

**CHAPTER 13**  
**QUALITY IMPROVEMENT**

Section A. Quality Improvement Program.

1. Mission.....	1
2. Background.....	1
3. Internal Quality Assurance Reviews.....	1
4. External Quality Improvement Reviews.....	1
5. Goals .....	2
6. Operational Health Readiness Program (OHRP).....	2
7. Objectives .....	2
8. Definitions.....	3
9. Responsibilities.....	4
10. Confidentiality Statement .....	7
11. QIP Review and Evaluation.....	7

Section B. Credentials Maintenance and Review.

1. Background.....	1
2. Definitions.....	1
3. Pre-selection Credentials Review .....	2
4. Provider Credentials File (PCF).....	3
5. Documentation.....	4
6. Verification .....	5
7. Contract Provider Credentials Review.....	6
8. Reverification.....	6
9. National Practitioner Data Bank (NPDB).....	7
10. National Provider Identifiers Type 1 (NPI) .....	7

Section C. Clinical Privileges.

1. Purpose.....	1
2. Background.....	1
3. Definitions.....	1
4. Applicability and Scope.....	3
5. Clinical Privileges.....	4

Section D. Operational Health Readiness Program.

1. Background.....	1
2. Purpose.....	1
3. Overview.....	1
4. OHRP Compliance Process .....	2

Section E. Quality Improvement Implementation Guide (QIIG).

- 1. Background .....1
- 2. Responsibilities .....1

Section F. National Provider Identifiers.

- 1. National Provider Identifiers (NPI) Type 1 .....1
- 2. Clinic National Provider Identifiers (NPI) Type 2 .....1

Section G. Health Insurance Portability and Accountability Act (HIPAA).

- 1. Background .....1
- 2. HIPAA Privacy/Security Officials (P/SO).....1
- 3. HIPAA Training Requirements .....4
- 4. Handling HIPAA Complaints and Mitigation .....7
- 5. Unintentional Disclosures of Protected Health Information.....9
- 6. Protected Health Information and the Coast Guard Messaging System.....10
- 7. Other CG Members Who Utilize Protected Health Information .....10
- 8. Electronic Transmission of Protected Health Information .....11

Section H. Quality Improvement Studies.

- 1. Background .....1
- 2. Responsibilities .....1
- 3. Definitions.....1
- 4. General information .....2
- 5. QIS Focus.....2
- 6. QIS Process.....2
- 7. QIS Report Form.....2
- 8. Frequency of Quality Improvement Studies .....2
- 9. Completing the QIS Report Form.....2
- 10. Follow-up Reporting.....5
- 11. Integration .....5
- 12. Filing.....5

Section I. Peer Review Program.

- 1. Background .....1
- 2. Characteristics of a Peer Review Program.....1
- 3. Responsibilities .....1
- 4. Process .....2
- 5. Definitions.....2

Section J. Infection and Exposure Control Program.

1. Introduction.....	1
2. Policy .....	2
3. Standard Precautions.....	2
4. Precautions for Invasive Procedures.....	5
5. Precautions for Medical Laboratories.....	6
6. Handling Biopsy Specimens.....	6
7. Using and Caring for Sharp Instruments and Needles.....	7
8. Infection Control Procedures for Minor Surgery Areas and Dental Operatories .....	8
9. Sterilizing and Disinfecting .....	14
10. Clinic Attire .....	19
11. Storage and Laundering of Clinic Attire, PPE and Linen.....	19
12. Cleaning and Decontaminating Blood or Other Body Fluid Spills .....	20
13. Infectious Waste.....	20
14. Managing Exposures (Bloodborne Pathogen Exposure Control).....	21
15. Training Personnel for Occupational Exposure.....	26

Section K. Patient Safety and Risk Management Program.

1. Purpose.....	1
2. Informed Consent.....	1
3. Adverse Event Monitoring and Reporting.....	4
4. Patient Safety Training .....	8

Section L. Training and Professional Development.

1. Definitions.....	1
2. Unit Health Services Training Plan (In-Service Training) .....	1
3. Emergency Medical Training Requirements .....	3
4. Health Services Technician "A" School .....	4
5. Health Services Technician "C" Schools .....	4
6. Continuing Education Programs .....	5
7. Long-Term Training Programs .....	6

Section M. Patient Affairs Program.

1. Patient Sensitivity .....	1
2. Patient Advisory Committee (PAC) .....	1
3. Patient Satisfaction Assessment.....	2
4. Patient Grievance Protocol .....	2
5. Congressional Inquiries .....	3
6. Patient Bill of Rights and Responsibilities .....	3

This page intentionally left blank

Section A. Quality Improvement Program.

1. Mission. ....	1
2. Background.....	1
3. Internal Quality Assurance Reviews. ....	1
4. External Quality Improvement Reviews. ....	1
5. Goals.....	2
6. Operational Health Readiness Program (OHRP). ....	2
7. Objectives.....	2
8. Definitions.....	3
9. Responsibilities.....	4
10. Confidentiality Statement.....	7
11. QIP Review and Evaluation.....	7

This page intentionally left blank.

## Section A. Quality Improvement Program.

1. Mission. The Commandant and Director of Health, Safety, and Work-Life are committed to providing the highest quality health care to Coast Guard beneficiaries. The Health Services Quality Improvement Program (QIP) described here establishes policy, prescribes procedures, and assigns responsibility for Quality Improvement (QI) activities at CG health services facilities. It is intended to function as an integral component in a quality healthcare system aimed at improving patient outcomes while also achieving patient satisfaction. This is accomplished by using quantitative methods to continuously improve the health services program. It is essential that the QIP integrates into the CG's overall healthcare system in order to improve health care delivery at all organizational levels. The Health, Safety, and Work-Life Directorate, HSWL SC, unit COs, health care providers, and patients must cooperate to ensure successful implementation of the quality improvement concept in the health care arena.
2. Background. Healthcare quality, as defined by the Institute of Medicine (IOM), is “the degree to which health services for individuals and population increase the likelihood of desired health outcomes and are consistent with professional knowledge”. For many years, CG health care facilities have conducted QI activities, usually as a normal outgrowth of complying with this Manual’s directives and the consequence of CG practitioners’ good medical and dental practices. Since Maintenance and Logistics Commands were established in 1987 and the Quality Assurance Division was reorganized in 1989 in the Office of Health and Safety, a concerted effort has been made to develop a CG-wide quality program designed to address quality-of-care issues at our facilities. This program has been tailored to CG medical and dental practices and incrementally phased it in over an extended time period. This program has been very successful in creating a quality foundation to the CG health care system. It is now time for us to expand this quality focus to broader views that reflect recommendations from health care quality studies in recent years.
3. Internal Quality Assurance Reviews. The CG first established an internal healthcare quality assurance (QA) program in the early 1990s to monitor the quality of healthcare delivered at its clinics. The MLCs (k) initially administered the program by conducting QA surveys at each clinic every three years by members of the MLC staff. Clinics passing the MLC survey were awarded a three-year certificate that verified the clinic met CG QA standards. In 2004 the internal QA review process changed to the current format which provides for an external accreditation organization to perform the Quality Improvement (QI) surveys of CG clinics and issue a one or three-year accreditation. The HSWL SC review process concentrates on CG-specific and Operational Health Readiness issues.
4. External Quality Improvement Reviews. The standard of healthcare in the U.S. is for QI program surveys to be conducted by external auditors. Additionally, external auditors help the CG meet DoD and TRICARE QA healthcare requirements. In 2004, the CG contracted an external accreditation organization to independently conduct CG clinic QI surveys. The external accreditation organization standards mirror many CG standards that were being implemented by clinics in accordance

with the Medical Manual, COMDTINST M6000.1 (series). The standard external survey cycle will be every three years. To receive a three-year accreditation, clinics must demonstrate compliance with the survey standards and Quality Improvement Studies (QIS) must be implemented on a continuous basis. The external accreditation organization is the sole accrediting body for CG clinics.

5. Goals. All CG health care facilities with medical or dental officers assigned shall have a QIP to organize efforts to achieve and document quality health care for eligible beneficiaries. The QIP described here contains the essential elements required at all CG facilities and assigns responsibilities for program initiatives. All active duty, reserve, and civilian health care providers treating patients at CG clinics must participate in on-going QIS designed to assess the quality and appropriateness of the services they provide.
6. Operational Health Readiness Program (OHRP). CG specific QI and operational health readiness issues will be managed and monitored by the HSWL SC under the Operational Health Readiness Program (OHRP) addressed in 13.D. The HSWL SC will no longer survey QA/QI issues that are addressed by the external accreditation surveyors nor provide a certification.
7. Objectives.
  - a. Communicate information. Communicate important QI information to enable sound clinical and management decision-making at all organizational levels.
  - b. Review credentials and approve privileges. Ensure a safe and professional health care team by reviewing credentials and approving privileges of health care providers that work in CG clinics.
  - c. Standards. Establish criteria to assist and ensure that clinics meet external accreditation standards, by integrating quality improvement processes into daily health care delivery and to ensure clinics attain and sustain compliance with CG specific QI and operational health readiness issues.
  - d. Monitor. Systematically monitor health services to identify opportunities to improve patient care, and use a systematic method of improvement changes to ensure effective improvements are made and sustained.
  - e. Significant patterns. Integrate, track, and analyze patient care information to identify significant patterns that may require additional review or intervention.
  - f. Resources. Identify and justify resources required to maintain high quality patient care standards.
  - g. Risk assessment. Identify, assess, and decrease risk to patients and staff, thereby reducing liability exposure.
  - h. Educational and training. Identify educational and training/professional development requirements and assure satisfactory education and training/professional development standards are established and maintained.



- i. Patient satisfaction. Establish and maintain adequate systems to monitor and assess patient satisfaction; respond to patient and command concerns about access and quality of care.
8. Definitions.
- a. Quality. The desired level of performance as measured against generally accepted healthcare standards.
  - b. Quality Health Care. According to the Institute of Medicine, quality health care is the degree to which health services for individuals and population increase the likelihood of desired health outcomes and are consistent with professional knowledge.
  - c. Quality Assurance. Those functions that attempt to ensure the desired level of performance by systematically documenting, monitoring, evaluating, and, where necessary, adjusting healthcare to meet established standards. These functions must meet the minimum compliance with the Accreditation Association for Ambulatory Health Care (AAAHC) and the Coast Guard Medical Manual, COMDTINST M6000.1 (series) healthcare standards. QA functions do not necessarily contain QI functions.
  - d. Quality Improvement. A system that attempts to proactively improve on the minimum healthcare standards established by the contracted external accreditation organization and the Medical Manual, COMDTINST M6000.1 (series). QI involves a continuous review of QA elements and operational procedures of healthcare delivery. QI always contains QA elements.
  - e. Quality Improvement Studies (QIS). Those clinical processes that are identified as needing review for improvement. These initiatives demonstrate a commitment to making things better and always looking for and studying ways to improve. QIS help: evaluate the extent, severity and impact of a need or problem; assess and compare the effectiveness of various clinical or administrative approaches to resolution; identify areas for educational efforts; set performance goals, and track performance improvements. QIS replace the Monitoring and Evaluations.
  - f. Professional Oversight. QIS provided by CG health care personnel and non-Federal providers, including among others, technical guidance and assistance, peer review, resource utilization review, external accreditation, and CG specific QI and operational health readiness issues managed and monitored by the HSWL SC to ensure compliance with the CG Health Care QIP and other CG directives.
  - g. Governing Body. The agency that has ultimate authority and responsibility for establishing policy, maintaining quality patient care, and providing organizational management and planning. This is the Commandant (CG-11)

Executive Leadership Council. The Executive Leadership Council is comprised of Commandant (CG-112) (chair), Commandant (CG-11d), Commandant (CG-111), Commandant (CG-113), and the HSWL SC.

9. Responsibilities.

a. Director of Health and Safety.

- (1) Establish at all CG health care facilities a comprehensive QIP which meets industry standards published by independent accrediting organizations. The HSWL SC implements the QIP as established by the Director of Health and Safety.
- (2) Govern CG health care facilities with delegated responsibilities to the Senior Health Services Officer (SHSO) at each facility.
- (3) Establish and promulgate health care policy including professional performance standards against which quality can be measured.
- (4) Establish and promulgate productivity and staffing standards for the health services program.
- (5) Conduct periodic Quality Improvement Meetings for Headquarters and HSWL SC QI staffs to coordinate and implement program policy at all organizational levels.
- (6) Review credentials and grant privileges for all CG medical and dental officers.
- (7) Develop and promulgate the Quality Improvement Implementation Guides.
- (8) Identify education and professional development training requirements and assure high quality standards are established and maintained. Coordinate and fund continuing professional education for all health services personnel.

b. Health, Safety, and Work-Life Service Center (HSWL SC).

- (1) Ensure the Commandant's Health Care QI Program is executed at the field level.
- (2) Periodically conduct site assist visits to ensure compliance with external accreditation organization standards and Operational Health Readiness Program (OHRP) goals of all health services facilities in their area in accordance with Section 13.D.
- (3) Develop and maintain standard operating procedure manuals and/or health services support program guides necessary to provide operational guidance for clinic activities.
- (4) Develop and maintain Quality Improvement Self Assessment Checklists for assist visits.

