documentation of follow-up on VA Form 119, Report of Contact. If an involved practitioner cannot be located, the Medical Center Director must provide documentation of the comprehensive efforts (e.g., query of relevant State Licensing Boards, internet search, query with medical center affiliates, liaison with credentialing office) made to locate and contact that practitioner.

d. The Medical Center Director is responsible for providing all involved practitioners access to the same medical record as that which was submitted for panel review.

6. Medical Chart Information

a. Provide organized legible copies of medical records pertinent to the care that led to the claim. **NOTE:** Follow VHA Handbook 1100.17 subparagraphs 8d and 8e to assemble the required information.

b. Information not meeting the requirements in VHA Handbook 1100.17 is not suitable for submission to the Review Panel and will be returned in total for revision and resubmission.

7. Send all information in one package to:

Director, Office of Medical-Legal Affairs (11ML)
VA WNY Healthcare System
3495 Bailey Avenue
Buffalo, NY 14215

8. Call (716) 862- 8521 with any questions.

cc: VISN Director
VISN Chief Medical Officer
VA Medical Center Chief of Staff
VA Medical Center Quality Manager
Risk Manager

OFFICE OF MEDICAL-LEGAL AFFAIRS CHECKLIST

COMPLETE, SIGN AND DATE, AND RETURN WITH YOUR PACKAGE

Patient Name _____ SS# _____

VISN _____ Medical Center _____

Preparer (PRINT) _____

Preparer (SIGN) _____ Date _____

Medical Center Chief of Staff (PRINT) _____

Medical Center Chief of Staff (SIGN) _____ Date _____

MEDICAL RECORDS Pertinent to the care that led to the claim: All materials must be legible, sectioned using letter size index tabs per below, and in chronological order (earliest date first) within each section.

	Enclosed	
	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Tab "Admissions" Provide separated dated tabs for each admission.	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Discharge Summary:" Discharge summary	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Emergency Department:" Emergency department notes including 10-10M form and other handwritten information	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Operative Reports:" Dictated operative report, nursing intraoperative report, anesthesia intraoperative clinical report and patient consent	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Inpatient Progress Notes:" Inpatient admission and progress notes	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Consultation Reports:" Consultation reports	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Radiology Reports:" Radiology reports (send films and/or electronic images if relevant)	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Laboratory Reports:" Laboratory reports	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Pathology and Autopsy Reports:" Pathology and autopsy reports	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Other:" Specify _____	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Outpatient"	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Outpatient Progress Notes:" Outpatient evaluation and progress notes including primary care, consultations, and allied health notes	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Radiology Reports:" Radiology reports (send films and/or electronic images if relevant)	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Laboratory Reports:" Laboratory reports	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Pathology Reports:" Pathology reports	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Other:" Specify _____	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Administrative Board of Investigation Report"	<input type="checkbox"/>	<input type="checkbox"/>
Administrative Board of Investigation (ABI) Report	<input type="checkbox"/>	<input type="checkbox"/>
Date ABI Convened (if ABI not convened, so document)	<input type="checkbox"/>	<input type="checkbox"/>
Tab "Office of Medical-Legal Affairs Checklist"	Required	
Office of Medical-Legal Affairs checklist signed and dated by preparer and medical center Chief of Staff		

INVOLVED PRACTITIONER INFORMATION (use additional lines if needed):

a. For each practitioner, provide a copy of the practitioner notification letter in compliance with VHA Handbook 1100.17. For each practitioner not providing a statement, submit documentation of practitioner's receipt of notification in compliance with VHA Handbook 1100.17.

PRACTITIONER NAME (TYPE OR PRINT)	Specialty or Subspecialty	Resident or Fellow		Practitioner statement enclosed		Practitioner receipt of notification enclosed	
		<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Submit this information for panel review by delivery service (such as FedEx, UPS, or USPS) with tracking.

c. Materials not meeting the quality requirements per VHA Handbook 1100.17 are not appropriate for submission to the Review Panel and the complete submission will be returned in total to the Medical Center Director for revision and resubmission.

d. The Office of Medical-Legal Affairs must receive all required materials in accordance with VHA Handbook 1100.17 no later than 75 calendar days from the date of the Office of Medical-Legal Affairs' request for submission of these materials.

