



DEPARTMENT OF THE NAVY
NAVAL MEDICAL CENTER
620 JOHN PAUL JONES CIRCLE
PORTSMOUTH, VIRGINIA 23708-2197

IN REPLY REFER TO:

NAVMEDCENPTSVAINST 5112.2G
00K

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NAVMEDCENPTSVA INSTRUCTION 5112.2G

Subj: MEDICAL STAFF POLICY AND PROCEDURES

Ref: (a) BUMEDINST 6010.17B
(b) Comprehensive Accreditation Manual for Healthcare Organizations, Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
(c) BUMEDINST 6320.66D
(d) BUMEDINST 6320.67A
(e) NAVMEDCENPTSVAINST 6320.7E
(f) NAVMEDCENPTSVAINST 6320.70A
(g) NAVMEDCENPTSVAINST 6320.65A
(h) NAVMEDCENPTSVAINST 5450.1G
(i) NAVMEDCENPTSVAINST 6320.28C
(j) NAVMEDCENPTSVAINST 5420.4C
(k) NAVMEDCENPTSVAINST 5212.4B
(l) NAVMEDCENPTSVAINST 6320.61F
(m) NAVMEDCENPTSVAINST 6550.2D
(n) NAVMEDCENPTSVAINST 6550.5B
(o) Command Process Improvement Plan
(p) NAVMEDCENPTSVAINST 6000.7A

Encl: (1) Disclosure of Unanticipated Outcomes
(2) Peer Review Process

1. Purpose. To publish Naval Medical Center (NAVMEDCEN), Portsmouth, Virginia medical staff policies and procedures per references (a) through (p).

2. Cancellation. NAVMEDCENPTSVAINST 5112.2F

3. Scope. This instruction applies to the core medical center and all outlying clinics which comprise the NAVMEDCEN Portsmouth command.

4. Background. References (a) and (b) set forth Bureau of Medicine and Surgery (BUMED) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements on medical staff functions. It is Navy policy that, to the extent practical within available resources and in keeping with military mission, NAVMEDCEN will meet the standards of references (a) and (b). This instruction defines how this command fulfills those facility-specific requirements and standards.

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5. Local Medical Staff Membership Policy. Procedures are contained in reference (a). The medical staff will attend at least one "Meeting of the Medical Staff" per year, where issues will be discussed (i.e., policy, procedures, requirements), questions may be asked, and information disseminated.

6. Executive Committee of the Medical Staff (ECOMS)

a. The Commander will appoint an ECOMS, which is empowered to act for the medical staff in the intervals between medical staff meetings.

b. Membership Eligibility. All members of the medical staff are eligible for appointment to the committee. All members of the committee are voting members unless otherwise specified.

(1) The Chairperson will be the President of the Medical Staff, as elected by the medical staff at large and then appointed by the Commander. Each year there will be a president and a president-elect. The president will serve for 1 year, with the president-elect assuming president status the following year. There will be an annual election for the president-elect of the Medical Staff.

(2) The Director for Medical Education will be appointed to ECOMS by the Commander.

(3) The Chairs of the Credentials Committee and the Pharmacy and Therapeutics Committee will be appointed to ECOMS by the Commander.

(4) Three members will be elected to ECOMS from the medical staff within the Fleet and Family Medicine Directorate. One member will represent the outlying clinics.

(5) Two members will be elected to ECOMS from the medical staff within the Surgical Services Directorate.

(6) One member will be elected to ECOMS from the medical staff within the Clinical Support Services Directorate.

(7) A Physician Advisor for Surgical Quality Management and a Physician Advisor for Medical (nonsurgical) Quality Management will be appointed to ECOMS by the Commander.

(8) The medical staff at large will elect one Licensed Independent Practitioner (LIP) to be appointed to ECOMS by the Commander.

(9) Other nonmedical staff members may include, but are not limited to, the Senior Nurse Executive and Associate Director for Healthcare Quality Improvement. All nonmedical staff members will be nonvoting and appointed to the committee by the Commander.

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(10) Unless otherwise stated, the nominating subcommittee of ECOMS will bring chairman position nominees to ECOMS for review and ECOMS will make nominations known to the Commander for final approval and appointment. The subcommittee will be chaired by the ECOMS President-elect.

c. The majority of ECOMS members must be fully licensed physician members of the medical staff actively practicing in the facility.

d. Initial appointment and renewal appointment periods will not exceed 2 years for each term.

e. Membership will be automatically terminated upon revocation, suspension, or limitation of clinical privileges for reasons related to conduct or professional performance listed in reference (d) or for other reasons at the discretion of the Commander. A member must attend at least 50 percent of the meetings averaged over the year to remain eligible for continued membership. If a voting member of ECOMS is absent, they can send a nonvoting medical staff substitute to attend the meeting. Members should send surrogates (who are non-voting) when unable to attend. When prolonged absence is expected, the responsible director should appoint a temporary representative (who will be a voting member).

f. The committee will meet at least 11 times per year. Meeting minutes (business, action, and discussion) will be completed for each meeting.

g. The committee will review issues concerning patient care and services that involve the medical staff, as described in reference (a). ECOMS is charged with monitoring the effectiveness of the medical staff's participation in the facility's performance assessment and improvement activities (reference (a)).

h. ECOMS will review and act on reports and recommendations from medical staff committees, clinical directorate or work areas, process action teams, and other assigned activity groups (reference (a)).