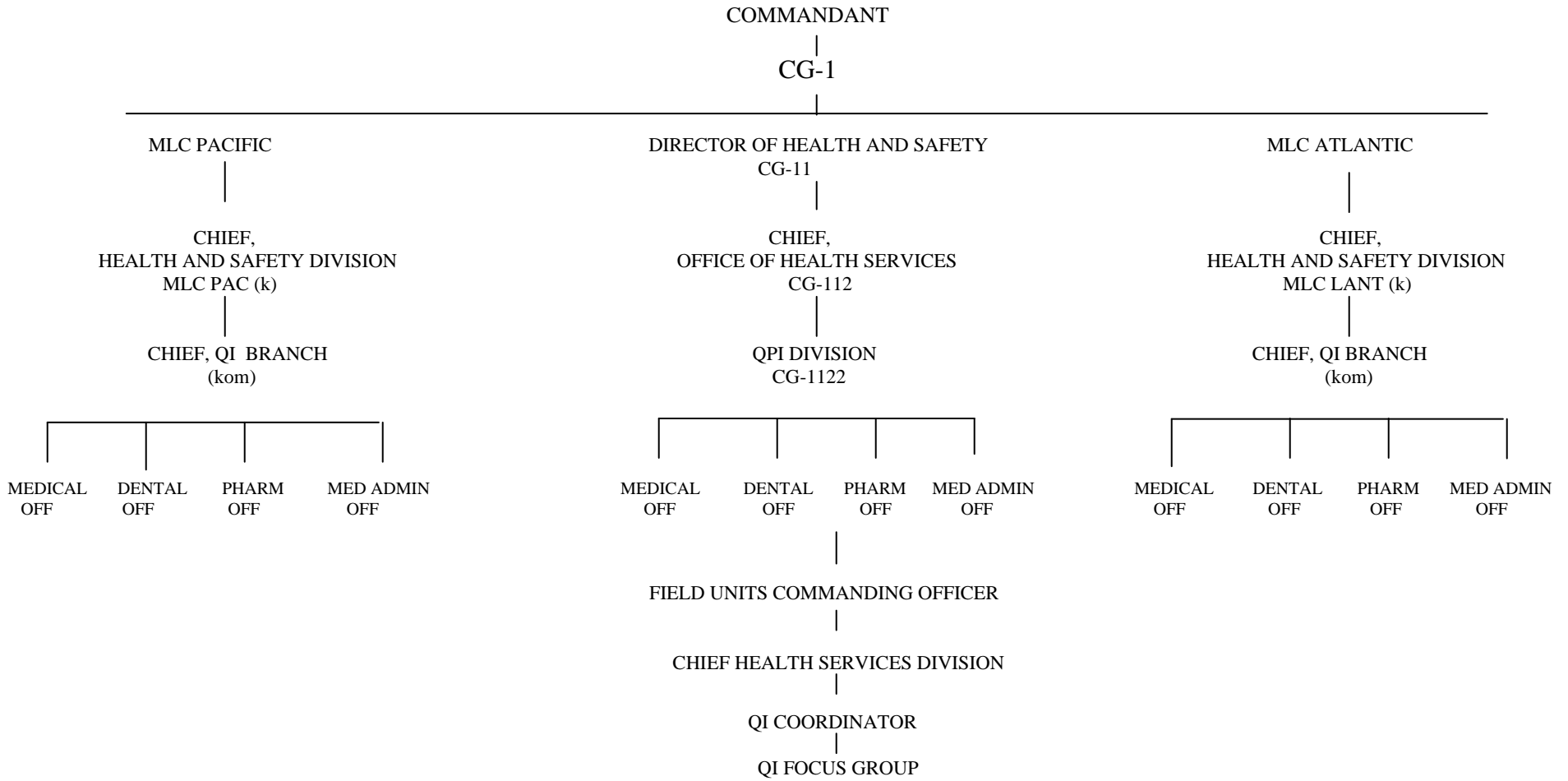
- (5) Perform utilization review of clinic expenditures, staffing, equipment, supplies, and facilities; review and process all requests for non-Federal medical care from units in its jurisdiction.
  - (6) Provide technical and professional advice regarding health services to units, as required.
  - (7) Conduct site visits on an appropriate schedule to verify standards compliance and to provide assistance in meeting the expectations of the Operational Health Readiness Program.
- c. Commanding Officers.
- (1) Ensure the unit actively pursues health services quality standards.
  - (2) Appoint in writing an individual to serve as Health Services Quality Improvement Coordinator in accordance with Paragraph 13.A.6.e.
- d. Senior Health Services Officer (SHSO). Represents the Governing Body locally for Quality Improvement and related activities.
- e. Health Services QI Coordinator. The Health Services QI Coordinator should be a senior health services staff member with these characteristics:
- (1) Demonstrates the ability and motivation to provide and ensure quality health care.
  - (2) Knows the requirements of the Medical Manual, COMDTINST M6000.1 (series).
  - (3) Communicates well in both writing and speaking.
  - (4) Well versed in delivering CG health care and supports the goals of health care quality improvement.
  - (5) Is an E-6 or above if military, or appropriate civilian employee.
- f. The Health Services QI Coordinator responsibilities. The Health Services QI Coordinator responsibilities are as follows:
- (1) Directs Health Services QI Focus Group activities.
  - (2) Implements the health care QI program locally by identifying and coordinating resolution of health care QI problems through design and implementation of QIS.
  - (3) Develops and promulgates an annual QI calendar which sets the agenda for all QI activities at the unit, including among other activities QI Focus Group meetings and all quality improvement studies.
  - (4) Other health care QI functions as necessary.
  - (5) Appoint health services staff members to serve on a Health Services Quality Improvement Focus Group in accordance with Paragraph 13.A.6.f.

- (6) Forward copies of QI Focus Group meeting minutes to the HSWL SC.
- g. Alternate Health Services QI Coordinators. The SHSO or Clinic Administrator may also be appointed as the Health Services QI Coordinator. However, this is not recommended in larger clinics since these two individuals are expected to provide necessary management expertise and clinical guidance in conducting the health care QI program and effecting any required program adjustments. The Health Services QI Coordinator's relationship to the SHSO is advisory.
- h. Accrediting Body. An external accreditation organization will be used as the sole accrediting body for CG clinics. All facilities will be expected to be compliant with the current standards. The regular accreditation cycle is once every three years.
- i. Less than 3 year certification. Facilities that do not receive a three-year accreditation will be resurveyed within 12 months of the initial survey.
- j. Health Services Quality Improvement Focus Group (QIFG).
- (1) The Health Services QIFG shall consist of all clinic staff to a maximum of 15 members, depending on unit size, including both enlisted members and officers who broadly represent the health care services provided at that unit.
  - (2) Members will include at least a medical or dental officer, a clinic supervisor, and department representatives, e.g., pharmacy, physical therapy, x-ray, and laboratory. If desired, the QIFG at small units may operate as a "Committee of the Whole" of all staff members.
  - (3) The QIFG advises the SHSO about the quality of the facility's health care and performs these functions:
    - (a) Identifies and resolves problems which affect the quality of health care delivery at the facility. The SHSO may delegate investigating and resolving a particular QI problem to the staff member responsible for the clinical area where the problem has been identified (e.g., laboratory, patient reception).
    - (b) Ensures all required health services committee meetings are held according to the provisions of the CG Medical Manual, HSWL SC standard operating procedures and operational guides, and local instructions, including, among others, the Patient Advisory Committee.
    - (c) Uses existing CG standards, HSWL SC self assessment checklists, and QIS to review and evaluate the quality of services delivered both in-house and by contract providers.
    - (d) Performs systematic, documented reviews of health records for compliance and adherence to Medical Manual standards and HSWL SC standard operating procedures, health and safety support program guides, and self assessment checklists, and HIPAA privacy and security requirements.

- (e) Solicits and monitors patient perceptions and satisfaction by surveys and questionnaires. Reports negative trends and potential solutions to the HSWL SC as a part of the QIFG meeting minutes.
  - (f) The QIFG shall meet at least quarterly and more often as local needs dictate. The clinic will maintain these meetings' original minutes for five years and will electronically forward copies of the minutes along with quality improvement studies through the chain of command to the HSWL SC for review on CG Central. The HSWL SC will provide electronic access to Commandant (CG-1122).
  - (g) Assists in obtaining and maintaining standards compliance necessary to achieve external accreditation.
10. Confidentiality Statement. All documents created under authority of this instruction are health services QI records and part of the CG's QIP. They are confidential and privileged under 14 USC 645 provisions. Releasing a health services QI document is expressly prohibited except in limited circumstances listed in 14 USC 645.
11. QIP Review and Evaluation. The Director of Health and Safety will annually review and evaluate the QIP. The review will reappraise the QI Plan and incorporate comments from the HSWL SC on implementation activities at field units during the preceding year.
- a. QI Review and Evaluation Report. By 30 November annually, HSWL SC shall provide to Commandant (CG-11) a written QI Review and Evaluation Report addressing these topics during the previous fiscal year:
    - (1) Summary of clinic accreditations.
    - (2) Summary of clinic Operational Health Readiness compliance.
    - (3) Summary of significant clinical problems identified.
    - (4) Summary of peer review activities.
    - (5) Recommended QIP modifications.
    - (6) HSWL SC QI Plan for upcoming calendar year.

FIGURE 13-A-1

ORGANIZATIONAL CHART FOR QUALITY IMPROVEMENT PROGRAM



Section B. Credentials Maintenance and Review.

1. Background.....	1
2. Definitions .....	1
3. Pre-selection Credentials Review .....	2
4. Provider Credentials File (PCF) .....	3
5. Documentation.....	4
6. Verification .....	5
7. Contract Provider Credentials Review .....	6
8. Reverification.....	6
9. National Practitioner Data Bank (NPDB).....	7
10. National Provider Identifiers Type 1 (NPI) .....	7

This page intentionally left blank.



Section B. Credentials Maintenance and Review.

1. Background. Commandant (CG-11) is responsible for ensuring health care providers in CG facilities are competent and capable. Verifying licensed/certified healthcare providers qualifications are essential to assure providers are prepared for the scope of practice for which they are employed. Primary sources verification is needed. (Primary source verification is documented verification by an entity that issued a credential, such as a medical school or residency program, indicating that an individual's statement of possession of a credential is true). Primary sources must certify that certain valid credentials, including qualifying professional degree(s), license(s), graduate training, and references are met before a provider may practice independently in CG health care facilities. All candidates for CG employment, CG civil service employees, assigned PHS commissioned corps officers, CG Auxiliant healthcare providers, and contract providers who provide direct patient care in CG health care facilities will comply with this chapter's provisions as applicable. The credentials shall be reviewed for each healthcare provider appointed to a position providing patient care. Privileges will be assigned based on this review.
2. Definitions.
  - a. Contract Provider. An individual holding valid certification/licensure as a physician, dentist, dental hygienist, dental assistant, physician assistant, nurse practitioner, physical therapists or optometrists other than uniformed services personnel, who provide care in a CG health services facility under a contractual agreement with the CG. Contract providers will not be considered medical or dental officers as it relates to duties and responsibilities.
  - b. Credentials. Documents constituting evidence of education, professional clinical training, licensure, experience, clinical competence and ethical behavior.
  - c. Credentials Maintenance. Filing, updating, modifying or completing files, documents and databases about practitioner credentials.
  - d. Credentials Review. The process of checking a practitioner's verified credentials and other supporting documents to evaluate potential assignments assign or rescind clinical privileges, or take administrative or personnel actions.
  - e. Credentials Verification. The process of verifying a practitioner's license, education, training, and competence before initial assignment or employment.
  - f. Dental Officer. A PHS commissioned officer assigned to the CG, who is a graduate of an accredited US school of dentistry and holds a valid, current state license to practice dentistry.
  - g. License (Current, Unrestricted, Active). A certificate issued by one of the 50 states, District of Columbia or US Territories (Guam, Puerto Rico, Virgin Islands) that permits a person to practice medicine, dentistry, or other allied health profession.

- h. Medical Officer. A commissioned CG or PHS officer assigned to the CG who has graduated from an accredited educational institution and is currently licensed as a physician, a nurse practitioner holding a valid certification by the American Academy of Nurse Practitioners or the American Nurses Credentialing Center or as a physician assistant holding valid certification from the National Association on Certification of Physician Assistants (exempt from licensing requirement).
  - i. Pharmacy Officer. A commissioned PHS officer assigned to the CG who graduated from an accredited US educational institution and is currently licensed as a pharmacist.
  - j. Primary Source Verification. Verification of a credential with an individual or institution possessing direct knowledge of the validity or authenticity of the particular credential.
  - k. Privileges. Type of practice activities authorized to be performed in the facility, within defined limits, based on the providers' education, professional license as appropriate, experience, current competence, ability, judgment, and health status.
  - l. Provider. A person granted individual clinical privileges to diagnose and treat diseases and conditions, including physicians, dentists, physician assistants, nurse practitioners, podiatrists, optometrists, and clinical psychologists.
3. Pre-selection Credentials Review.
- a. PHS Liaison Officer. The PHS liaison officer at Commandant (CG-112), in cooperation with the PHS Division of Commissioned Corps Assignments (DCCA) in the Office of Commissioned Corps Operations (OCCO) shall perform a pre-employment review and verify minimum standards before appointing Commissioned personnel. DCCA also screens individuals and certain credentials as part of the commissioning process. CG procedures are designed to complement DCCA's; the CG may alter its policies to reflect OCCO policy changes.
  - b. HSWL SC or local command. The HSWL SC or local command by direction shall perform a pre-employment review of credentials of Civil Service employees and contractors providing care in CG health care facilities, and students.
  - c. Student credentials. To review and verify student credentials, obtain a letter from the school stating the student is in good academic standing. Document malpractice coverage arrangements through an appropriate affiliation agreement. Student Externship Programs (SEP), COMDTINST 6400.1 (series).
4. Provider Credentials File (PCF). Through a Memorandum of Understanding between Commandant (CG-1122) and the Armed Forces Institute of Pathology

(AFIP) and the Department of Legal Medicine, the AFIP shall initiate and maintain PCFs for all Civil Service, Uniformed Service, Auxiliariist, and contracted licensed practitioners for the entire length of their employment or service. For contract providers (physician, dentist, PA/NP, physical therapists, optometrists or registered dental hygienist) the hiring entity (HSWL SC or HQ) will initiate the creation of the PCF upon offer or intent to hire the provider by sending the credentialing documents to AFIP as per 13. B. 5. a. Persons unable or unwilling to provide required information may be disqualified for employment or accession. These files must contain the following information:

- a. Curriculum vitae. A curriculum vitae (CV) accounting for all time since the qualifying degree was received and prior to employment with the CG. For employed CG providers, their CV should remain current within three years.
- b. Educational degrees. Copies of qualifying educational degrees (diploma, certificate) needed to perform clinical duties with the documents' primary source verification; see Section 13-B-6.
- c. Postgraduate training certificates. Copies of required postgraduate training certificates for the area of work; for example, internship, residency, fellowship, nurse practitioner or physician assistant training, and primary source verification of these documents' authenticity.
- d. State licenses. Copies of state licenses for all states in which the practitioner is licensed (active or inactive), current renewal certificates, and Educational Commission for Foreign Medical Graduates (ECFMG) certification if the practitioner graduated from a medical school not in the Continental US, Hawaii, Alaska, or from a medical school not accredited by the American Association Liaison Committee on Medical Education. The practitioner must attach a statement of explanation for lapsed state licenses or those subject to disciplinary action. The provider must maintain at least one unrestricted, current, and active license. The primary source must verify all licenses or renewal certificates.
- e. Specialty board. Copies of specialty board and fellowship certificates with primary source verification of these documents.
- f. Proof of competence and letters of reference. Proof of current (within one year) competence, i.e., two letters of reference for initial appointment/accession and a description of recent clinical privileges held (practitioner's supervisor(s) from last five years must note concurrence with applicant's position, scope of practice and approval of privilege performance).
  - (1) The official, reviewing letters of reference, is authorized to contact the author of the letters to verify authorship and authenticity of letters. The official is also authorized to request a second letter of reference from an author when the first letter is deemed unclear. The official reviewing a letter of reference is authorized to contact the author via telephone in cases

in which the author declines to respond in writing. In such cases, the official will document in a telephone log the site, date, time, identity of call participants, and a detailed description of the conversation.

