DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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BUMEDINST 6010.18C
BUMED-N10G
5 Jun 2024

BUMED INSTRUCTION 6010.18C

From: Chief, Bureau of Medicine and Surgery

Subj: PARTICIPATION IN THE NATIONAL PRACTITIONER DATA BANK

Ref: (a) Title 28 U.S.C.
(b) Title 10 U.S.C.
(c) OPNAVINST 5450.215F
(d) Title 45 CFR Part 60
(e) DHA-PM 6025.13, Volumes 3 through 5
(f) DoD Instruction 6025.13 of 26 July 2023
(g) BUMEDINST 6010.13
(h) BUMEDINST 6010.21
(i) BUMEDINST 6010.30

Encl: (1) National Practitioner Data Bank Reporting of Medical Malpractice Cases
(2) National Practitioner Data Bank Querying Procedures
(3) National Practitioner Data Bank Reporting of Clinical Adverse Actions

1. Purpose. To establish Bureau of Medicine and Surgery (BUMED) policy, to assign responsibility, and to prescribe procedures for the querying and reporting of Navy Reserve and operational clinical healthcare providers to the National Practitioner Data Bank (NPDB). All official correspondence with the NPDB covered under this instruction must be conducted by the Chief, BUMED unless otherwise specified. This instruction is in alignment with references (a) through (i) as practicable. This instruction is a complete revision and should be reviewed in its entirety.

2. Cancellation. BUMEDINST 6010.18B.

3. Scope and Applicability. This instruction applies to Navy Reserve and Navy and Marine Corps operational clinical healthcare providers, regardless of platform type or installation. It is applicable to all aforementioned privileged and non-privileged healthcare personnel (i.e., military, civilian, contractors, volunteer, and Reserve Component) who are required to possess a license or granted privileges to provide healthcare services to active-duty members or any other military health system beneficiaries, and who are covered under Federal law for liability purposes to include the Federal Tort Claims Act (FTCA), per section 1346(b) of reference (a) and Military Claims Act (MCA), per section 2733 of reference (b).

4. Background. The Secretary of the Navy (SECNAV) has policy oversight of the clinical quality management program within the Department of the Navy. The Chief, BUMED serves as

the principal advisor to SECNAV on all health and medical matters of the Navy and Marine Corps, including policy development relating to such matters, per references (b) and (c).

5. Policy. The Department of Health and Human Services operates an alert system to facilitate a comprehensive review of healthcare providers' professional credentials. This system includes the NPDB, which is a confidential information clearinghouse containing reports of medical malpractice payments, adverse licensure actions, adverse clinical privileges actions, adverse professional membership actions, healthcare-related criminal convictions and civil judgements, and other adverse government administrative actions. The NPDB is governed by regulations of the Department of Health and Human Services, per reference (d). The responsibility assigned to the Surgeon General (SG) of the Navy, outlined in references (b), (c), (e), (f), (g), and (h) will be executed through authority as Chief, BUMED.

6. Roles and Responsibilities

a. Chief, BUMED is the sole Report Authority for Navy Medicine actions that occur under assigned area of responsibility which meet NPDB reporting criteria. The Report Authority reviews, approves, and directs reporting of actions and providers to the NPDB.

b. Chief Medical Officer, (BUMED-N10CMO)

(1) As directed by Chief, BUMED, the BUMED-N10CMO reports medical malpractice claim payments, including FTCA, MCA, active-duty death, and disability payments to the NPDB. A report is made in the name of a healthcare provider anytime Chief, BUMED determines a provider failed to meet standard of care (SOC), and in turn, caused harm to the patient. Per reference (f), a final decision on SOC must be made within 180 days of notification of payment, or all identified providers must be reported to the NPDB. If SOC is subsequently found to have been met, the report must be voided and removed from the NPDB. Enclosure (1) outlines the medical malpractice process for reporting. Per reference (e), all NPDB reports must be entered into the Centralized Credentials Quality Assurance System (CCQAS).