(1) At a minimum, the following committees will provide quarterly information to ECOMS:

- (a) Medical Records Review Committee
- (b) Blood Transfusions/Utilization Committee
- (c) Operative and Other Procedures Committee
- (d) Pharmaceuticals and Therapeutics Committee
- (e) Infection Control Committee

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(f) Utilization Management Committee

(g) Credentials Committee

(h) Cardiac Arrest Committee

(2) Chair nominations will be made to ECOMS. An ECOMS subcommittee, chaired by the ECOMS President-elect, will be formed to review all nominees. The final nominations will be made to ECOMS for review. The nominations will be recommended to the Commander for final appointment. The Infection Control Committee chair is exempt from this process. Due to the specific training this chair must have, the Commander will appoint the member.

(3) Medical staff committees, by instruction, will determine the composition of their membership with an emphasis on fair representation of the entire medical staff. Each medical staff committee instruction will be reviewed by ECOMS on an annual basis.

i. All decisions, policies, and procedures developed by and/or modified by ECOMS must be communicated to the medical staff, administrative areas, and annotated in NAVMEDCEN instructions. Each member of ECOMS represents a specific group of the medical staff, an administrative area, or the positions overlap. Each member will ensure efficient communication with the medical staff in their area of cognizance, via e-mail, work area/directorate meetings, and other training as required. Cognizant individuals will ensure changes are made to medical center instructions as changes are made. Members of ECOMS who are also members of the Executive Steering Committee (ESC) ensure efficient communication of processes at morning ESC meetings. In addition, ECOMS will use e-mail to reach the medical staff or the entire staff to identify changes in policy, new instructions, and training.

7. Appointment and Reappointment Policies. Procedures are contained in references (a) and (c). Upon appointment and reappointment, providers must pledge to provide for the continuous care of their patients.

8. Privilege Policies and Procedures. Procedures are contained in references (a), (c), and (e). Adverse privileging action, peer review panel procedures, and healthcare provider reporting are described in references (d) and (e). In those situations where the patient's safety is imminently endangered by an impaired provider, then a service line leader, director, officer in charge (OIC), or Command Duty Officer may initiate the process delineated in reference (d).

9. Scope of Services

Level II Emergency Services	Internal Medicine (Adolescents)
General Surgery	Allergy/Immunology
Vascular Surgery	Cardiology
Thoracic Surgery	Endocrinology
Colorectal Surgery	Gastroenterology
Anesthesia	Hematology Oncology
Dental/Oral Surgery	Infectious Disease/HIV
Neurosurgery	Nephrology
Ophthalmology	Neurology
Orthopedics	Nuclear Medicine
Otorhinolaryngology	Occupational Medicine
Obstetrics/Gynecology	Primary Care Medicine
Urology	Preventive Medicine
Pediatric Surgery	Pulmonary Medicine
Plastic Surgery	Rheumatology
General Practice	Pathology
Radiation Oncology	Radiology (with subspecialties)
Dermatology	Pediatrics (with subspecialties)
Critical Care Medicine	Psychiatry
Optometry	Psychology
Occupational Therapy	Clinical Social Work
Physical Therapy	Podiatry
Clinical Pharmacy	Clinical Nutrition
Gynecologic Oncology	Geriatric Medicine
Family Practice	Neonatology
Maternal-Fetal Medicine	Reproductive Endocrinology
Pain Management	Speech Pathology
Physical and Rehabilitation Medicine	

Each directorate/service line/department must define its scope of services and list qualifications and restrictions in its Policy and Procedures Manual.

10. Medical Staff Organization

a. Organization of the medical staff is described in reference (h). The medical center is organized into directorates, service lines, and departments.

b. Responsibilities of the service line leaders are found in references (a), (c), and (e). Additional responsibilities include:

(1) The integration of the service line into the primary functions of the organization.

(2) The coordination and integration of service line and departmental services.

(3) The development and implementation of policies and procedures that guide and support the provision of services.

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(4) Recommendations to ensure adequate staffing.

(5) The maintenance of quality control and process improvement programs.

(6) The orientation and continuing education of all persons in the service line.

(7) Recommendations for space and other resources needed by the service line.

(8) Recommendations for off-site sources for needed patient care services not provided by the service line.

c. Medical staff monitoring functions are described in references (o) and (p).