- (2) Documents of reference submitted to DCCA for appointment in the USPHS may be used as letters of reference.
  - (3) In cases of a provider being acquired from other branches of the military, copies of officer fitness reports (OER) and/or performance assessment reviews (PARS) may be substituted for letters of reference.
- g. Malpractice cases. A statement explaining any involvement in malpractice cases and claims, including a brief review of the facts about the practitioner's involvement.
  - h. Disciplinary action. A statement is needed explaining any disciplinary action from hospitals, licensing boards, or other agencies.
  - i. Basic Cardiac Life Support certification. A current Basic Cardiac Life Support (for Healthcare Providers), certification is required in accordance with Chapter 13 Section L of this Manual.
  - j. Advanced Cardiac Life Support. A current Advanced Cardiac Life Support certification is required for all active duty and reserve CG Medical Officers in accordance with Chapter 13 Section L of this Manual.
  - k. Drug Enforcement Agency (DEA). Copies of all current and prior Drug Enforcement Agency (DEA) registration, as appropriate.
  - l. National Practitioner Data Bank (NPDB). National Practitioner Data Bank (NPDB) query, current within two years.
  - m. Attestation Form.
  - n. Release of Information Letter.
  - o. National Provider Identifiers (NPI) Type 1. See Section F.
5. Documentation.
- a. Credential Documents. Send the credential documents to AFIP and Commandant (CG-1122), via traceable means (e.g. DHS authorized Commercial Carriers FedEx or UPS); US Postal Service (USPS): 1) Express Mail or 2) Proof of Delivery using Extra Services which are either Certified, Delivery Confirmation, or Signature Confirmation. The technical review by the HSWL SC does not constitute official Coast Guard credentialing or privileging.

- b. Confidentiality. AFIP will maintain files in a locked cabinet. PCFs and their contents are Class III (maximum security) records and protected from disclosure under the Privacy Act. Do not release documents in the PCF to any other individual or entity unless the provider has given express written permission.
  - c. Organization. Documents are placed in a six-section folder as follows:
    - (1) Section One. CG clinical privileging documents, Interagency Credentials Transfer Brief and Miscellaneous Supporting documents (i.e. support of supplemental privileges).
    - (2) Section Two. Letters/documents of reference, curriculum vitae (current within three years), National Provider Identification Number, and Release of Information/Attestation.
    - (3) Section Three. National Practitioner Data Bank queries, Health and Human Service Office of Inspector General List of Excluded Individuals/Entities, adverse actions, malpractice documents, proof of malpractice coverage, and statements about adverse information or malpractice claims.
    - (4) Section Four. Copies of license(s), diploma(s) or degree certificates, certificate (if applicable) from the Educational Commission for Foreign Medical Graduates (ECFMG), board certification, and Drug Enforcement Administration (DEA) number certificate.
    - (5) Section Five. Copies of post graduate training certificates, Accreditation Council for Graduate Medical Education letters, Basic Cardiac Life Support, (BCLS), Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS), Basic Trauma Life Support (BTLS), Advanced Trauma Life Support (ATLS), and aviation/operational medicine courses.
    - (6) Section Six. Letter from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Accredited Hospital regarding admitting privileges and privileges granted by other/previous institution(s).
6. Verification.
- a. How to perform verification. To verify education, training, licensure or registration, certification, ECFMG and board certification, obtain either an original letter from the educational institution or certifying body attesting to successful completion of specialty training, print out of online internet verification, or verify by telephone call between the CG/AFIP representative and the educational institution or specialty board. Record telephone verification on the document itself and on official letterhead signed and dated by the person making the call. Place all verification documents with their source documents in PCF Section Six.

- b. AFIP verification. AFIP will verify credentials of uniformed services providers before appointment/accession.
- c. MLC verification. Before selection of Civil Service and contract providers, there will be a review of education, training, licensure, experience, certification or registration, and current competence completed by the HSWL SC as directed in section 3.b. All Civil Service and contract providers will require privileging to practice in CG facilities.
- d. Verify experience. To verify experience and current competence requires at least two recommendation letters from appropriate sources as listed below. Commandant (CG-1122) or the HSWL SC shall receive direct letters from the person providing the reference. Verify descriptions of recent clinical privileges as above.
  - (1) A letter either from the hospital chief of staff, clinic administrator, professional head, or department head if the individual has professional or clinical privileges or is associated with a hospital or clinic; or
  - (2) A letter from the director or a faculty member of the individual's training program if he or she has been in a training program in the previous two years; or
  - (3) A letter from a practitioner in the appointee's discipline who is in a position to evaluate the appointee's peer and a professional association or society association (mandatory if the appointee is self-employed).

7. Contract Provider Credentials Review.

- a. Contracting agency. The contracting agency has the responsibility for initial and ongoing primary source verification of credentials of all contract providers. Physician Assistants must be certified by the National Commission on Certification of Physician Assistants. Nurse Practitioners must be certified by the American Academy of Nurse Practitioners or the American Nurses Credentialing Center. Malpractice insurance must be provided and verified by the contracting agency.
- b. Technical review. At the contracting officer's request, HSWL SC will perform a technical review of the providers' credentials. This does not constitute a privileging authorization.

8. Reverification.

- a. Renewable credentials. These credentials are renewable and will be primary source verified on renewal: License, PA certification, Board certification, and contract providers' malpractice coverage. Reverify contract providers' updated credentials is at contract renewal.

- b. Reverify these credentials by original letter or telephone contact. The person making the call will record telephone contact on the document or by a separate, signed memorandum.
9. National Practitioner Data Bank (NPDB).
  - a. Commandant's role. Commandant (CG-11) possesses sole authority to report to the NPDB. Commandant (CG-1122) is designated as the appropriate entity for all NPDB queries. Coordinate all queries for patient care providers through this branch.
  - b. NPDB requirements. A reply from the NPDB is not required before the practitioner begins providing services. However, any provider whose credential verification is not fully completed will be considered to have a conditional appointment until all credentials are verified as required.
10. National Provider Identifiers Type 1 (NPI).
  - a. Requirement for NPI. All health care providers who furnish health care services or those who may initiate and/or receive referrals must obtain an NPI Type 1. NPI Type 1 is assigned at no fee by the Centers for Medicare and Medicaid Services (CMS) National Plan and Provider Enumeration System (NPPES). Providers shall apply for and will receive one and only one NPI Type 1. This NPI Type 1 will be a permanent identifier. CMS has an on-line NPI Type 1 application available at <https://nppes.cms.hhs.gov>.
  - b. Filing the NPI. Once a provider obtains their NPI Type 1, they shall provide a copy to the CG credentialing office, Commandant (CG-1122). The information will be entered into the Centralized Credentials Quality Assurance System (CCQAS) database. A photocopy of the original hardcopy will be filed in the Practitioner Credentials File.
  - c. Instructions. Instructions for obtaining and maintaining NPI Type 1 for health care providers are to be included in all privileging packages.
  - d. HIPAA compliance. HIPAA compliance requires that NPPES be updated within 30 days of a change in the NPI Type 2 data.
  - e. Privileging authority facility name. In order to ensure standardized addresses are being used in the mailing address and in the practice location fields on the NPI Type 1 application, providers (other than Reserve component providers) are to use the privileging authority facility name (USCG HQ, COMMANDANT (CG-1122)) as the address of record.

This page intentionally left blank.



Section C. Clinical Privileges.

1. Purpose.....	1
2. Background.....	1
3. Definitions.....	1
4. Applicability and Scope.....	3
5. Clinical Privileges.....	3

This page intentionally left blank.

### Section C. Clinical Privileges.

1. Purpose. Granting individual clinical privileges to independent licensed providers who are providing services in health care organizations is an essential component of quality health care. Clinical privilege granting and rescinding activities define the provider's scope of care and services available to patients. The privileging process is directed solely and specifically at providing quality patient care; it is not a disciplinary or personnel management system. However, privileging actions may accompany administrative or judicial actions or engender them. Granting and rescinding clinical privileges is highly confidential, and must be conducted according to strict rules to prevent improper or prejudiced actions. This section establishes processes and procedures to grant and rescind clinical privileges. These provisions fall outside the scope of the Administrative Investigations Manual, COMDTINST M5830.1 (series).
2. Background. Commandant (CG-11) is responsible for planning, developing, and administering a comprehensive, high-quality health care program which must ensure the persons providing care have appropriate, verified licenses, education, and training. CG health care providers must adhere to commonly accepted standards for treatment and therapeutic modalities. In the CG, adherence to accepted standards is achieved by rigorous quality improvement (QI) and providers' peer reviews.
3. Definitions.
  - a. Abeyance. The temporary removal of a health care provider from clinical duties while an inquiry into allegations of provider impairment or misconduct is conducted. Periods of abeyance provide privileging authorities the opportunity to review allegations while ensuring patient safety and protecting providers from unwarranted adverse privileging action. An abeyance terminates upon referral to a peer review hearing or at the end of 28 days, whichever occurs sooner. An abeyance is not an adverse action and is non-punitive.
  - b. Adverse Privileging Action. Any action that denies, suspends, reduces, or revokes a provider's clinical privileges for greater than 30 days.
  - c. Clinical Privileges. Type of practice activities authorized to be performed in the facility, within defined limits, based on the providers' education, professional license as appropriate, experience, current competence, ability, judgment, and health status.
  - d. Convening Authority. Commandant (CG-11).
  - e. Document Review. A review of medical record documentation and other pertinent data as defined by the Convening Authority.

- f. Expiration of Credentials. It is ultimately the responsibility of the provider to ensure that all credentials required for clinical privileges are renewed prior to their expiration dates. If any credential required for clinical privileges is allowed to expire, the provider may have clinical privileges suspended or terminated. This will remove the provider from direct patient care and may render the provider ineligible to receive any special pay for clinical duties while the provider is in this status.
- g. External Review. Administrative, non-judicial, or criminal investigations initiated by entities other than the CG health services program. This external review may be conducted by an outside agency.
- h. Focused Review. An internal administrative mechanism to evaluate information about clinical care or practice. CG health services officers conduct focused reviews as part of the quality improvement program.
- i. Full Staff Privileges. Unrestricted privileges as defined by "Clinical Privileges" above reevaluated and renewed every three years.
- j. Impairment. Any personal characteristic or condition that may adversely affect the ability of a health care provider to render quality care. Impairments may be professional, behavioral, or medical. Professional impairments include deficits in medical knowledge, expertise, or judgment. Behavioral impairments include unprofessional, unethical, or criminal conduct. Medical impairments are conditions that impede or preclude a health care provider from safely executing his or her responsibilities as a health care provider.
- k. National Practitioner Data Bank (NPDB). The agency established per regulations issued by the Department of Health and Human Services to collect and maintain data on substandard clinical performance and unprofessional conduct of health care providers. Requires reports of adverse privileging actions taken against providers and payments made to settle or satisfy claims or judgments resulting from medical malpractice of providers.
- l. Peer Review. Review by an individual (or individuals) who possess relevant professional knowledge or experience, usually in the same discipline as the individual under review. This external review may be conducted by an outside agency.
- m. Privileging. The process through which providers are given the authority and responsibility to make independent decisions to diagnose illnesses and/or initiate, alter, or terminate a regimen of medical or dental care.
- n. Privileging Authority. Director, Health & Safety Commandant (CG-11) is the corporate privileging authority for all CG health care providers.

- o. Professional Review Committee (PRC). A committee appointed by Commandant (CG-11). The committee shall be composed of the Deputy Director of Health and Safety, Commandant (CG-11d), the Chief of the Operational Medicine and Medical Readiness, Commandant (CG-1121), and the Chief of Quality Performance and Improvement Division, Commandant (CG-1122) or their designees. The committee shall have at least two Medical Officers (one of which shall be a physician and the other may be a PA or NP) and one Dental Officer. Other officers may participate as required (e.g. Auxiliarist Medical Officer).
  - p. Provider. For this chapter, an individual granted clinical privileges to independently diagnose and treat diseases and conditions. Physicians, dentists, physician assistants, and nurse practitioners and other professions so designated by the privileging authority are provider disciplines within the CG health services program.
  - q. Special Professional Review Committee. A Professional Review Committee designated by the Convening Authority to address allegation and/or complaints regarding a CG provider.
  - r. Summary of Suspension. The temporary removal of all or part of a provider's clinical privileges before the completion of due process procedures. A summary of suspension would be used during the period between an abeyance and the completion of due process procedures. Summary of suspension of privileges is not reportable to the NPDB unless the final action is reportable.
  - s. Suspension. The temporary removal of all or part of a provider's clinical privileges resulting from lack of current competence, negligence, or unprofessional conduct after due process procedures are completed. The suspension of privileges is reportable to the NPDB. Suspension of privileges would be used when in the privileging authority's judgment, additional training, education, or treatment may correct underlying deficiencies and allow reinstatement of full privileges. In such cases, the NPDB must be notified of the suspension, and then informed when privileges are reinstated, or if not reinstated, when privileges are reduced or revoked.
4. Applicability and Scope. All military, Civil Service, contract civilian, and auxiliarist CG health care providers shall have clinical privileges assigned. Health services personnel (other than providers) who function under a standard job or position description or standard protocol, policies, and procedures, or who must consult with another provider before or during medical or dental treatment will not receive clinical privileges.
5. Clinical Privileges.

a. General.