(2) As directed by Chief, BUMED and in coordination with BUMED General Counsel (N01L), reports final adverse clinical privileges actions, healthcare-related military criminal convictions, and other government administrative actions, based on acts or omissions that affect or could affect the delivery of a healthcare item or service to the NPDB.

(3) Maintains a record of all cases reported to the NPDB or other outside agencies per SECNAV Manual 5210.1 of 23 September 2019.

c. The Centralized Credentials and Privileging Directorate (BUMED-N10) Detachment, Jacksonville:

(1) Queries the NPDB prior to employment, initial medical staff appointment, or whenever there is a change in privileges.

(2) Ensures information obtained from the query is maintained in the provider's CCQAS credentials record. Per reference (i), the appropriate privileging authority will be notified upon the Centralized Credentials and Privileging Directorate's receipt of any adverse information. Enclosure (2) outlines the query procedure details.

d. Medical Healthcare Professionals must disclose when notified that a medical malpractice payment was made in their name. Being identified as a significantly involved provider (SIP) in an adverse event is an unproven allegation of medical malpractice until a final Chief, BUMED decision has been made on SOC.

7. Confidentiality

a. All documents generated through professional review activities are protected as Medical Quality Assurance Program documents, per reference (b), section 1102. These documents must not be released without proper authority.

b. Litigation reports are protected under the attorney client privilege and are not quality assurance documents. Litigation reports will not contain quality assurance information or records protected under reference (b). The Office of the Judge Advocate General is the release authority for all litigation reports.

c. Any breach of Medical Quality Assurance Program records and documents must be reported immediately to the command Privacy Office for required breach response activities and to the BUMED Privacy Office (BUMED-N61) using DD 2959 Breach of Personally Identifiable Information (PII) Report.

8. Records Management

a. This instruction directs collecting and maintaining information protected by the Privacy Act of 1974 authorized by Title 10, United States Code, section 8013, Secretary of the Navy. System of Records Notice N06320-3, Quality Assurance/Risk Management applies.

b. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the Department of the Navy Directorate for Administration, Logistics, and Operations, Directives and Records Management Division portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx.

c. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact the local records manager or the Department of the Navy Directorate for Administration, Logistics, and Operations, Directives and Records Management Division program office.

9. Review and Effective Date. Per OPNAVINST 5215.17A, BUMED-N10 will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, Department of Defense, Secretary of the Navy, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim, and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

10. Forms and Information Management Control

a. Forms

(1) DD 2959 Breach of Personally Identifiable Information (PII) Report is available at: https://www.esd.whs.mil/Directives/forms/dd2500_2999/.

(2) SF 95 Claim For Damage, Injury, or Death is available at: https://www/gsa.gov/forms#SF.

b. Information Management Control. Reports required in paragraph 5, enclosures (1) and (3) of this instruction are exempt from reports control per Secretary of the Navy Manual 5214.1 of December 2005, part IV, subparagraph 7k.

D. K. VIA

Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site , https://www.med.navy.mil/Directives/

NATIONAL PRACTITIONER DATA BANK REPORTING OF MEDICAL MALPRACTICE CASES

1. Policy. Chief, BUMED as the report authority is responsible for reviewing all paid medical malpractice cases, including FTCA and MCA cases, and all active duty death or active duty disability cases where there is a question of whether the health care provided caused or contributed to the death or disability. Review must include a standard of care (SOC) determination for each significantly involved provider and must be completed no later than 180 days after notification of payment.

2. Responsibilities Upon Notification of a Payment

a. Director, High Reliability Office Clinical Quality Management (BUMED-N10G), must:

(1) Obtain all medical records, litigation reports, or quality assurance investigations.

(2) Create a summary of all information received.

(3) Obtain any additional specialty reviews.

(4) Identify significantly involved providers (SIP), locate them, and give them an opportunity to review the information and make a statement. This is the only input that SIPs have to explain their role and decision-making regarding the care they delivered.