11. Clinical Supervision. Levels of clinical supervision of house staff/trainees by members of the privileged medical staff (licensed independent practitioner (LIP)) are predetermined and contained in individual work area training manuals. The manuals are made available to the medical staff in their area of responsibility. Clinical privileges cannot be denied or limited for members who choose not to participate in the teaching programs. The medical staff assures that each participant in a professional graduate medical education program is supervised in his/her patient care responsibilities by an LIP who has been granted clinical privileges through the medical staff process. The Graduate Medical Education Department Head makes decisions about each participant's progressive involvement and independence in specific patient care activities. Medical staff policies and procedures also delineate those participants in professional education programs who may write patient care orders, what orders they are allowed to write, and when an order must be countersigned by a supervising LIP (paragraph 13d(2)). The Chair, Graduate Medical Education Committee is a member of the Executive Committee of the Medical Staff to ensure proper communication concerning the Graduate Medical Education Program and the medical staff.

12. Emergency Services for Ambulatory Care Clinics

a. Core Medical Center. In the event of a medical emergency developing in or presenting to any ambulatory care clinic within the Charette Healthcare Center, the patient will be evaluated, stabilized, and transported (if appropriate) to Emergent and Urgent Care for further evaluation, treatment, and/or admission as deemed necessary by the responsible physician. Medical emergencies occurring at NAVMEDCEN but in locations outside Charette will be handled by calling the Emergency Medicine Department (EMD) for response.

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b. Outlying Clinics

(1) In the event of a medical emergency developing in or presenting to an outlying clinic, the patient will be evaluated, stabilized, and transported by ambulance to the nearest appropriate hospital Emergency Department. All reasonable efforts will be made to use Emergent and Urgent Care at the core medical center.

(2) All outlying clinics, except TRICARE Prime Virginia Beach and TRICARE Prime Chesapeake, will provide 24-hour/7 days a week ambulance coverage for the areas they serve. This coverage may be accomplished by in-house staff and equipment, Base Fire Department, or through Memoranda of Understanding (MOU) with Emergency Medical Services (EMS) agencies in the local community. Ambulances will be staffed, at a minimum, with a certified Emergency Vehicle Operator and Virginia State-certified Emergency Medical Technician (EMT). When at all possible, the ambulance crew will be staffed with a Tidewater Emergency Medical Services (TEMS) sanctioned advance life support pre-hospital care provider (i.e., EMT-Cardiac Technician or EMT Paramedic). Additional personnel can be assigned to the transport of an emergency patient at the discretion of the Operational Medical Director (OMD)/NAVMEDCEN Portsmouth Emergency Medical Staff physician.

(3) The Commander NAVMEDCEN has appointed the OMD to provide administrative and operational oversight and develop policies and procedures related to Tidewater Navy EMS personnel and ambulances. The OMD will meet the qualifications set forth in the Rules and Regulations of the Commonwealth of Virginia Board of Health.

(4) In the event of ambulance nonavailability, the local civilian Emergency Rescue Squad will be requested to respond to calls for emergency patient service/transport.

13. Medical Staff Rules and Regulations

a. Medical Staff and Care of Patients. Members of the active medical staff are responsible for assuring that all emergency, ambulatory, and inpatient care provided at NAVMEDCEN Portsmouth is done in a safe manner. A part of command mission is to conduct graduate and post-graduate education programs for designated medical students and Navy Medical Department officers enrolled in clerkships, internships, or any of the accredited residency programs. All NAVMEDCEN patients, whether emergency, ambulatory, or inpatient, may be managed by authorized graduate medical education trainees under the supervision of active medical staff members. Supervision of trainees by the active medical staff must be documented in the inpatient chart or outpatient health record.

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b. NAVMECEN Portsmouth is committed to providing quality medical care to its patients and the communities it serves. Despite constant and committed efforts to provide and improve care, occasions may arise when unanticipated outcomes occur. While sometimes these outcomes of care are unavoidable, at other times they result from preventable mistakes or errors in the provision of care. Occasionally a deviation in care or a procedure may occur, but it is recognized before it reaches the patient, without an unanticipated outcome resulting. NAVMECEN Portsmouth analyzes adverse outcomes to prevent the recurrence of such events. We are also committed to respecting the right of patients and their families to be informed about such events. Enclosure (1) provides for healthcare professionals in the event of an unanticipated outcome.

c. Admission of Patients. While all physicians and qualified Oral and Maxillofacial Surgeons with core privileges have technical privileges to admit patients to the hospital, admission to inpatient services will be per policy and procedures within the medical center service lines. Podiatrists, nurse midwives, and dentists may admit patients; however, podiatrists, nurse midwives, and dentists who admit must obtain a prompt, complete medical evaluation of the patient by a qualified physician and member of the medical staff who is granted the clinical privileges to perform a history and physical examination or to admit independently. Physicians in training may admit for members of the active medical staff, but the "admitting physician" is the member of the active medical staff. The delineation of an individual's clinical privileges includes the limitations, if any, on the privilege to admit and treat patients or to direct the course of treatment for the condition for which the patient was admitted. Once a patient is admitted, the inpatient chart must always identify the active medical staff member responsible for the patient, beginning with the admission order. A note, written by the staff physician responsible for the patient, which indicates the admission diagnosis, is entered into the medical chart within 24 hours of admission and/or prior to surgery. In emergency situations, a note written by the resident physician indicating that the patient has been discussed with the staff physician will be entered into the medical record prior to surgery. Whenever the active Medical Staff member responsible for a patient changes, this must be stated in the Doctor's Orders and Progress Notes.