- (1) Commandant (CG-11) will grant clinical privileges (to include initial appointment, reappointment and assignment or curtailment of clinical privileges) based on education, specific training, experience, license or certification status, current competence and needs of the service. He or she shall consider limitations (facility, support staff, equipment capability, etc.), which may prevent a provider from conducting certain activities. Commandant (CG-11) shall assign or require providers to perform professional duties only if their education, training, and experience qualify them to perform such duties. Commandant (CG-11) shall also consider the provider's health status and ability to treat coworkers and patients with dignity and respect when granting privileges.
- (2) In order to request or renew privileges the provider shall use Request for Clinical Privileges, CG-5575. For core privileges, the provider shall sign, scan or route the request to the SME or SDE for signature. The SME or SDE shall sign, scan or route the request to the Professional Review Committee (PRC). The PRC will review the request and make recommendations to the Privileging Authority for a decision. If supplemental privileges are requested, supporting documentation verifying the training and experience for requested privileges should accompany the Request of Clinical Privileges, CG-5575. The requesting provider shall sign, scan or route the request to the SME or SDE for signature. The SME or SDE signs, scans or routes the request to HSWL SC Chief, Clinical Staff (HCCS) for signature with concurrence of the HSWL SC SME or SDE. HCCS reviews, signs, scans or routes the request to the PRC. The PRC will review the request and make recommendations to the Privileging Authority for a decision. A provider (AD, reserve, contract, auxiliary, and student) shall not be granted access authority in CHCS, PGUI, or ALHTA until their privileges have been approved by Commandant (CG-11).
- (3) Absence of clinical privileges must not delay treatment in an emergency (a situation in which failure to provide treatment would result in undue suffering or endanger life or limb). In such cases the providers are expected to do everything in their power to save patients.
- (4) On transfer, the provider shall submit a new Request of Clinical Privileges, CG-5575 as per 13.5.b.
- (5) When providers in the CG are assigned TAD for greater than 90 days, the TAD orders issuing authority shall request that Commandant (CG-1122) transmit a copy of the provider's clinical privileges to the host SMO/SDO who will evaluate the privileges and advise the provider if any privileges will be restricted at that site.

- (6) When providers from DoD are assigned TAD to CG clinics, their parent command shall transmit an Inter-agency Credentials Transfer Brief (ICTB) and a copy of their clinical privileges to the host command prior to their arrival. The SME/SDE will determine if any of the privileges should be restricted and shall contact Commandant (CG-1122) for clarification where needed.
- b. Procedures.
- (1) The CG PHS liaison in Commandant (CG-112) will inform new PHS providers assigned to the CG that they must request clinical privileges in writing before accession to active duty or formal employment, using the Request of Clinical Privileges, CG-5575. New PHS providers shall send written requests for clinical privileges to Commandant (CG-112) by mail at least 45 days before accession. The PHS provider must have a privileging authority approved the Request of Clinical Privileges, CG-5575 before finalizing assignment orders to the agency. For contract providers who require privileging the gaining SHSO/Supervisor shall verify that AFIP/Commandant (CG-1122) has received the required credentialing documents (per 13. B. 5.) and submit original, Request of Clinical Privileges, CG-5575 to Commandant (CG-1122) via traceable means (e.g. DHS authorized Commercial Carriers FedEx or UPS); US Postal Service (USPS): 1) Express Mail or 2) Proof of Delivery using Extra Services which are either Certified, Delivery Confirmation, or Signature Confirmation. Providers who have not received an approved Request of Clinical Privileges, CG-5575 from Commandant (CG-11) will not be authorized to perform any sort of health care tasks.
  - (2) Armed Forces Institute of Pathology, Department of Legal Medicine, (AFIP) is under contract to assist in the collection and review of appropriate credentialing information and presents this information at the PRC Meetings. AFIP shall maintain all original records of providers.
  - (3) AFIP shall maintain a paper Practitioner Credentials File in accordance with the CG Medical Manual that validates each MD/DO, DDS/DMD, PA, NP, Optometrist (OD), Physical Therapist (PT), and Dental Hygienist (RDH).
  - (4) AFIP shall complete the primary source verification and prepare each individual credentials portfolio within 30 days (45 days for foreign graduates) from the date all essential documents are received from the CG. These time frames may be extended when primary sources or references are slow or unresponsive. In such instances, partially-completed portfolios may be accepted by CG, with the understanding that the missing documents will be forwarded after receipt from the pertinent institution.

- (5) AFIP shall monitor, maintain and keep the CG credentials files in Centralized Credentials Quality Assurance System (CCQAS) current, generate any letters and reports required, contact providers to request updated credentialing elements and otherwise update the files with new acquisitions and information on a regular basis.
- (6) Primary source verification will be carried out in a timely and reasonable manner, and be fully documented. To the maximum extent possible, all appropriate documents will be verified at the primary source by telephone, fax, mail, electronically or otherwise.
- (7) The CCQAS database will be used for all applicants. Data on new acquisitions will be entered into CCQAS as that information becomes available, including primary source verification information, and be maintained by the AFIP.
- (8) Provisional clinical privileges are effective for one year, or until recommended for full privileges by PRC action. This status should be sought as an exception only. All efforts should be made to request and obtain full privileges for clinical practice in a CG facility. When granting provisional privileges, the risks associated with the activities for which a new provider seeks privileges and the frequency with which he or she performs the procedures shall be considered. The SME, SDE, and SHSO shall evaluate the provider's provisional privileges after one year, or prior to that time if deemed appropriate. Providers may apply for full staff privileges after one year of successful performance or if recommended by the SME/SDE.
- (9) Privilege request documents, PRC actions, and any other documents relating to the granting, maintaining, reviewing or rescinding clinical privileges will be maintained in the individual provider's credentials file.
- (10) The PRC will evaluate full staff privileges every three years. Providers will submit written privilege requests to Commandant (CG-112) at least 90 days before privileges are due for renewal.
- (11) Commandant (CG-1122) shall give notice to providers when privileges are due to expire, AFIP shall give notice when credentials are about to expire. Privileges and credentials expiration notification will be given 90 days prior so that the provider will have time to ensure currency.
- (12) Although Commandant (CG-1122) will provide notice of renewal, it is ultimately the responsibility of the provider to ensure they maintain current credentials and privileges at all times. Current credentials and privileges are considered a condition of employment, therefore, expiration of credentials or privileges may result in an inability to provide patient care, which will affect the ability to renew special pay contracts.



- (13) In the event that a new request for privileges has not arrived at Commandant (CG-1122) within 30 days of the current privileges expiration date, a letter/e-mail will be forwarded to the Commanding Officer and the provider, with a copy to the HSWL SC, notifying them that the provider's current privileges are due to expire in 30 days, and when expired the provider will no longer be allowed to provide patient care.
- c. Routine Operations of the Professional Review Committee (PRC).
- (1) The Quality Improvement (QI) Division, Commandant (CG-1122) is responsible for monitoring and administering the granting of clinical privileges for all providers in the Health and Safety Program that require clinical privileges to perform their duties.
  - (2) Commandant (CG-1122) will maintain a Practitioner Credentials File (PCF) for providers in the CG Health and Safety Program that will be used for granting clinical privileges.
  - (3) The local QI Coordinator at each field unit is responsible for maintaining a list of the expiration dates of all significant documents required to grant clinical privileges as stipulated in Section 13-B and will notify the provider when these documents are within 90 days of expiration.
  - (4) It is ultimately the responsibility of the provider to take appropriate actions to prevent these documents from expiring and to ensure that current documents are entered in the PCF.
  - (5) Commandant (CG-1122) and AFIP will also monitor the expiration dates on these documents and will notify provider of impending expiration dates.
  - (6) The PRC will make recommendations to Commandant (CG-11) on the granting of clinical privileges.
  - (7) The PRC will routinely review requests for clinical privileges for providers upon reporting to new CG duty stations and every 3 calendar years.
  - (8) The PRC can also be convened by Commandant (CG-11) to review PCFs for situations other than the routine review of clinical privileges. This is described further in Chapter 13. Section C.5.d.
  - (9) Commandant (CG-1122) will conduct a preliminary review of all requests for clinical privileges as well the entire PCF selected to be presented before the PRC.
  - (10) Commandant (CG-1122) will forward requests for clinical privileges as well as the PCFs, to the cognizant Program Manager who will evaluate the PCFs and decide if they should be presented before the PRC or if further information or action is required before submission to the PRC.

- (11) After Commandant (CG-1122) and the cognizant Program Managers have decided which records will be presented to the PRC, Commandant (CG-1122) will prepare an agenda and will schedule a PRC meeting.
- (12) The PRC will be comprised of Commandant (CG-11) staff to include:
  - (a) Commandant (CG-11d) as Chair of the PRC.
  - (b) At least 2 Medical Officers (at least 1 Physician and 1 PA or NP).
  - (c) At least 1 Dentist.
  - (d) Commandant (CG-1121)
  - (e) Commandant (CG-1122)
  - (f) One member acts as recorder.
  - (g) Other members of Commandant (CG-11), including Auxiliarist assigned to Commandant (CG-1122) as necessary.
- (13) The PRC will evaluate each PCF and recommend any of the following actions for each case:
  - (a) Grant all requested privileges.
  - (b) Revoke all current privileges or certain specific privileges.
  - (c) Reduce all current privileges or certain specific privileges.
  - (d) Suspend all current privileges or certain specific privileges.
  - (e) Hold in abeyance all current privileges or certain specific privileges.
  - (f) Monitored or supervised performance of clinical privileges.
  - (g) Request any decision regarding privileges be deferred until additional supporting information is submitted to the PRC.
  - (h) Maintain or modify current privileges while more information is forthcoming or an investigation is being conducted.
  - (i) Request a document focused review or other type of internal investigation.
  - (j) Request an external review or investigation.
  - (k) Other actions as dictated by circumstances.

- (14) The PRC will discuss each case but the decision to recommend approval or rejection of a privileging action will be made by Commandant (CG-11d).
  - (15) The PRC will forward its recommendations for privileging actions in the minutes of the meeting to Commandant (CG-11) via Commandant (CG-1122), Commandant (CG-112), and Commandant (CG-11d)
    - (a) Commandant (CG-1122) will prepare the minutes for each meeting of the PRC.
    - (b) The minutes will specify the recommended privileging action.
    - (c) In the event of a recommendation by the PRC for any privileging action less than granting full privileges, the minutes shall specify the reasons or justification for that recommendation.
  - (16) After receiving the minutes, Commandant (CG-11) will make a decision on the recommendations of the PRC. In cases where the PRC has recommended the granting of full privileges, the Request for Clinical Privileges will be submitted to Commandant (CG-11) for final approval.
  - (17) In cases forwarded to Commandant (CG-0944) for a legal opinion, Commandant (CG-11) will have 3 working days after receiving the legal opinion from Commandant (CG-0944) to make a final decision on how to act. In all cases of granting less than full privileges, Commandant (CG-11) will attempt to contact the provider by telephone and inform him/her of the action;
    - (a) Commandant (CG-11) will forward a letter to the provider by mail;
    - (b) Commandant (CG-11) will inform the HSWL SC by letter; and
    - (c) The HSWL SC will notify the provider's local command and the SHSO.
- d. Adverse Privileging Actions.
- (1) All actions and processes on granting, reducing, suspending, and revoking clinical privileges are conducted in accordance with provisions of the CG health services Quality Improvement Program. The Privacy Act (5 USC§552a) and the medical quality assurance confidentiality statute (14 USC§645) protect all documentation related to these processes. These documents will be filed in the Practitioners' Credentials File, under the Privacy Act System of Record Notice (DHS/CG 052).
  - (2) Actions to review, reduce, or withdraw clinical privileges will be taken promptly if reasonable cause exists to doubt a provider's competence to

practice or for any other cause affecting patient safety. Reasonable cause includes: a grossly negligent single incident; a pattern either of inappropriate prescribing or substandard of care; an incompetent or negligent act causing death or serious bodily injury; abuse of legal or illegal drugs or diagnosis of provider substance dependence; practitioner disability (physical and/or mental psychiatric conditions(s) impairing clinical duties); or a provider's significant unprofessional conduct.

- (3) If a reasonable cause exists to doubt a provider's competence, or in the event of allegations of substandard or improper medical or dental treatment by a provider occurring in a CG health care facility, notification containing the allegations shall be forwarded by mail or facsimile to the Convening Authority. In cases where notification originates from military members or organizations, transmittal shall be via the chain of command to include the HSWL SC.
- (4) Upon review of allegations, the Convening Authority shall, within 5 working days, designate appropriate follow-up action or disposition that may include the appointment of a Special Professional Review Committee (SPRC). The Convening Authority shall designate the composition of the SPRC when one is appointed.
- (5) Once appointed, the SPRC shall convene and complete all review within a time not to exceed 15 working days. After reviewing the allegations, the SPRC shall make recommendations to the Convening Authority that may include: a focused review team, a documentation review, or other disposition as appropriate.
- (6) Based on the nature of the allegation(s) and the recommendations of the SPRC, the Convening Authority may order a focused review team (on-site), a document review, or other disposition. In cases requiring further review, the Convening Authority will designate focused review team members or the document review officer through the HSWL SC within 10 working days from receipt of the SPRC's recommendation, and shall further define the particular review process based upon the nature of the allegations giving rise to the review.
- (7) The focused review team or document reviewing officer shall initiate and complete the review action within 30 working days after the Convening Authority designates the review action.
- (8) If the provider under review is a physician, the focused review team shall consist of at least three CG physicians. If the provider under review is a Flight Surgeon, Aviation Medical Officer (AMO), or Aeromedical Physician Assistant at least one of the reviewing physicians must be a Flight Surgeon. For a Dental Officer, the reviewing team shall consist of at least three CG Dental Officers. For a physician assistant or nurse

practitioner, the team shall consist of three Medical Officer reviewers, one of which must be a physician assistant or nurse practitioner as applicable. The Convening Authority may assign additional team members (not to exceed 5 total team members) to assist in the review process.