(5) Schedule and prepare separate packages for each required review.

b. External Peer Review

(1) Every case that results in a payment, active duty disability or active duty death gratuity, must be forwarded to the medical peer review agency external to the Department of Defense as designated by the Assistant Secretary of Defense (Health Affairs) for review.

(2) The external peer reviewer must be of the same profession and specialty as the provider(s) reviewed and must provide a written opinion on whether SOC was met for each provider, and whether the provider caused the injury for which the payment was made.

(3) The external peer reviewer's curriculum vitae, and other pertinent information from the external review (such as current supporting literature used in the external peer SOC report), must be provided with the external peer SOC by the external peer review agency.

(4) The external review report is considered quality assurance-protected and cannot be released to the healthcare provider under review, per reference (b).

c. Professional Case Review Panel

(1) Membership

(a) Members must be of the same Corps or civilian profession as the provider being reviewed; however, there is no requirement they be of the same medical, dental, nurse, or ancillary subspecialty.

(b) Each of the respective Corps Chiefs must appoint an officer to represent their community in matters involving the professional case review panel. Upon notification of need to schedule a professional case review panel, the officer must appoint a minimum of three providers to perform as the professional case review panel. The appointed officer may, but need not act, as a professional case review panel member.

(c) Professional case review panel members must not participate in the review of a case in which the member acted as the investigating officer or specialty reviewer or has a personal conflict.

(2) Administrative Support. BUMED-N10G:

(a) Notifies the respective Corps Chief's Office (BUMED-N01C) when a case is ready for review and provides a case file for each member to review.

(b) May attend the professional case review panel and provide additional information as requested, and may take part in the deliberations, but has no vote.

(3) Deliberations

(a) Professional case review panel reviews are not adversarial proceedings.

(b) Neither potential subjects of NPDB reports nor their personal representatives will be permitted to make a personal appearance before the professional case review panel.

(c) Professional case review panel deliberations are protected under reference (b), section 1102.

(d) The file, pertaining to the medical malpractice payment and compiled for review by the professional case review panel, if reasonably available, must include:

1. A copy of the initial investigation with enclosures and endorsements.

2. All specialty reviews.

3. Available closed claim documentation, which may include a copy of the SF 95 Claim For Damage, Injury, or Death, and a copy of the settlement memorandum or judgement.

4. The provider's statement or documentation showing provider declined to make a statement, or documentation showing reasonable attempts to contact provider.

(e) The professional case review panel may seek additional documents for consideration, however, the professional case review panel must not consider any documents unless the involved providers have also reviewed the same documents, with the exception of specialty reviews.

(f) The professional case review panel's recommendation must be based solely on the information provided in the case file.

(g) The professional case review panel must use these standards to determine whether an NPDB report should be recommended:

1. Payment was made in response to a claim either as settlement or court action or as a result of an active duty death gratuity or disability payment.

2. Payment was caused by the failure of one or more providers to meet SOC.

3. Regarding attending practitioners supervising trainees:

a. When a trainee is an SIP subject to report, the attending practitioner responsible (not the trainee) for the delivered case must be identified and must be reported to the NPDB.

b. If the attending practitioner clearly met all reasonable standards of supervision, and the trainee's act or omission was not reasonably foreseeable by the attending practitioner, then the trainee (not the attending practitioner) must be reported to the NPDB.

4. Supervision of unlicensed providers:

a. When an SIP is under a plan of supervision or requires ongoing supervision, the supervising provider responsible for the delivered care must be identified and must be reported to the NPDB.

b. If the supervising provider clearly met all reasonable standards of supervision and the unlicensed provider's act or omission was not reasonably foreseeable, the unlicensed provider must be reported to the NPDB.

5. No report is required for cases in which "system problems," rather than the failure of significantly involved providers to meet the professional SOC, were responsible for the payment.