d. Inpatient Chart

(1) History and Physical Examinations

(a) Inpatients. History and physical examinations must be completed, signed, and entered into the medical record within 24 hours of the time of admission, prior to the patient arriving in the operating room, or prior to discharge, whichever occurs first. If a patient is admitted within 30 days of a prior history and physical examination, a photocopy of the history and

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physical examination may be used if an interim progress note to include a physical examination written within 7 days is included. If a patient arrives in the operating room without a documented history and physical examination, the surgery will be delayed until the history and physical is completed or the attending surgeon details, in writing, how such delay would constitute a hazard to the patient. When podiatrists, certified nurse midwives (CNM), and dentists are privileged to admit patients, provisions must be made for prompt medical evaluation and a history and physical examination by a physician, or a history and physical may be performed by the CNM on obstetrics (OB) patients if the finding, conclusions, and assessment of risks are confirmed or endorsed by a qualified physician and member of the medical staff within 24 hours. Qualified Oral and Maxillofacial Surgeons who admit patients may perform history and physical examinations on their patients per reference (a).

(b) Outpatients Requiring Sedation. The sedation of patients is governed by references (f) and (g). Each clinical area will establish written policies for its implementation.

(2) Orders. Orders may be written by any provider within the limits of their privileges or graduate medical education status at this command. All orders must be in writing, dated, and timed. All orders will be automatically discontinued and require rewriting when a patient goes to the delivery room or operating room, is transferred to a different level of care, or to a different service. All medication orders will follow the automatic stop policy as approved by ECOMS: subcutaneous and oral anticoagulants, 3 days; meperidine, 4 days; and ketorolac, 5 days. Initial parenteral antibiotic orders written for adults will be ordered utilizing the Adult Parenteral Antibiotic Order Form. Parenteral antibiotic orders for pediatric usage should be written on the Pediatric Parenteral Antibiotic Order Form. Antibiotic orders in the Neonatal Intensive Care Unit should be written on the Doctor's Order Form (SF 508). Antibiotics will be automatically discontinued after 7 days or less, per antibiotic order form, depending on the indication for usage (prophylactic, empirical, or therapeutic, respectively). Antibiotics may be reordered on the standard Doctor's Order Form (SF 508).

(a) A verbal order can be given by Post-Graduate-Year 1 and above trainees or staff physician in emergency situations only (i.e., CPR, precipitous delivery, etc). Verbal orders can be accepted for action by only professional nursing staff (registered nurses). All verbal orders will be legibly documented by the physician or registered nurse on Doctor's Order Form (SF 508) following the standard format. The physician will countersign the verbal order as soon as the situation safely permits or within 72 hours, whichever occurs first.

(b) Post-Graduate-Year 1 and above and staff physicians may dictate telephone orders to professional staff as outlined below:

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1. Registered Nurse. Can accept any order.
2. Registered Dietitian. Can accept orders related to dietary changes and other associated nutritional needs.
3. Registered Respiratory Therapist. Can accept orders related to initiation of and changes to respiratory treatment.
4. Registered Physical Therapist. Can accept orders related to initial, ongoing, and progressive physical therapy needs.
5. Registered Pharmacist. Can accept orders related to medicinal therapy, parenteral nutrition, and pertinent laboratory orders.

(c) All telephone orders will be legibly documented on a Doctor's Order Form (SF 508) following the standard format and appropriately flagged. The registered nurse (RN) staff will transcribe orders. All "STAT" orders must be personally communicated to the RN staff by the professional receiving/documenting the order. Telephone orders must be repeated to the provider issuing them. All telephone orders must be signed within 72 hours by the physician provider who gave the order.

(d) FAX orders are encouraged to expedite processing providers' orders. Faxed orders must include the patient's full name and prefix with social security number. When orders are faxed, the original orders must be inserted in the chart within 24 hours. In the interest of patient confidentiality, a cognizant recipient must be ready to accept the faxed orders.

(3) Progress Notes. Any healthcare provider may write progress notes. Progress notes must be recorded whenever there is a significant change in the patient's condition or treatment plan. The notes by trainees must state that the responsible active medical staff member is aware of the patient's present status. Progress notes must be written no less frequently than once a week for the Medical Holding Company. Patients on other clinical services must have progress notes written at least daily. Progress notes must reflect privileged staff involvement by a note or co-signature of a progress note every 72 hours. It is required that the date be indicated for each progress note. If a patient received an anesthetic during hospitalization, a statement must be included in the progress notes that addresses the presence or absence of anesthesia-related complications after the patient leaves the recovery room. If discharge is to occur before a post-anesthetic visit can be made by a member of Anesthesia, a progress note may be written by any member of the operating team. It must indicate that the active Medical Staff Surgeon approves of the discharge decision. A progress note is required at the time a patient dies, is discharged, or is

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transferred. It must state that the active medical staff member responsible for the patient is aware of the situation. Transfer or discharge from the Post-Anesthesia Recovery Room, the recovery area as stated in references (f) and (g), or Ambulatory Surgery Unit may be via predetermined discharge criteria which have been approved by the Executive Committee of the Medical Staff.