- (9) In cases requiring a document review officer, the HSWL SC, shall take measures to ensure the document review officer is impartial and will not represent any conflict of interest. The document review officer shall be of the same discipline as the provider under review, except when the provider being reviewed is a Physician Assistant or Nurse Practitioner; the document review officer may be a physician.
- (10) The provider under review need not be present for records or other document review, but when possible should be available to answer questions for the focused review team or document review officer.
- (11) The document review officer or focus review team shall brief the unit CO about significant findings at the end of the visit. Within 10 working days of concluding the review, the Convening Authority shall receive a written report for disposition containing findings, conclusions and specific recommendations, through the HSWL SC.
- (12) Focused team or document review reports shall contain at least one of these recommendations:
  - (a) No action.
  - (b) Administrative action, such as verbal counseling.
  - (c) Assignment to additional training.
  - (d) Reassignment to another facility for observation, supervision, and/or additional training (may or may not involve reduction of privileges).
  - (e) Privilege reappraisal.
  - (f) Reduction of privileges (specify extent of reduction).
  - (g) Privilege suspension (indefinite).
  - (h) Permanent removal from clinical duties (privilege revocation).
  - (i) Further review.
- (13) If the document review officer or focused review team recommends immediate adverse privileging action, they shall contact the Convening Authority by the most expedient means possible.

- (14) Upon review of the written report, the Convening Authority shall within three working days, determine further disposition that may include reconvening the SPRC for further review and recommendations. In the event that the written report recommends adverse privileging action, the Convening Authority shall reconvene the SPRC for further review and recommendations.
  - (15) If reconvened, the SPRC shall review all available records, may contact potential witnesses to assist in their deliberation, and shall provide recommendations to the Convening Authority within 30 working days.
  - (16) If the SPRC recommends adverse privileging action, the CG-112 Office Chief shall contact the provider under review the same duty day if possible, either by phone or in person. Written notification will be sent to the provider under review within five working days via traceable means (e.g. DHS authorized Commercial Carriers FedEx or UPS); US Postal Service (USPS): 1) Express Mail or 2) Proof of Delivery using Extra Services which are either Certified, Delivery Confirmation, or Signature Confirmation, which shall include notification that an adverse privileging action has been recommended against him or her and the reasons for the proposed action. The written notice shall further delineate that the provider has a right to request an appeal on the proposed action and the time limit (up to 30 working days) within which to request such an appeal in writing and specify the provider's rights in the appeal process.
  - (17) The provider's failure to request or appear at the appeal, absent good cause, constitutes a waiver of further appeal and appeal rights, and the proposed adverse privileging action shall be finalized by the Convening Authority.
  - (18) In the case where an adverse privileging action becomes final, all adverse privileging actions that restrict or suspend clinical privileges for longer than 30 days will be reported to the National Practitioner Data Bank (NPDB) according to the Memorandum of Understanding between the Department of Health and Human Services and Department of Homeland Security. Providers may dispute Data Bank information as provided in 45 CFR 60, "National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners."
- e. Appeal Process.
- (1) If a provider requests a hearing in writing within the time limit, CG-112 shall within 10 working days schedule the appeal hearing. Notification of the appeal hearing to the provider must state the hearing place, time, and date; which shall be convened not less than 30 days but not longer than 60

days after the date the written request for an appeal hearing was received by CG-112. The provider will also be given a written list of witnesses (if any) expected to testify at the hearing on behalf of the hearing committee.

- (2) CG-112 will assign the hearing committee, consisting of three CG/PHS officers equivalent or higher in rank to the provider under review, not previously involved in the internal review process. The disciplines represented shall be the same as required for the focused review team. Each hearing committee member will have one vote.
- (3) The provider under review has these rights:
  - (a) To consult with CG legal counsel or civilian legal counsel at his/her own expense. The provider shall request approval in writing to Commandant (CG-11) the services of CG legal counsel. While such counsel may attend the hearing and advise the provider during the proceedings, the counsel will not be allowed to participate directly in the hearing, (e.g., may not ask questions, respond to questions on behalf of the provider, or seek to enter material into the record).
  - (b) To obtain a transcript of the proceedings by paying any reasonable preparation charges.
  - (c) To call, examine, and cross-examine witnesses. The provider is responsible for arranging the presence of his or her witnesses and failure of the witnesses to appear will not constitute a procedural error or basis for delaying the proceedings.
  - (d) To present relevant verbal or written evidence regardless of its admissibility in a court of law.
  - (e) To submit a written statement at the close of the hearing.
- (4) The hearing committee shall review all relevant records, hear all witnesses, and have the right to interview all witnesses. The hearing committee **should** request assistance from Commandant (CG-0944) throughout the hearing process.
- (5) The hearing committee will base its recommendation on whether or not to sustain, reduce, suspend, or revoke a provider's clinical privileges on a preponderance of the evidence as judged by a majority vote. A report of the hearing committee's final recommendations will be reported to the Convening Authority within two working days after the hearing ends.

- (6) The Convening Authority will review the hearing committee's recommendations within three working days of receiving their report; make a decision and notify the provider under review the day of the decision either by telephone or in person; and send written notice to the provider by DHS authorized commercial traceable means, within five working days after the hearing ends. The Convening Authority's decision shall be final.



Section D. Operational Health Readiness Program.

1. Background.....	1
2. Purpose.....	1
3. Overview.....	1
4. OHRP Compliance Process. ....	2

This page intentionally left blank

D. Operational Health Readiness Program (OHRP).

1. Background. The CG established an internal healthcare quality assurance (QA) program in the early 1990s to monitor the quality of healthcare delivered at its clinics. The MLCs administered the program by conducting QA surveys at each clinic every three years by members of the MLC staff utilizing Quality Assurance Checklists. Clinics passing the MLC survey were awarded a three year certificate that verified the clinic met CG QA standards. QA survey items were retroactively reviewed. The internal QA certification program was augmented by an external accreditation program in 2004. However, the need for a program that ensures clinic compliance with CG specific healthcare issues and health readiness still exists. CG specific QA and operational health readiness issues are monitored by the HSWL SC under the Operational Health Readiness Program.
2. Purpose. The intent of the OHRP is to assist and ensure all clinics monitor and comply with CG specific healthcare-related requirements not reviewed by the external accreditation organization surveyors.
3. Overview.
  - a. Definitions.
    - (1) Operational Readiness. Standards established by the CG that determine whether individual members and units are prepared to meet their assigned missions.
    - (2) Quality Assurance, Quality Improvement – See Chapter 13. Section A.5.a-d
  - b. Program Elements. The OHRP is designed for clinics to monitor those healthcare-related QA issues not reviewed by external surveyors and to ensure units within their area-of-responsibility (AOR) are operationally ready in accordance with CG standards. There are three issues that require oversight. One, QA items historically reviewed by HSWL SC during their triennial surveys, but not reviewed by the external accreditation organization. Two, policies and procedures that apply to operational health readiness. Three, areas of interest that are not directly related to operational health readiness, but involve a supportive role. These three issues will be overseen by the HSWL SC on a continuous basis.
  - c. Collaborative Program. The primary mission of the CG clinics is to maintain the operational health readiness of active duty and reserve personnel by assuring their availability to physically and mentally meet worldwide deployment standards in accordance with the Medical Manual COMDTINST M6000.1 (series). Maintaining a high level of health readiness involves collaboration between providers, commands, clinics and the HSWL SC.
  - d. Monitoring the OHRP. Clinics must review the operational health readiness of active duty/reserve members within their AORs on a regular basis. It is the Command's responsibility to ensure medical and dental readiness of the active duty/reserve members in their AOR. It is the responsibility of the SHSO to develop and maintain a plan that ensures optimal health readiness for all active duty/reserve members within the designated AOR in accordance with guidance provided in this instruction. The HSWL SC will review CG-specific QA and operational health readiness issues on a

continual basis and provide needed assistance to clinics to ensure a high level of health readiness. Operational health readiness compliance will be accomplished through reviews of each individual clinic's information posted in OHRP databases, QA public folders on CG Central and the MLC assist visits. A post-visit OHRP evaluation report will be provided to the clinics through the CO.

- e. Assistance Program. The OHRP is designed to provide an environment in which QI and operational health readiness of clinics are monitored on a continuous, versus retroactive, basis. The OHRP is an assistance program designed to ensure a high level of care is provided at CG clinics and that a high level of operational health readiness is maintained. The program assists clinics in meeting both AAAHC and CG readiness and QI standards.
  - f. Accreditation. The OHRP assessment does not confer accreditation or certification status. Operational readiness is a command-directed process. The MLCs provide assistance in meeting OHRP goals, QA/I standards and preparation for the AAAHC survey. The AAAHC is the sole healthcare quality assurance/improvement accrediting body recognized by the CG.
4. OHRP Compliance Process.
- a. Responsibility.
    - (1) Unit. The unit CO is responsible for ensuring the command's health care facility complies with standards set forth in the Coast Guard Medical Manual and the HSWL SC OHRP.
    - (2) Clinics. The SHSO is responsible for routinely monitoring the progress of medical, dental, pharmacy readiness within their AOR and the implementation of the OHRP.
    - (3) HSWL SC. Responsible for developing and coordinating process checklists, self-assessment tools, assist visits to the clinics, and process reviews
    - (4) Headquarters. Chief, Directorate of Health and Safety coordinates and directs the program, adjudicates appeals, and promulgates appropriate standards governing CG providers' delivery of health care and policies on managing and operating CG health care facilities.
  - b. Process Checklist. The process checklists show QA and/or operational readiness tasks that clinics must address on a regular basis. The checklists are not all-inclusive because they do not list tasks that do not directly apply to QA or operational readiness (e.g. "take out trash"). Clinics must determine what tasks they do on a regular basis and have mechanisms in place to ensure these tasks get completed. The HSWL SC will assist in this effort. To view the most current OHRP compliance checklist go to the HSWL SC microsite on CG Central.
  - c. Self-Assessment. Health readiness and policy adherence is a continuous process and must be routinely reviewed by the clinic and HSWL SC. Self-assessment tools serve as a guide to assess how well the intent of the OHRP is being met through the daily

operations of the clinic. Clinics that are diligent in addressing the issues listed on the self-assessment sheets should meet AAAHC QI and CG OHRP standards. The self assessments mirror the previous MLC QA checklist items formerly used for certification surveys.

- d. Quality Improvement Studies (QISs). Clinics must demonstrate that they have a system in place to monitor healthcare delivery. Previously this was done through retroactive data reviews of given topics (i.e. monitoring and evaluation reports). With external accreditation, clinics must review areas of concern or interest and implement quality improvement studies. QISs may be adapted for operational readiness or other issues not reviewed by the external accreditation organization.
- e. CG Central. CG Central serves as the primary repository for OHRP QA/QI documents such as QIFG meeting minutes, SOPs, and Letters of Designation, and other items listed on Quality Improvement Calendar, CG-6000-5.
- f. Public QA/I Folders. Public folders may be used for depositing QA/QI documents (e.g. CBRN antidote inventories) but do not take the place of using CG Central.

This page intentionally left blank.

Section E. Quality Improvement Implementation Guide (QIIG).

1. Background.....	1
2. Responsibilities.....	1

This page intentionally left blank.



E. Quality Improvement Implementation Guide (QIIG).

1. Background. The QIIG is a series of exercises designed to assist commands in meeting Health Services QI Program requirements and to augment policy that is outlined in the Medical Manual. Serving as a guideline, the QIIG minimizes the QI program administrative requirements by providing direction and, in many cases, templates for addressing critical quality issues. The exercises often eliminate the need for each clinic to develop its own policies and procedures by providing generic frameworks clinics can adapt to local conditions. In some cases, clinics may be required to submit evidence of completing an exercise to the HSWL SC for data evaluation purposes.
2. Responsibilities.
  - a. Commandant (CG-112). Commandant (CG-112) develops exercises as needed on critical quality issues for inclusion in the QIIG and posts them on <http://www.uscg.mil/hq/cg1/cg112/cg1122/QIIG.asp>.
  - b. HSWL SC. HSWL SC ensures exercises are available to Commands for clinic personnel to complete and also reviews clinic's use of the QIIGs as part of the Operational Health Readiness Program.
  - c. Unit QI Coordinator. Unit QI Coordinators ensure staff promptly complete all QIIG exercises and maintain a complete, updated QIIG folder.

This page intentionally left blank.

Section F. National Provider Identifiers.

1. National Provider Identifiers (NPI) Type 1 (NPI).....	1
2. Clinic National Provider Identifiers (NPI) Type 2. ....	1

This page intentionally left blank.