6. No report is required for payments based on administrative or litigation considerations as contrasted to clear evidence establishing on the record that provider(s) failed to meet SOC.

(4) Opinions and recommendations must be majority vote.

(5) A memorandum must be provided for the senior member to sign and date and must include the date the panel met, the names of the panel members, and the panel's recommendation for each SIP reviewed. The completed memorandum must be submitted to the High Reliability office (BUMED-N10G).

d. BUMED-N01C Review and BUMED-N10CMO Review.

(1) Upon receipt of the professional case review panel's recommendation and the external peer reviewer's opinion, a case file that summarizes all documentation received must be forwarded for BUMED-N01C and BUMED-N10CMO review. The file, if reasonably available, must include:

(a) A copy of the initial investigation with enclosures and endorsements.

(b) All specialty reviews.

(c) Available closed claim documentation, which may include a copy of the SF 95 and a copy of the settlement memorandum or judgement.

(d) The provider's statement or documentation showing provider declined to make a statement, or documentation showing reasonable attempts to contact provider.

(e) The panel's recommendation memorandum.

(2) Each reviewer must provide a written recommendation to Chief, BUMED, within the timeframe specified in the package provided for review.

e. Report Authority Action

(1) BUMED-N10G, upon receipt of the individual BUMED-N01C and BUMED-N10CMO recommendations, must prepare a case file that summarizes all documentation received and forward to Chief, BUMED, for decision on whether to report any SIPs. The file, if reasonably available, must include:

(a) A copy of the initial investigation with enclosures and endorsements.

(b) All specialty reviews.

(c) Available closed claim documentation, which may include a copy of the SF 95 and a copy of the settlement memorandum or judgement.

(d) The provider's statement or documentation showing provider declined to make a statement, or documentation showing reasonable attempts to contact provider.

(e) The panel's recommendation memorandum.

(f) A letter addressed to each individual provider notifying them of the decision to report them to the NPDB.

(2) Only Chief, BUMED, can make the decision on which SIPs are reported to the NPDB for cases under their jurisdiction. If a report is to be made, Chief, BUMED, must sign the individual notification letters which are then mailed to the provider(s) with a copy of the actual NPDB report.

3. Reports

a. As directed by Chief, BUMED, BUMED-N10G must prepare all documents required to report.

b. Closed claim reporting files must be created from the existing case file, scanned and retained indefinitely. These files may be necessary for future audits by outside agencies reviewing NPDB reporting compliance.

c. The information concerning the report must be recorded in the CCQAS risk management data base and a copy of the NPDB report must be uploaded into the individual providers CCQAS credentials record.

4. Mandatory Reporting Requirement

a. A report to the NPDB is required per reference (f) unless the reporting authority has made a final SOC determination that the payment was not made on behalf of any SIP within 180 calendar days from notification of payment.

b. If no final decision has been made by the report authority within 180 calendar days all SIPs must be reported to the NPDB. If an SIP is subsequently found to have met the SOC, the report will be voided.

c. Medical healthcare professionals are required to disclose when a medical malpractice payment was made in their name.

d. Once a provider is reported to the NPDB, only the Defense Health Agency Director or the Service Surgeon General who reported the provider can remove the report.

5. Active Duty Member Cases

a. Cases where SOC was not met and resulted in an active duty death or active duty disability are processed per subparagraphs 2c(3)(g)1 through 2c(3)(g)6 of this enclosure.

b. Cases where SOC was not met, and there is no active duty death or active duty disability, the information will be recorded in the CCQAS risk management data base and in the individual providers CCQAS credentials record.

c. Cases where SOC was not met and the deviation of SOC caused or contributed to the disability or pending death and the risk for future disability or death payment is high, a report to the NPDB is permissible as an "other adjudication action" even though the amount of the future payments is unknown. When the death or disability payment becomes known at a later date, a revision-to-action report is made to include the payment information.