(4) Laboratory and Radiology Study Requests. Laboratory and radiology studies must be specifically ordered for each patient upon admission. Routine standing orders for admission laboratory tests are not permitted. All clinical and demographic data required must be provided on the laboratory and X-ray request forms before they are forwarded.

(5) Pharmacy Requests. All pharmacy items must be specifically ordered for each patient. Experimental drugs may be ordered only by members of the active medical staff who have been granted investigator status by the command. Drugs that are a critical component of the care provided for a specific diagnosis are monitored at the clinic/ward level. Drug utilization is monitored by the Pharmacy and Therapeutics Committee. All demographic data required must be provided on the pharmacy request forms before they are forwarded.

(6) Narrative Summaries. The narrative summary is to briefly describe the patient's hospitalization. It should state the criteria upon which the diagnosis was established, the treatment followed, significant events that occurred during hospitalization, discharge instructions to the patient, and the patient's condition upon discharge. Narrative summaries should be brief but complete. They must be dictated for active duty patients by 2400 on the day of discharge. It is desirable that narrative summaries for non-active duty patients be dictated prior to 0800 chart pick-up on the first regular workday following discharge, but may be dictated in the Medical Records Section up to 72 hours after the patient's discharge. The narrative summary must be signed, if dictated by a trainee, by an active medical staff member involved in the patient's care.

(7) Provider Identification. All medical staff providers will be given a name stamp with provider ID number. It will be used on prescriptions and all areas in the inpatient chart and outpatient health record where signatures are required except when the document contains a printed name to be signed out. Each provider will sign and stamp the medical record entry. If the name stamp is not available, block printing of name and ID number (last four digits of the SSN) is acceptable.

e. Consent. Reference (i) is the authoritative document for consent requirements for medical treatment and must be cited in all clinical area and nursing care area Policy and Procedure Manuals where patient care occurs. Informed consent must be obtained prior to any patient undergoing operative and other invasive or non-invasive procedures including radiotherapy,

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hyperbaric treatment, CT scan, and MRI. All planned operative procedures will be listed in the consent form. Informed consent must include a discussion of risks, benefits, potential complications, as well as alternative options. Discussion of these components must be documented in the medical record. If blood transfusion or use of blood components is possible, informed consent to include risks, benefits, and alternatives must be obtained. Patients must receive adequate information to participate in care decisions and provide informed consent. If the patient's condition does not allow for such interaction, appropriate documentation to that effect must be placed in the medical record. Informed consent is obtained by a Graduate Medical Education trainee or a member of the medical staff, or in the case of CT scans or MRIs, may also be obtained by the Radiology technologist performing the procedure. Except in rare circumstances, informed consent is obtained in person. The informed consent process must permit discussion and questions from the patient.

f. Consultations. Active medical staff members are responsible for assuring that consultations are obtained when indicated. Repetitive failure to obtain consultations will be a cause for referral to the Credentials Committee for review and appropriate action. When an emergency exists such that a delay (to obtain a consultation) would jeopardize the patient's welfare, the physician in charge may proceed with treatment without consultation. In such instances, the physician must enter a full explanation in the medical record indicating the circumstances that caused the failure to comply with this requirement. A consultant must be well qualified within the guidelines of the receiving clinic/ward policy to give an opinion in the field in which the specialty opinion is sought. When a consultant desires the consultant to assume responsibility for a patient's care, this should be indicated on the Consultation Request Form (SF 513). The consultant should likewise indicate that he/she accepts responsibility for the patient's care. Acceptance of responsibility occurs if the consultant admits the patient to his/her clinical service. Consultants must answer Consultation Requests in the time frame stipulated in the consult. If unable to do so, the consultant must notify the consultant and the patient of the inability to answer the Consultation Request. When an emergent/urgent consultation is requested, it requires physician-to-physician communication.

g. Discharge Planning. Discharge planning and documentation are described in reference (j). The responsibility of the medical staff includes, but is not limited to:

- (1) Identification of patients early in the course of treatment (either inpatient or outpatient) who may require placement or an additional service post-hospitalization.

- (2) Participation in multidisciplinary patient care conferences and patient/family education.

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(3) Determination of approximate length of stay and proposed treatment plans.