- F. National Provider Identifiers.
1. National Provider Identifiers (NPI) Type 1 (NPI).
    - a. Who must have a Type 1 NPI. All health care providers who provide health care services or those who may initiate and/or receive referrals must obtain an NPI Type 1. A NPI Type 1 is assigned at no fee by the Centers for Medicare and Medicaid Services (CMS) National Plan and Provider Enumeration System (NPPES). Providers shall apply for and will receive one and only one NPI Type 1. This NPI Type 1 will be a permanent identifier unique to that provider. CMS has an online NPI Type 1 application available at <https://nppes.cms.hhs.gov>.
    - b. Copies of the NPI. Once a provider obtains their NPI Type 1 they shall provide a copy to Commandant (CG-1122). The information will be entered into the Centralized Credentials Quality Assurance System (CCQAS) database. A photocopy of the original hardcopy will be filed in the Practitioner Credentials File.
    - c. Obtaining and maintaining a NPI. Instructions for obtaining and maintaining NPI Type 1 for health care providers are to be included in all privileging packages.
    - d. Updates. HIPAA compliance requires that NPPES be updated within 30 days of a change in the NPI Type 1 data. (Example: provider changes their name or provider changes their duty station).
    - e. Privileging authority address. In order to ensure standardized addresses are being used in the mailing address and in the practice location fields on the NPI Type 1 application, providers (other than Reserve component providers) are to use the privileging authority facility name (USCG HQ, COMDT (CG-1122)) as the address of record.
  2. Clinic National Provider Identifiers (NPI) Type 2.
    - a. Who must have a NPI Type 2. Per the HIPAA NPI Final Rule, 45 CFR, Part 162, all health care facilities that provide health care services must have an NPI Type 2. The NPI Type 2s are assigned at no fee by the Centers for Medicare and Medicaid Services (CMS), National Plan and Provider Enumeration System (NPPES). CMS has an online NPI Type 2 application available at <https://nppes.cms.hhs.gov>.
    - b. SHSO. Each SHSO is responsible for submitting the initial NPI application and updates. Once a clinic obtains their NPI Type 2 they shall provide a copy to Commandant (CG-1122). The clinic shall maintain the NPI Type 2 in a permanent record.
    - c. Updates. HIPAA compliance requires that NPPES be updated within 30 days of a change in the NPI Type 2 data. (Example: Address change).

This page intentionally left blank.

Section G. Health Insurance Portability and Accountability Act (HIPAA).

1. Background.....	1
2. HIPAA Privacy/Security Officials (P/SO).....	1
3. HIPAA Training Requirements .....	4
4. Handling HIPAA Complaints and Mitigation .....	7
5. Unintentional Disclosures of Protected Health Information.....	9
6. Protected Health Information and the Coast Guard Messaging System.....	10
7. Other CG Members Who Utilize Protected Health Information .....	10
8. Electronic Transmission of Protected Health Information .....	11

This page intentionally left blank.



G. Health Insurance Portability and Accountability Act (HIPAA).

1. Background.

- a. Health Insurance Portability and Accountability Act, (HIPAA). On 21 August 1996, the Health Insurance Portability and Accountability Act, (HIPAA), was signed into law as Public Law 104-191. The Act included provisions for health insurance portability and renewability, preventing fraud and abuse, medical liability reform, tax-related health provisions, group health plan requirements, revenue offset provisions and administrative simplification requirements. Title II, Subtitle F on Administrative Simplification required the Secretary of Health & Human Service to publish standards for electronic exchange, privacy and security of health information.
- b. Federal Regulations. The promulgated regulations, known as the Privacy Rule are found at 45 Code of Federal Regulations (CFR) Part 160 and Part 164, Subparts A and E. The Security Standard is found at 45 CFR Part 164, Subpart C. These regulations became effective as of April 21, 2003, and must be complied with as of April 21, 2006. These regulations are available at the following web sites:

- (1) <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/> or
- (2) Parallel Department of Defense implementing regulations are found at <http://www.dtic.mil/whs/directives/corres/html/602518r.htm>

2. HIPAA Privacy/Security Officials (P/SO). 45 CFR Part 164.530 (a) requires (1) the designation of a privacy official responsible for the development and implementation of policies and procedures and (2) the designation of a contact person who is responsible for receiving complaints and providing further information about matters covered under the Notice of Privacy Practices. 45 CFR Part 164.308 (a) (2) requires that the CG “identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity.”

a. The CG Privacy and Security Official.

- (1) The Chief, Office of Health Services Commandant (CG-112) shall designate an officer as the CG Privacy and Security Official, residing within Commandant (CG-1122). This official shall serve as the Privacy and Security Official (P/S O) for the CG Health Care System and as the CG Service Representative to the TRICARE Management Activity (TMA) Privacy Office.
- (2) Responsibilities of the CG Privacy and Security Official are:
- (a) Provide coordination between the CG and Tricare Management Activity (TMA) Privacy Office on all HIPAA related issues.
- (b) Maintain current knowledge of applicable Federal and State privacy laws, accreditation standards and CG regulations. Monitor advancements in emerging privacy and health information security

technologies to ensure that the Coast Guard is positioned to adapt and comply with these advancements.

- (c) Establish, modify and disseminate CG HIPAA policy.
  - (d) Serve as the CG HIPAA liaison to receive complaints and provide further information about matters covered by the notice required by the HIPAA Privacy Rule, 45 CFR Parts 160 and 164, from Health and Human Services (HHS), Tricare Management Activity (TMA), and Congress.
  - (e) Serve as the local P/SO for the Health, Safety, & Work-Life Directorate and Commandant (CG-11).
- b. HSWL SC Privacy and Security Official.
- (1) The Commanding Officer, HSWL SC, shall designate a junior officer as Privacy and Security Official for the CG Health Care System who will provide reports to the CG-1122 Privacy and Security Official.
  - (2) Responsibilities of the HSWL SC Privacy and Security Official are:
    - (a) Serve as the CG HIPAA liaison to receive complaints and provide further information about matters covered by the notice required by the HIPAA Privacy Rule, 45 CFR Parts 160 and 164, from all Coast Guard commands and all Regional Practice Privacy and Security Officials.
    - (b) Maintain a log of all Regional Practice Privacy and Security Officials and a file of all letters of designation.
    - (c) Develop Standard Operating Procedures (SOPs) for Regional Practice implementation of the HIPAA Privacy and Security Regulation requirements.
    - (d) Establish and recognize best practices relative to the management of the privacy and security of health information.
    - (e) Serve as a liaison to other P/SOs.
    - (f) Review all system-related information security plans throughout the local health care network to ensure alignment between security and privacy practices, and act as liaison to the information systems department.
    - (g) Serve as the point of contact for HIPAA Privacy and Security compliance, monitoring and assuring staff compliance with HIPAA training requirements. The officer will administrate the databases that track data disclosures and complaints; conduct Privacy and Security risk assessments; participate in the HIPAA compliance quality assurance and improvement process; and report findings to the CG P/SO.

- c. Regional Practice Privacy and Security Officials.
- (1) The Regional Practice Privacy and Security Official serve as the point of contact for CG treatment facilities within the AOR/Regional Practice. The P/SO oversees activities related to the implementation and maintenance of Regional Practice HIPAA SOPs covering the access to and privacy of patient health information.
  - (2) The Regional Manager is responsible for designating in writing the HIPAA Privacy and Security Official for their respective Regional Practice. The designee must be of the rank of E-7 or above. A copy of this letter of designation shall be forwarded to the HSWL SC Privacy and Security Official. Whenever there is a change in the Regional Practices's P/SO the Regional Manager must designate another member as P/SO, notify HSWL SC of the change by email, and fax or email a copy of the letter of within 10 working days of the effective date of such letter.
  - (3) Responsibilities of the Regional Practice Privacy and Security Official are:
    - (a) Oversee, direct, monitor and ensure delivery of initial HIPAA privacy and security training and orientation to all clinical staff. Ensure annual refresher training is conducted in order to maintain workforce awareness and to introduce any changes to HIPAA privacy or security policies to the health care workforce. The P/SO may share or delegate responsibilities for monitoring compliance with HIPAA training requirements to another appropriately trained health care workforce individual as a HIPAA Training Administrator at the unit.
    - (b) Perform initial and periodic information privacy and security risk assessments and conduct related ongoing compliance monitoring activities in coordination with applicable CG directives. Report findings as required.
    - (c) Ensure a mechanism is in place within all respective treatment facilities for receiving, documenting, tracking, investigating all complaints concerning the organization's privacy and security policies and procedures in coordination and collaboration with other similar functions, and, when necessary, legal counsel.
    - (d) Document disclosures of Protected Health Information (PHI) using the Protected Health Information Management Tool (PHIMT) to allow patients and other qualified individuals to review or receive reports on such activity as required by law.
    - (e) Understand the content of health information in its clinical, research and business context.
    - (f) Understand the decision-making processes that rely on health information. Identify and monitor the flow of information within the clinic and throughout the local health care network.

- (g) Serve as privacy/security liaison for users of clinical and administrative systems.
- (h) Collaborate with other health care professionals to ensure appropriate security measures are in place to safeguard protected health information and to facilitate exchange of information between entities.
- (i) Initiate, facilitate and promote activities to foster information privacy awareness within the organization and related entities.
- (j) Serve as the advocate for the patient relative to the confidentiality and privacy of health information.

3. HIPAA Training Requirements.

- a. 45 Code of Federal Regulations (CFR). 45 CFR 164.530 (b) specifies the training requirement standards under HIPAA. All CG health care workforce members are required to complete designated training within 30 working days of reporting on duty to the CG or being assigned to a specific CG unit. Meeting with the Regional Practice Privacy and Security Official should be included as a required element of all in-processing for health care workforce members.
  - (1) The Regional Practice P/SO will provide the individual with the domain identification number for their respective unit to complete web-based training requirements. When a health care workforce member leaves the treatment facility, the local P/SO should direct the member to change the domain identifier to that of the receiving treatment facility where the member will be assigned.
  - (2) Required training includes at least (1) those courses corresponding to the appropriate HIPAA Job Position provided through the TRICARE Management Activity (TMA) Privacy Office on the Military Health System's Training Portal; (2) training on the Regional Practice policies and procedures; (3) any other HIPAA privacy and security training as determined by the Regional Practice Privacy and Security Official.
  - (3) Training shall be completed by utilizing the web-based training courses available through the Military Health System's Training Portal, MHS Learn, at <https://mhslearn.satx.disa.mil/>. Each individual should choose the "HIPAA Job Position" which is most closely aligned with their functional responsibilities.
    - (a) These requirements apply to all active duty and reserve members, contract staff and Auxiliarists within the CG health care workforce.
    - (b) Completion of the HIPAA core and refresher training courses is required prior to obtaining access and for continued access to the electronic health record system such as CHCS and PGUI. Individuals who are greater than ninety (90) days overdue for their annual refresher training will have their access deactivated.
    - (c) CG health care workforce members are required to complete annual HIPAA refresher training during their birth month.

- (d) Health Service technicians shall choose the “Nursing” job position for their training requirements.
- (e) P/SOs shall choose the “Senior Management” job position for their training requirement.
- (f) Clinic Administrators who are not P/SOs shall choose the “Medical Records” job position for their training requirement.
- (g) The following table provides narrative descriptions of each of the HIPAA Job Positions found at the MHS Learn website.

**HIPAA Job Positions and Descriptions**

<b>HIPAA Job Position</b>	<b>Description</b>
Ancillary Clinical	Ancillary clinical staff including technicians: <i>Behavioral Health personnel, Work-Life staff, Optometrist, Pharmacist, Physical Therapist, Podiatrist, Social Worker, Medical Laboratory Technician, Medical Technologist, X-ray Technician, Clinical support volunteers. Audiologist, Chiropractor, Clinical Psychologist, Dietician, Occupational Therapist, Optician, Speech Pathologist, Dental Laboratory Technician, Dermatology Technician, Histopathology Technician, Respiratory Therapy Technician</i>
Patient Services	Patient Assistance staff or Administrative Support Staff: <i>Administrative Support Staff, Administrative Assistants, Executive Assistants, Receptionists, and File Clerks.</i>
Operations and Finance	Resource Management, Personnel staff, Medical Operations ( <i>Readiness, Education, Training, Security</i> ), Business & Finance personnel
Support Services	All non-clinical support personnel: ( <i>Biomedical Repair, Chaplain/Religious Services, Environmental Health Services, Facilities Management- Janitorial, Housekeeping, Maintenance, Food Service, Industrial Hygiene/Safety, Logistics, Occupational Health, Transportation, Supply</i> )
Information Systems	Information Management/Information Technology staff, Telecommunication; Mailroom, Biomedical Illustrator; Photographer
Medical Records	Clinic Administrators, Health Benefits Advisors, Medical Records staff, Patient Admin staff, Coders, Transcriptionists, Clinical/Ward Admin staff, Administrative volunteers
Nursing	Staff Nurse- RN/LPN/LVN, Nurse Mid-wife, Nurse Anesthetist, Medical Assistants, Dental Hygienist, Dental Assistants, Health Service Technicians, Corpsmen, Medics, Emergency Medical Technicians
Providers	Physicians- all specialties, Physician Assistants, Dentists- all specialties, Nurse Practitioners, Research Clinicians, Dental Science and Research
Senior Management	Commanders, Executive staff/leadership, general administration staff, hospital legal staff, Public Affairs /Marketing staff, Medical Administration Officers

Table 13-G-1

4. Handling HIPAA Complaints and Mitigation.
- a. Requirements. The CG Health Care Program must be prepared to address beneficiary inquiries, concerns and complaints related to the protection of the individual's health information. The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Notice of Privacy Practices describe how the MHS/CG Health Care Program may use and disclose an individual's protected health information (PHI) and outlines patient rights regarding the use and disclosure of PHI.
  - b. Inquiries or complaints. Beneficiaries may file complaints regarding perceived misuse or disclosure of their PHI. This information includes demographics such as age, address, or e-mail address and others, and relates to past, present or future health information and related health care services. Inquiries or complaints may be received at any level of the organization, or TRICARE Management Activity (TMA) by mail. Individuals also have the right to make inquiries or address complaints directly to the Department of Health and Human Services (HHS). The HHS Office for Civil Rights (OCR) Web site gives instructions to individuals who wish to make a HIPAA complaint about a covered entity when they perceive that their protected health information has been used or disclosed in a manner not compliant with the covered entity's privacy policies. The CG Health Care Program, the covered entity, should try to resolve patient and individual complaints before they become complaints to OCR. Privacy incidents do happen, and may be inadvertent disclosures (technical/practical errors that are not generally deliberate, planned, or malicious disclosures). It is realistic to expect that complaints will occur.
  - c. HIPAA Complaints Received at the Local Treatment Facility.
    - (1) A Privacy/Security Official (P/SO) will generally be the initial contact for response to privacy incident. If an individual arrives in person to complain, talk with him or her about his or her complaint. The P/SO will inform the individual about the complaint form on the TRICARE HIPAA site. There are advantages of asking the individual to fill out the form, including getting the complaint in his or her own words, obtaining the individual's signature, and making sure all the information is completed.
    - (2) Beneficiary complaints should be directed in writing to the respective Regional Practice P/SO. The beneficiary also has the right to submit complaints to the TMA Privacy Officer or HHS if he/she feels the issue has not been appropriately addressed at the local level. The address and complaint form for submission to TMA can be found on the website <http://tricare.osd.mil/tmaprivacy/hipaa/hipaacompliance/beneficiaries/index.htm>. The address and form for HHS is on their website <http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html>. The complaint must include:
      - (a) Beneficiary's name, address, phone number, social security number and clinic accessed for care