NATIONAL PRACTITIONER DATA BANK QUERYING PROCEDURES

1. General. The NPDB is operated by the Department of Health and Human Services as a validation process designed to facilitate a comprehensive review of healthcare providers' professional credentials. It includes medical malpractice payment, adverse licensure actions, adverse clinical privileges actions, adverse professional membership actions, health care related criminal convictions, other adjudicated actions or decisions, and Medicare or Medicaid exclusion reports. The NPDB is intended to augment, not replace, traditional forms of credentials reviews and is used in conjunction with information from other sources when performing credentials review, granting clinical privileges, or making employment or affiliation decisions.

a. Per reference (i), a query of the NPDB is required before privileges may be granted (i.e., at time of initial medical staff appointment, initial granting of clinical privileges, renewal of privileges, or when requesting to add new privileges).

b. A query of the NPDB for non-privileged providers must be done as part of the credentialing process.

c. For privileging by proxy using an Inter-facility Credentials Transfer Brief, the NPDB query is optional.

2. Initial Query Requirements Prior to Granting a Medical Staff Appointment or Privileges

a. Direct Accessions, Navy Reserve Applicants, Recalls to Active Duty, and Inter-Service Transfers to the Department of the Navy. Applicants must submit a copy of a current NPDB query results as part of their application package for review by the applicable professional review board.

b. New Civil Service Employees. Applicants are required, as part of the application process, to provide a copy of a current NPDB query results to the local human resources office for review by the applicable professional review board.

c. New Contract Providers. Contracting agencies must include a copy of a current NPDB query results, as part of the credentials package, for review prior to approving the provider's application for review by the applicable professional review board.

d. Personal Service Contractors or Partnership Providers. Applicants must submit a copy of a current NPDB query results, as part of their package, for review by the applicable professional review board.

e. American Red Cross Volunteers. Applicants must submit a copy of a current NPDB query results, as part of their package, for review by the applicable professional review board.

3. Authorized Querying Agent or Entity. Only eligible entities that are registered with the NPDB are authorized to query the NPDB. The Centralized Credentials and Privileging Directorate, Jacksonville, is the authorized query entity for Navy medicine.

a. Upon notification of query request, initiate NPDB query.

b. Upon receipt of query results, upload information into the provider's CCQAS credentials record.

c. If there is any adverse information on file, the appropriate privileging authority will be notified via the provider's CCQAS credentials record upon the Centralized Credentials and Privileging Directorate's receipt of the adverse information.

NATIONAL PRACTITIONER DATA BANK REPORTING OF CLINICAL ADVERSE ACTIONS

1. Purpose. The clinical adverse action process protects patient safety, preserves the quality and safety of healthcare, protects the rights of the involved healthcare provider, and ensures timely resolution of issues and reporting to regulatory entities.

2. General. Clinical adverse actions that must be reported to the NPDB:

a. Adverse privileging actions based on incompetence, misconduct or any other professional conduct which adversely affects or could adversely affect the health or welfare of a patient or delivery of health care.

b. Surrender of clinical privileges or failure to renew clinical privileges while under investigation.

c. Summary suspension of clinical privileges exceeding 30 days.

d. Criminal convictions, civil judgements, or government administrative actions taken against healthcare providers (includes unlicensed providers), based on acts or omissions which affect or could adversely affect, the delivery of healthcare items or services.

3. Action. The clinical adverse action process is not a disciplinary tool. Concerns for incompetence, misconduct or any other professional conduct that adversely affect, or could adversely affect, the health or welfare of a patient or delivery of health care may be the basis for clinical adverse action. Only the privileging authority that granted the privileges can take a clinical adverse action. However, the privileging authority must inform any other known locations where the provider is also practicing when a provider's privileges have been adversely affected.

4. Reporting. NPDB reports must be made by the Report Authority consistent with the NPDB regulations and guidelines. NPDB reports are submitted within 30 calendar days of Chief, BUMED approval of the adverse action or appeal decision, and for summary suspension of clinical privileges exceeding 30 calendar days.