(4) Completion of applicable portions of necessary forms which facilitate transfer, placement, or other discharge requirements.

h. Special Treatment Procedures

(1) Restraint and seclusion on the psychiatry wards and electroconvulsive or other forms of convulsive therapy will be governed by Psychiatry's Policy and Procedures Manual. On wards, restraint will be governed by reference (1), but will be applied only on a physician's order (except that a nurse may apply restraint to protect a patient while awaiting a physician's order). A Doctor's Progress Note must document the need for restraint, type of restraint, and continued need for restraint no less than every 24 hours.

(2) The following special treatment procedures are not allowed at this command:

(a) Surgical procedures done to alter or intervene in an emotional, mental, or behavioral disorder.

(b) Abortions, except as permitted by applicable instructions and law.

(c) Sex change operations except for infants born with ambiguous genitalia.

(3) Outpatient IV fluid administration for hydration may be done in designated areas within the medical center and the outlying clinics.

(4) Moderate sedation will be conducted as described in reference (f).

(5) The use of fluoroscopy will be conducted in accordance with NAVMECENPTSVAINST 6470.3A.

i. Surgical Procedures. Except in emergencies, a surgical operation will be performed only with the informed consent of the patient or his/her legal representative as stated in reference (i). Major operative procedures, those procedures done in the Main Operating Room or its satellites, must be approved by a medical staff member. Requirements for attendance by the credentialed medical staff member during the procedure are delineated in the applicable clinic/ward Policy and Procedures Manual. The surgeons will be in the operating room and ready to commence an operation at the time it is scheduled. There will be a sufficient number of qualified personnel available for each surgical procedure. Tissue removed from patients must be sent to Laboratory Medicine for at least gross examination, with the

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exception of circumcision specimens from newborns (complicating factors excluded). Foreign objects, including orthopedic hardware, may be discarded appropriately without submitting to Laboratory Medicine, at the discretion of the provider. All operations performed will be fully described by the medical staff operating surgeon or a designated member of the operative team, by dictation or in writing, immediately after the completion of surgery. Operative reports dictated or written immediately after surgery should record the name of the primary surgeon and assistants, findings, technical procedures used, specimens removed, the type of anesthesia used, and postoperative diagnosis. When the operative report is not placed in the medical record immediately after surgery, a progress note is entered immediately. The responsible surgeon must be a member of the active medical staff and be privileged to perform the procedure. The responsible surgeon must be designated by name in the Operative Note, even if his/her participation in the case was only in a supervisory role. The responsible surgeon must review and sign the Operative Report. Surgical Case Review is described in reference (k). The sedation of patients outside the Main Operating Room is governed by references (f) and (g). Each clinical work area will establish written policies for its implementation.

j. Medical Records in General. Reference (k) describes policies which pertain to medical records.

(1) All medical records, both inpatient and outpatient, are the property of the United States Government. Inpatient charts must be received in Medical Records by 0800 on the next regular work day following the patient's discharge. No medical record will be filed until it is complete, except on the recommendation of the Chairman of the Medical Records Review Committee, with the approval of the Commander. Medical records become delinquent if they are incomplete 30 days after the day of the patient's discharge. The definition of a completed medical record, suitable for filing is: the history and physical examination, diagnostic and therapeutic orders, progress notes, operative summary, final diagnosis, pathology report (if applicable), and narrative summary are entered and the chart is signed with date and time by a responsible active medical staff member. Greater than 25 records per provider, per month, or greater than 100 delinquent records per department, per month, may be a cause for referral to the Credentials Committee for review and action if necessary. For the purpose of expediency, in cases of active duty patients returning to duty upon discharge and non-active duty patients on emergency transfer, an abbreviated written discharge summary (in place of a dictated one) is acceptable until the typed narrative summary is signed.

(2) Free access to the medical records of patients will be afforded to medical staff members for Institutional Review Boards (IRB)-approved study and research unless measuring

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outcomes of patient care or peer review. This access must preserve confidentiality of personal information.

(3) At the core medical center, inpatient medical records may not be removed or released without coordination through the Health Information Management Division Officer per the Manual of the Medical Department and Manual of the Judge Advocate General. In cases of readmission, all available records will be made available for use of the medical staff, as requested.

(4) At the outlying clinics, outpatient health records will be controlled as delineated in reference (h).

k. Deaths

(1) Autopsy. All autopsies will be performed by a NAVMEDCEN pathologist or by a physician deemed as qualified by existing instructions or laws. The pathologist will notify the medical staff, particularly the attending physician, of the date and time of the performance of the autopsy. A complete protocol of the autopsy findings must be completed within 30 working days for routine autopsies and 90 days for complicated cases. A preliminary autopsy report must be available within 2 working days. These reports are to be incorporated into the patient's medical record. Every active medical staff member or his/her qualified trainee should seek legal consent for the authorization of an autopsy for all deaths for the purposes of quality assessment, graduate medical education, staff education, and enhancing patient care. Consent for autopsy will be sought for all deaths, especially the following:

(a) Deaths in which an autopsy may explain unknown and unanticipated medical complication.

(b) Deaths in which the cause is not known with certainty on clinical grounds.

(c) Cases in which an autopsy may help allay concerns of the family and/or public regarding death.