SAMPLE PROVIDER NOTICE LETTER

Date:

From: Medical Center Director (00)

Subj: National Practitioner Data Bank Review Panel

To: (Insert Practitioner Name)

1. You have been identified as a participant in the episode of care of a patient treated at this facility that led to a tort claim. Since there was a paid settlement or judgment in favor of the claimant in the tort claim, you may be reported to the National Practitioner Data Bank (NPDB) according to Title 38 Code of Federal Regulations 46.
2. Reporting to the NPDB is based on the conclusions of a Review Panel that there was substandard care, professional incompetence, or professional misconduct. Attending staff are responsible for actions of interns and residents assigned under their supervision. When a licensed resident in training is identified as a provider of substandard care, professional incompetence, or professional misconduct, the attending physician may be reported in the supervisory capacity without mention of the licensed trainee, except when the resident's care is described as gross negligence or willful professional misconduct. In this case, the resident will be reported without mention of the attending.
3. Practitioners are provided an opportunity to submit a written statement concerning the care that led to the claim. The statement must be submitted to the Medical Center Director, or to the Director, Office of Medical-Legal Affairs, within 60 calendar days of your receipt of this memorandum. This is your only opportunity to provide information for consideration by the Review Panel. The request for a statement does not imply blame or fault, but, rather, is your opportunity to submit information for consideration by the Review Panel.
4. Payments made for claims of malpractice in which the Review Panel determines that the standard of care was met and there was no professional incompetence or misconduct, or which are due solely to circumstances beyond the control of the practitioner shall not be reported.
5. You may contact an attorney at your own expense. Regional Counsel is not authorized to represent you in matters related to Data Bank reporting.
6. Contact (Name of appropriate individual) at (Telephone number) at the time you receive this memorandum to answer questions and to arrange access to the medical record.

s//Medical Center Director

SAMPLE PANEL EXCLUSION LETTER

Date:

From:

Subj: Panelist's Guidelines

To: Director, Medical-Legal Affairs (11ML)

CASE IDENTIFIER: _____«Last Name», «First Name»_____

Social Security Number (SSN): Last 4 numbers

1. I have reviewed the following restrictions for prospective Veterans Health Administration (VHA) National Practitioner Data Bank (NPDB) panelists. I have circled those that apply and hereby exclude myself from participating in panel review of the above referenced case.

a. My spouse, minor child or any relative with whom I have a close personal relationship with is the claimant or practitioner;

b. The claimant or practitioner is a member of my household;

c. The claimant or practitioner is a person with whom I have a close personal relationship;

d. The claimant or practitioner is a person for whom I serve as a general partner, officer, director, trustee or employee;

e. The claimant or practitioner is a person for whom, within the last year, I have served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;

f. The claimant or practitioner is a person for whom, to my knowledge, my spouse, parent, or any relative with whom I have a close personal relationship serves as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;

g. The claimant or practitioner is a person with whom I am seeking employment or with whom I have an arrangement for future employment; or

h. The claimant or practitioner is a person with whom I have, or seek, a contractual, business, or other financial relationship, other than an employment relationship described in the previous clause.

2. None of the preceding apply to me, and I am able to serve on the panel.

(Signature) (Date)

SAMPLE REPORT OF REVIEW PANEL

Date:

From: Director, Medical-Legal Affairs (11ML)

Subj: Conclusions of Review Panel

To: Director (00)
VA Medical Center

CASE IDENTIFIER: _____ «Last Name», «First Name» _____

Social Security Number (SSN): Last 4 numbers

A three-member panel was convened on _____ (Insert Date) _____ to review the tort claim of _____ (Name of Referenced Patient) _____. The conclusions require reporting of the following provider(s) to the National Practitioner Data Bank (NPDB):

PROVIDER(S): **Provider Name and Title**

1. The act or omission for which payment was made according to the Regional Counsel:
2. Case Summary:
3. Panel Conclusion and Rationale:
4. A copy of the Panel's conclusions is to be made available to the involved practitioner(s).
5. The required report is to be submitted to the NPDB, and a copy forwarded to this office, within 30 calendar days of receipt of this memorandum. The NPDB sends a copy of the submitted report to the practitioner(s) with a limited comment period in which to make changes or append comments.
6. Copies of this report are to be sent to:

cc: VISN Director (10N__)
VISN Chief Medical Officer
VA Medical Center Chief of Staff
VA Medical Center Quality Manager
VA Medical Center NPDB Coordinator