- (b) Date complaint taken/submitted
  - (c) Description of complaint and approximate date incident occurred
  - (d) Facility and location where incident occurred
- (3) The Regional Practice P/SO is responsible for ensuring the investigation into the complaint is conducted and if necessary any further actions taken. The P/SO determines whether a complaint is a HIPAA complaint, a grievance under another privacy law, or not a HIPAA complaint. In investigating an incident, the CG Administrative Investigation process shall be used. As necessary, witnesses, managers and staff can be interviewed, the scene of the incident can be visited, action can be taken to limit scope of incident, and copies of relevant files should be retrieved. Disclosures may be identified as incidental to routine business, accidental or due to malicious intent.
  - (4) The Regional Practice P/SO shall notify the HSWL SC and CG P/SOs of all complaints received at the treatment facility so that CG P/SO can provide assistance, guidance and review of the response and facilitate any coordination necessary with the TMA Privacy Office or legal counsel.
  - (5) A summary and corrective action plan can include: a summary of the incident, the cause of the incident, any procedural changes required, any training changes required, the staff involved and sanctions applied, and any specific corrective actions to implement.
  - (6) Once this process is complete, the Regional Practice P/SO will provide a written response to the beneficiary and a copy will be sent to the HSWL SC and CG P/SOs. In the case of complaints made by beneficiaries directly to the HHS and forwarded to TMA for resolution, responses are required to be provided to the TMA Privacy Office for review and endorsement to HHS. Direct communication to the complaining beneficiary will be at the discretion of HHS.
  - (7) The complaining party must receive a written response in a timely manner. The designated review authority (P/SO) shall reply within 30 days of the date of receipt of the complaint. If additional review is necessary, the reviewer can request an extension for an additional 30 days. When this occurs, the individual must be notified in writing that the issue is under investigation and the extension is being put into effect.
  - (8) Written documentation of the complaint and its disposition must be maintained by the activity receiving the inquiry or complaint. Each Regional Practice is required to ensure appropriate documentation. The complaint and any accounting of a disclosure must be recorded in the Protected Health Information Management Tool (PHIMT). If the issue required action at the TMA level, the TMA Privacy Officer will keep the file as well as all correspondence related to a complaint processed by TMA. Documentation must be maintained for a minimum of six years from the submission of the complaint.



- d. Complaints Received at Commands Other Than Treatment Facilities.
  - (1) Whenever possible, complaints received at Commands other than CG treatment facilities, should be redirected to the appropriate Regional Practice P/SO for investigation and response.
  - (2) Commands shall notify immediately the HSWL SC P/SO and CG P/SO Commandant (CG-1122) by email of all other complaints. The HSWL SC P/SO will assist and advise the Command's investigating officer; coordinate the response with legal counsel, where necessary; and review the written response of the investigating officer. The CG P/SO will coordinate the response with the TMA Privacy Office, where necessary. The Command's investigating officer should comply with the guidance provided in Chapter 13.Section G.4.c.(2).
5. Unintentional Disclosures of Protected Health Information.
  - a. Breach of security. If anyone within the CG discovers evidence or circumstances which would suggest that a breach of security of a system containing protected health information (PHI) or of an unintentional disclosure of PHI may have occurred, this information shall be immediately brought to the attention of the Commanding Officer and Regional Practice Privacy/Security Official (P/SO).
  - b. Procedures of Commanding Officer. The CO shall follow the guidance set forth in Commandant Instruction 5260.5, "Privacy Incident Response, Notification, and Reporting Procedures for Personally Identifiable Information (PII)".
  - c. Procedures of Regional Practice P/SO. The Regional Practice P/SO shall receive, document, and initiate an investigation of the incident, including conducting interviews of all individuals knowledgeable of the circumstances of the incident, or of the technical systems or administrative procedures which may have lead created the vulnerability.
  - d. Notification of the CG P/SO. The Regional Practice P/SO shall notify the HSWL SC and CG P/SOs of the incident via email or telephonically. The Regional Practice P/SO may confer with the HSWL SC or CG P/SO on any issue related to investigation or mitigation of the incident.
  - e. Time line. The Regional Practice P/SO through the local command authority shall provide notification of all individuals who's PHI may have been compromised within 10 business days of the conclusion of the investigation of the incident. This notification shall:
    - (1) Identify the nature and scope of the incident and the circumstances surrounding the loss, theft, compromise or disclosure of the PHI.
    - (2) What specific data was involved?
    - (3) The actions taken by the local facility to remedy the vulnerability.
    - (4) The potential risks incurred by the affected individuals as a result of the disclosure, compromise, loss or theft of PHI.

- (5) Actions which the individuals can take to protect against potential harm.
  - (6) A resource for obtaining further information and/or a point of contact to address any further questions the individual may have related to the potential compromise of PHI.
- f. Final report. A final report containing a description of the findings of the investigation, efforts made to mitigate any harm resulting from the disclosure, and corrective actions take to remedy weakness of technical systems, or administrative policies or procedures which lead to the vulnerability shall be made in writing, either electronically or by paper to the HSWL SC P/SO and CG P/SO within Commandant (CG-1122).
- g. Lessons learned. The HSWL SC P/SO will disseminate lessons learned from the incident to all Regional Practice P/SOs and appropriate command authorities so that local systems, policies and procedures can be review and appropriate corrective action and/or training can be completed.
6. Other CG Members Who Utilize Protected Health Information. Other members of the CG may routinely or occasionally have access to or utilize protected health information in the course of their duties. Although these members are not considered part of the “health care workforce,” and therefore, are not required by law and implementing regulations (see 45 CFR 164.530 (b)) to complete HIPAA training, it is critical that these members are aware of the intent of HIPAA and maintain the privacy and confidentiality of protected health information with which they are entrusted. To accomplish this objective, members assigned to the following organizations or performing duties in the following roles should complete appropriate HIPAA training:
- (1) National Maritime Center
  - (2) CG Personnel Command/Physical Disabilities Evaluation Board
  - (3) Special Needs Program staff
  - (4) Command Drug and Alcohol Representatives/ Drug and Alcohol Program staff
  - (5) Others as deemed necessary by COs

Members may complete HIPAA training through the Military Health System’s Training Portal, MHS Learn, at <https://mhslearn.satx.disa.mil/> by self-registering using the “Senior Management” HIPAA Job Position. Each member must select “MTF\Location\Unit” and “HIPAA Job Domain” identifiers. Select the domain established specifically for your organization such as “(CGPSC) USCG Personnel Support Center” or “(CGNMC) USCG National Maritime Center.” These HIPAA Job Domains may be located using the search function to the right of the block by clicking on the “flashlight,” expanding the “plus box” to the left of CG, selecting the appropriate choice and then clicking on “OK” at the bottom of the window. Contact your local HIPAA P/S O for all registration questions. After completing the core courses, registrants will be automatically

reminded by email to complete Annual HIPAA Refresher Course during their birth month of each year.

7. Electronic Transmission of Protected Health Information.

- a. Coast Guard Messaging System. Messages should not contain personally identifiable health information. This includes listing the name of the individual and any disease code (i.e., International Classification of Disease (ICD-9 or ICD-10) or Common Procedural Terminology (CPT)) which be used to identify the disease or condition of the individual. Messages requiring transmission of personally identifiable health information shall use the Inpatient Hospitalization Message format (see paragraph 7.b below).
- b. Inpatient Hospitalization Messages. Protected Health Information (PHI) will be sent utilizing the procedure described in Chapter 7.B.(3)(b) for the Disease Alert Report or Chapter 2.A.(2)(b) utilizing the Inpatient Hospitalization system. Send only the minimum necessary information to accomplish the intended purpose of the use, disclosure or request via e-mail to HQS-DG-HSWL Inpatient Hospitalization, as appropriate. This e-mail will only be viewed by limited command designated individuals at HQ and HSWL SC with a need to know. No other individuals shall be included or copied on this e-mail, nor shall the e-mail containing PHI be forwarded after the fact.
- c. Faxing Protected Health Information. Any individual who has access to protected health information (PHI) in the course of their duties is obligated to maintain the security of that information. Best practices to maintain the security of PHI include only faxing PHI to secure faxes, in other words, faxes in secured spaces where only those who utilize PHI have access to the secure fax. If information is sent to any other non-secure fax, it is required that the sender alert the receiver to stand by and receive the fax so that the fax containing PHI cannot be inadvertently intercepted by someone without authorization to receive and use PHI. The receiver should then contact the sender to acknowledge safe receipt of the fax containing PHI.
- d. Recommended Disclaimer on Protected Health Information Sent Electronically. The following disclaimer statement is recommended by the TMA Privacy Office. It may be placed in the footer of a Fax Cover Sheet for the transmission of PHI or may be used at the end of an email containing PHI. The word "Confidential" in bold should be placed at the beginning of the footer above this disclaimer as depicted below:

**CONFIDENTIAL**

This document may contain information covered under the Privacy Act, 5 USC552(a), and/or the Health Insurance Portability and Accountability Act (PL 104-191) and its various implementing regulations and must be protected in accordance with those provisions. Healthcare information is personal and sensitive and must be treated accordingly. If this correspondence contains healthcare information it is being provided to you after appropriate authorization from the patient or under circumstances that don't require patient authorization. You, the recipient, are obligated to maintain it in a safe, secure and confidential manner. Redisclosure without additional patient consent or as permitted by law is prohibited. Unauthorized redisclosure or failure to maintain confidentiality subjects you to application of appropriate sanction. If you have received this correspondence in error, please notify the sender at once and destroy any copies you have made.

Section H. Quality Improvement Studies.

1. Background.....	1
2. Responsibilities.....	1
3. Definitions. ....	1
4. General information.....	2
5. QIS Focus. ....	2
6. QIS Process.....	2
7. QIS Report Form. ....	2
8. Frequency of Quality Improvement Studies.....	2
9. Completing the QIS Report Form. ....	2
10. Follow-up Reporting.....	5
11. Integration.....	5
12. Filing.....	5

This page intentionally left blank.

## H. Quality Improvement Studies.

1. Background. In the early 1990s the CG established a Monitoring and Evaluation (M&E) program to examine areas of clinical care the CG deemed important in order to assess how well clinics provided this care. The M&E program centered on the review of historical data and, thus, was a retroactive program. Further, the program was strictly a QA program in that it was designed to ensure a set standard of care was met in specific areas. M&Es did not necessarily seek to improve care beyond a set standard. Quality Improvement Studies (QISs) will replace M&Es as the primary tool for evaluating healthcare delivery in clinics. M&Es will no longer be used as a QA tool. QISs provide a framework so that current QA clinic standards of care themselves are reviewed for improvement. Further, QISs are proactive versus retroactive in nature because data from QISs are reviewed as they become available.
2. Responsibilities.
  - a. HSWL SC. Monitors the QIS Program activities. The HSWL SC provides guidance to the program.
  - b. Quality Improvement Coordinator. The QI Coordinator ensures that at least four QISs are completed annually, in a timely manner, and in the proper format and are documented in the QI Focus Group (QIFG) meeting minutes. The QI Coordinator ensures that delegated tasks are completed by the appropriate clinic personnel.
  - c. Quality Improvement Focus Group. The QIFG meets at least quarterly and is responsible for approving and monitoring the QISs conducted in the clinic. The QIFG provides guidance to QIS investigators and other members of the staff involved in implementing QISs. On-going QISs are discussed in QIFG meetings and documented in its minutes. The QIFG, which includes providers and administrators, participates in the resolution of the problem or issue identified.
  - d. Clinic personnel. Ensure important problems that address clinical, administrative or cost issues, and patient outcomes are brought before the QIFG to initiate as QISs. All personnel participate in the identification and resolution of problems.
3. Definitions.
  - a. Problem. Any question to be considered, resolved, or answered in order to meet or improve upon Accreditation Association of Ambulatory Health Care (AAAHC) or Chapter 13 of the Medical Manual quality of care standards.
  - b. Quality Improvement Study. In a healthcare setting, a tool used to systematically review a single problem of healthcare delivery or operations within a clinic in order to determine if there is an improved and sustainable solution to the problem.
  - c. Quality Assurance, Quality Improvement. See Chapter 13 Section A 8 for the definitions of Quality Assurance and Quality Improvement.