(d) Unexpected or unexplained deaths following a medical, dental, or surgical diagnostic procedure and/or therapy.

(e) Sudden, unexpected, or unexplained deaths which are apparently natural and not subject to a forensic medical jurisdiction.

(f) Natural deaths that are subject to, but waived by, a forensic jurisdiction (e.g., persons dead on arrival, deaths occurring in hospitals within 24 hours of admission, and deaths in which the patient sustained an injury while hospitalized).

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(g) Deaths resulting from high-risk infections and contagious diseases.

(h) All obstetric deaths.

(i) All neonatal and pediatric deaths.

(j) Deaths where an autopsy might disclose a known or suspected illness.

(k) Deaths known or suspected to have resulted from environmental occupational hazards.

(l) All active duty deaths.

(2) Death Certificates. Preparation of death certificates is under the cognizance of the Patient Support Division Officer. The signature on the death certificate will be that of an active medical staff member.

(3) Death Reviews. Risk Management Department will initiate death reviews within 24 hours (or by the next working day) for all deaths that occur in the core medical center and all patients pronounced dead on arrival (DOA) at the core medical center. The cognizant clinical service line leader/department head will ensure the initial review is completed and forwarded to Risk Management. In the event the responsible medical staff member is the service line leader/department head, an alternate active medical staff member will be assigned and is responsible for the review. After the review is complete, Death Review Forms will be permanently filed in the Risk Management Office.

1. Supervision of Non-Physician Healthcare Providers. Supervision of non-physician healthcare providers will be in compliance with references (e), (k), (l), and (m). Formal supervision required for physician assistants is delineated in references (l) and (m).

m. Medical staff will participate in performance improvement efforts within their assigned work area as well as for the command. All trainees (residents, interns, fellows) should be included in this process. Peer review process will be conducted as described in enclosure (2).

n. Medical staff requiring medical or psychiatric care, which could give rise to questions of objectivity, should seek care from a clinic other than that which is the member's assigned location.

14. Action. The Professional Affairs Coordinator (PAC) is responsible for distribution of this instruction to all present and applicant medical staff members. The Graduate Medical Education Department Head is responsible for the distribution of this instruction to all residents and interns.

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a. Each medical staff member is responsible for review and compliance with this instruction.

b. The Executive Committee of the Medical Staff is responsible for the annual review and update of this instruction.

c. All to whom this instruction applies must read and comply with the requirements contained herein.



M. L. NATHAN
Deputy

Distribution:
NAVMEDCENPTSVAINST 5215.1D (List B)

DISCLOSURE OF UNANTICIPATED OUTCOMES

1. Purpose. To establish guidance for healthcare professionals in the event of an unanticipated outcome.
2. Reference. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) developed a Patient Safety Standard: "The responsible licensed independent practitioner or his/her designee clearly explains the outcome of any treatments or procedures to the patient, and, when appropriate, to the family whenever those outcomes differ significantly from the anticipated outcomes."
3. Background
 - a. An integral part of the diagnostic or treatment process is to provide the patient with outcome or results information. When patients are unable to receive this information, a legally authorized representative may be the recipient of the news. The results may be shared with a surrogate decisionmaker, the parents of minor children, or (with permission of the patient) a spouse, a sibling, or significant other. When feasible to do so, information is then presented to the patient to help make decisions regarding future treatment.
 - b. Sometimes diagnostic tests or treatments result in unplanned or unwelcome outcomes. An unanticipated outcome is a result that "differs significantly" from what was anticipated to be the result of a treatment or procedure. This is not necessarily the result of substandard practice, error, or medical malpractice. Unwelcome outcomes may occur even when treatment was within the standard of care. It is important to keep in mind that disclosure of an unanticipated outcome or error is not disclosure of negligence. Disclosure is merely a factual statement of outcome, and does not offer an analysis of what went wrong and whether the fault lies with human failures, system failures, or a combination. Disclose unanticipated outcomes as soon as possible after the test or treatment. This approach fosters maintaining good communication with patients and providing information to foster good decisionmaking.
4. Strategies
 - a. A fundamental component of the patient-physician relationship is communication. Communication is an important patient safety tool. Therefore, the discussion of treatment outcomes, whether anticipated or unexpected, rests with the attending physician. This responsibility stems from the patient-physician relationship, reinforced by the principle of informed decisionmaking by the patient. When it is impractical for the attending physician to discuss unanticipated outcomes with the patient and family, the use of a designee may be in order. The designee should be the next senior physician directly involved in the care of the patient. A chief or senior level resident is acceptable.

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b. An "unanticipated outcome" may actually be a known risk that could have been discussed in the consent process. Consent is a communications process. It is much more than a form. It is the opportunity for the caregiver to provide the patient with information with which to make a decision regarding diagnostic tests, medical treatment, or surgical intervention. The information is patient-specific, based upon salient medical history information and an understanding of the patient's desire for outcomes of the test or treatment. While the attending physician may delegate elements of the consent process, the ultimate responsibility for the authorization resides with the accountable attending. Provide the patient and family with empathetic support. Be a good listener. Provide expressions of concern. This does not mean an admission of liability. Sometimes the cause or causes of the result may not be known for a while. As details are learned about the unanticipated outcome, provide this information to the patient or family. NAVMECEN Portsmouth staff must ensure that the patient or family understands that any documents and records created for the purpose of Quality Assurance (QA) are confidential and privileged. NAVMECEN staff must also understand that no part of the QA document may be disclosed, subject to discovery, or admitted into evidence in any judicial or administrative proceeding, except per Title 10 U.S.C. 1102.

c. Healthcare professionals involved in an unanticipated outcome may also require understanding and support. It is very disturbing to dedicated physicians to see patients experience negative outcomes.

5. Action. Providers should be honest, compassionate, and helpful. Balancing the need to disclose in a timely fashion, providers should consider consultation with Risk Management, patient safety, and legal counsel prior to disclosure and should plan their conversation so that information is factual, objective, and complete. Disclosure should not include speculation about the cause of the outcome, nor acceptance or assessment of blame.

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MEDICAL STAFF PEER REVIEW

1. Purpose. To implement a Performance Improvement Program for the medical staff and to define the process for peer review.

2. Policy. There will be an objective review of occurrences based on generic screens with the initial step being the collection, aggregation, and analysis of information. Criteria approved by the medical staff will be used in the collection process in order to provide objective data to aggregate and analyze patterns.

3. Procedure

a. A Quality of Care Review (QCR) form is completed when an unexpected patient care management occurrence is identified. The QCR is routed to the Risk Management Department Head or Outlying Clinic Performance Improvement Coordinator within 24 hours of identification and should not be held until the patient is discharged. This ensures immediate review and intervention to prevent harm to the patient or others. Completed QCR forms are reviewed by the Risk Management Department Head or designee within 24 hours of receipt for identification of a sentinel event. Cases requiring immediate intervention are referred to the Assistant Physician Advisor to Performance Improvement, Senior Medical Officer (SMO), or President, ECOMS for review and action as appropriate. The following is a list of those events that have the potential to fall under the peer review process:

(1) Admission following recent hospital or Emergent and Urgent Care/outpatient clinic discharge.

(2) Readmission within 30 days for complications or incomplete management of problems on previous hospitalization.

(3) Unscheduled return to clinic less than 72 hours with same or related complaints.

(4) Unexpected transfer from general care bed to special care unit.

(5) Injury to patient (organ or body part) during procedures/treatment.

(6) Patient with adverse drug reaction with a known history of an allergy.

(7) Postoperative complication.

(8) Medication error.

(9) All deaths.

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(10) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

(11) Surgery on the wrong patient or body part, regardless of the magnitude of the procedure.

(12) Any unintended retention of a foreign body in a patient.

(13) Patient complaint.

b. The occurrences are categorized in the following manner:

(1) Patient-Related Issue (PRE). Defined as an event that is causally related to factors intrinsic to the patient or the underlying disease progress (e.g., AMA, self-injury, newly developed drug allergies).

(2) Meets Standard of Care (SOC). Care provided is per contemporary standards of the specialty and/or service line. These events are well known and are widely reported in literature and frequent in occurrence, or infrequent, but have been described in literature to occur in cases where the standard of care was met.

(3) Does Not Meet Standard of Care (NOT). Events that are outside the standard of specialty or expected work area standards.

(4) Admin System Problem (ADM). Primarily a systems problem.

(5) Other. Self-explanatory.

c. Other medical staff activities that fall under the peer review process are utilization management and drug utilization.

4. Responsibilities

a. Assistant Physician Advisor to Performance Improvement or Senior Medical Officer. Review all events that are medical staff related. Those events that clearly meet the Standard of Care (SOC) or Patient-Related Issue (PRE) are filed for trending purposes. All other cases are forwarded for additional review to determine whether or not the SOC was met and to identify additional extenuating circumstances or systems problems. These reviews are routed to the responsible medical staff (attending), department head (peer), and service line leader. Both data collected for trending purposes and individual reviews may be used to identify lessons learned and improve overall processes.

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b. Risk Management Department Head or Outlying Clinic Performance Improvement Coordinator. Monitor all events for development of trends. Monthly, submit a report summary to the service line leader/department head. The service line leader/department head will act upon the findings as deemed necessary. Medical staff profiling will be available to the service line leader/department head to review as needed. A summary of each medical staff will be available to the Credentials Committee at the time of reappointment.

c. Physician Advisor to Performance Improvement (PAPI). Review all those events categorized as NOT. Those reviews will be forwarded to ECOMS within 30 days of completion for final decision. The results of QCRs, with a narrative summary, will be forwarded to the medical staff involved, service line leader/department head, and Outlying Clinic Performance Improvement Coordinator. The service line leader/department head is responsible to examine that provider's clinical activity file for significant negative trends.