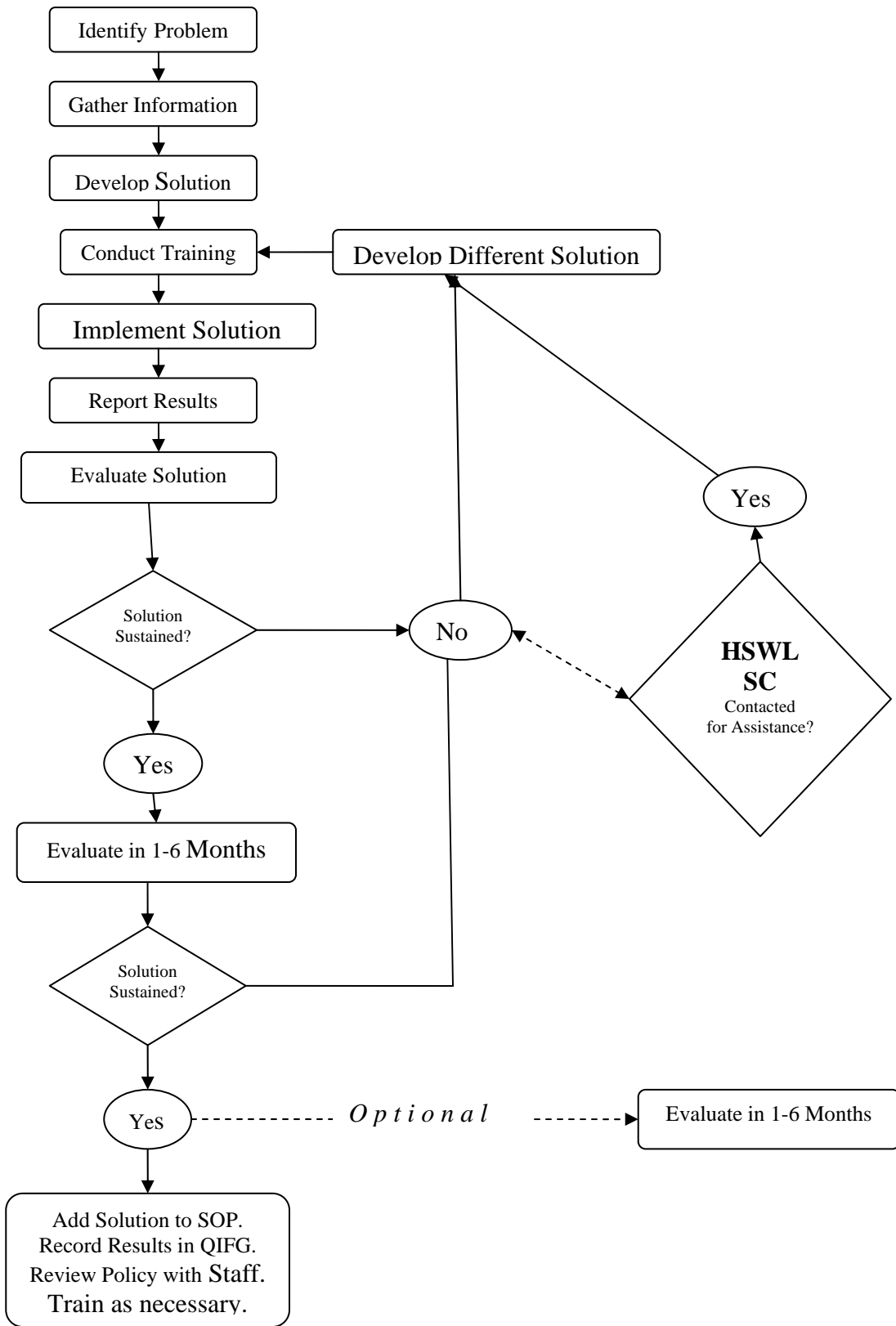
4. General information. The QIS Program must be active (implements at least 4 studies per year), organized (utilizes a systematic, “closed loop” process), peer-based (results reviewed by the QIFG, documented in the QIFG minutes, posted in clinic public folder for HSWL SC review), and integrated (includes issues from all clinical and administrative departments within the clinic, incorporates results into the clinic standard operating procedures, and provides staff training when necessary).
5. QIS Focus. QISs address or identify issues including standards of care, quality of care delivered, effectiveness of healthcare delivery, efficiency of operations, and additional issues or concerns unique to individual clinics. The QIS process must focus on one problem or issue per study although the clinic may conduct more than one QIS concurrently.
6. QIS Process. The QIS process is a sequential process that roughly parallels the scientific method. The process is outlined in a flow-sheet (See Figure 13-H-1).
  - a. Step 1: Identify problem.
  - b. Step 2: Gather information on problem.
  - c. Step 3: Develop solution to problem.
  - d. Step 4: Conduct training on solution.
  - e. Step 5: Implement solution to problem.
  - f. Step 6: Report results of implemented solution.
  - g. Step 7: Evaluate solution to problem.
7. QIS Report Form. Clinic QI activities are reported on the Quality Improvement Study Report Template, CG-6000-6 which follows the stepwise QIS process.
8. Frequency of Quality Improvement Studies. Quality improvement is a continuous process therefore clinics must initiate a minimum of four QISs per calendar year. QISs should be spread throughout the year when possible and involve different clinical areas when possible (e.g. lab, pharmacy, medical, administration).
9. Completing the QIS Report Form.
  - a. Overview. The QIS Report form is a major component of implementing a successful QI program. It serves as the building block for QI interventions and a record of QI activities. This section describes the major components of the form and how to complete it.
  - b. Name of study. Concise yet descriptive such as “health record tracking,” “lab results monitoring,” or “prescription error rate.”
  - c. Investigator. The person responsible for completing the QIS and presenting its findings to the QIFG.
  - d. Study. Select if the QIS is an initial study or a follow-up study.
  - e. Date completed. The date on which the current QIS Report form was completed.



- f. Problem Statement. The specific problem is described in one or two sentences. The name of the study should reflect what the problem is. Each QIS addresses a single problem. Each QIS must only address one problem. If there are multiple problems, a QIS must be done for each one.
- g. Background to problem/Known facts of problem. The background to the problem is described and the known facts of the problem are listed (who, what, when, where, how). Information on the problem is evaluated for reliability.
- h. Parameters of problem. The parameters that define the problem are determined. Problems with greater negative consequences that occur frequently should take precedence over those with lesser consequences that occur less frequently.
- i. Area of Care. Select the area of care that best describes the nature of the problem:
  - (1) Administrative. Examples include health record completeness, record tracking system, referral tracking, staffing utilization, staff satisfaction, medical/legal issues, cost issues, patient flow, health readiness, quality controls in clinic departments, monitoring of care, assessing patient satisfaction, wasteful practices, access to care.
  - (2) Ancillary. Examples include monitoring abnormal results, radiograph retakes.
  - (3) Clinical. Examples include tracking management of contagious disease cases, assessing for appropriateness of care according to standard guidelines, assessing changes in outcomes based on changes in practice, medications or ancillary treatments.
  - (4) Dental. Examples include annual Type 2 exam process, ensuring proper sterilization of instruments, and endodontic and periodontal treatment follow-up.
  - (5) Medical. Examples include physical exam process, diagnostic testing procedures, practice patterns of providers, and comparisons to national standards of care.
  - (6) Patient outcome. Examples include adverse events, medication errors, deviation from standard of care, clinical procedure processes, and peer review findings.
  - (7) Pharmaceutical. Examples include Non-Formulary Medication Utilization, Appropriate Use of Antibiotics to treat URIs, and Improving Patient Medication Outcomes.
- j. Parameters of problem Consequence. Determine what happens if solution to problem is not found. This step may assist clinics to determine on which issues to focus their efforts.
  - (1) Devastating. Problem results in intolerable outcome, loss of life, injury, economic penalty or legal issues.

- (2)  Serious. Problem could result in injury, hazard or economic penalty.
  - (3)  Moderate. Problem will probably not cause hazard or economic penalty.
  - (4)  Low. Problem does not have much implication to health or economics.
- k.  Standards used to evaluate problem. This element usually applies to clinical QISs that involve the comparison of clinic standards of care against national treatment or practice guidelines. Complete if applicable.
  - l.  Proposed solution to problem. Describe how and what information was gathered to determine course of action. Describe specifically what steps the clinic will take to address the problem. This will take a paragraph to describe.
  - m.  Desired outcome of solution. Discuss specifically what the clinic hopes to attain by implementation of the solution.
  - n.  Training Date. Give date on which the staff was trained on the proposed solution to the problem. Must ensure staff is trained so they know how to implement the solution and what is expected of them.
  - o.  Training Aids. Check applicable boxes. Generally, solutions that involve tasks with higher levels of consequence if an error occurs or those that involve tasks that occur less frequently require greater training intervention than those that have less consequences or occur more frequently. The QIFG must determine what training strategies to use in order to successfully implement the corrective solution. Training must involve at least two strategies that include memory tools, lectures, checklists, flow charts and practice/rehearsal.
  - p.  Implement solution to problem. Each task must have a person assigned to it who is responsible for its completion by a specified date. These tasks include those that originate from the statements listed under “proposed solution to problem.” Tasks are implemented concurrently or sequentially depending on the problem. As each task is completed the date is noted in the “completion date” column. The responsible party does not have to be the investigator. Progress is reported in the meeting minutes of the QIFG. The QIFG determines if the results achieved by the intervention provide sustainable improvements. If the solution involves a long-term project (i.e. one over six months to implement or review) such as an area renovation, check the appropriate box noting this fact. Interpret the QIS Flowchart in light of the time adjustments required for long-term projects.
  - q.  Report results of the implemented solution. Complete the “Initial QIS” section for the first study, the “Follow-up QIS” section for the second study and the “Additional QIS” section if a third study is warranted. For long term projects note the appropriate follow-up dates in the text.
  - r.  Evaluate solution to problem: Initial QIS. Check whether the solution was sustained or not sustained and fill-in the appropriate boxes. Note when the findings were documented in the QIFG meeting minutes.

- s. Evaluate solution to problem: Follow-up QIS. Check whether the solution was sustained or not sustained after the follow-up study was concluded. If sustained, check the appropriate boxes for what actions were taken to integrate the solution into clinic operations. Check what training tools were used to educate staff on new proposed solution. Note when the findings were documented in the QIFG meeting minutes.
  - t. Evaluate solution to problem: Additional QIS (if needed). For QISs that involve areas of high risk to patients or could result in devastating consequences if not resolved, an additional evaluation may be desired. Check whether the solution was sustained or not sustained after the additional study was initiated. Check what training tools were used to educate staff on new proposed solution. A new QIS Report Form must be started if the implemented solution is not sustained after a third study. Note when the findings were documented in the QIFG meeting minutes.
  - u. Evaluate solution to problem: HSWL SC assistance.
10. Follow-up Reporting. The QIS Report Form is designed to be used for the initial and follow-up study (or studies) for a particular problem. For follow-up or additional QISs add the findings to the “Report Results of Implemented Solution” section. Results are recorded in the QIFG minutes.
  11. Integration. Once a follow-up or additional QIS results in a sustainable solution, the corrective solution must be incorporated into the SOP and results reported in the QIFG minutes.
  12. Filing. The HSWL SC will establish a filing process for the clinics such as public folders or microsite on CG Central to ensure sharing of information.



Section I. Peer Review Program.

1. Background .....	1
2. Characteristics of a Peer Review Program .....	1
3. Responsibilities. ....	1
4. Process.....	2
5. Definitions.....	2

This page intentionally left blank.

- I. Peer Review Program.
  1. Background. In striving to improve the quality of care and promote more effective and efficient utilization of facilities and services, an accredited organization maintains an active, integrated, organized, peer-based program of quality management and improvement that links peer review, quality improvement activities, and risk management in an organized, systematic way.
  2. Characteristics of a Peer Review Program. The CG peer review program maintains an active and organized process for peer review that is integrated into the quality management and improvement program, evidenced by the following characteristics.
    - a. Health care providers. Health care providers understand, support and participate in a peer review program through organized mechanisms and are responsible to the governing body. The peer review activities are evidenced in the quality improvement program. Health care providers participate in the development and application of the criteria used to evaluate the care they provide.
    - b. Commandant (CG-1122). Commandant (CG-1122) provides ongoing monitoring of important aspects of the care provided by physicians, dentists, mid-level providers, and other health care professionals. Monitoring important aspects of care by individual practitioners is necessary for monitoring individual performance and establishing internal benchmarks.
    - c. Data criteria. Data related to established criteria are collected in an on-going manner and periodically evaluated to identify acceptable or unacceptable trends or occurrences that affect patient outcome.
    - d. Clinical privileges. Results of peer review activities are used as part of the process for granting continuation of clinical privileges.
    - e. Peer review activities are not designed to be punitive in nature, but can be used to identify trends requiring improvements, to enhance or improve professional competence, skill, and quality of performance of health care providers, and to guide educational programs and activities consistent with the CG mission, goals, and objectives.
  3. Responsibilities.
    - a. Commandant (CG-112). Establish and maintain contract with an external peer review organization. Collaborate with the HSWL SC to agree on specific ICD-9/CPT and CDT codes/medical and dental clinical guidelines to be used for each annual review. Coordinate with external peer review organization and clinics to schedule on-site peer reviews.
    - b. HSWL SC. Collaborate with Commandant (CG-1122) to identify specific ICD-9/CPT and CDT codes/medical and dental guidelines for each annual review. Conduct second level review, if necessary, based on report from the peer review organization.
    - c. Clinic Administrator. Select up to ten (10) patient records per provider based on the selected clinical guidelines as determined by Commandant (CG-1122) and HSWL SC.

- d. External Peer Review Organization. Conduct reviews utilizing the CG developed peer review instruments and clinical guidelines available on the Commandant (CG-112) website at <http://www.uscg.mil/hq/cg1/cg112/default.asp>. Reviewers are required to be experienced, clinically practicing physicians and dentists.

4. Process.

- a. Review of Providers. Annually, Commandant (CG-1122) and the external peer review organization will establish a schedule for reviewing all active duty and contract privileged providers (dentists, physicians, physician assistants, and nurse practitioners). Commandant (CG-1122), with input from the HSWL SC, will provide the specific medical and dental clinical guideline for each annual review. The schedule and information, including the peer review instrument and the appropriate medical/dental clinical guideline will be provided to the clinics by the HSWL SC.
- b. 8 Weeks Prior to Review. Eight weeks before a scheduled peer review, Commandant (CG-1122) will contact the Clinic Administrator to verify the date. Once confirmed, the external peer review organization and HSWL SC will be notified of the confirmed date.
- c. 2 Weeks Prior to Review. Two weeks before the scheduled visit, the clinic will be contacted by the peer review organization to arrange for access to the clinic and an in-brief with the Command.
- d. During the review. During the review, reviewers will engage the health care provider under review for any clarifications and input. At the conclusion of the review, reviewers will provide an out-brief to the Clinic Administrator, Quality Improvement Coordinator, and/or SHSO. Health care providers will be given their individual peer reviews – this will serve as a teaching tool to improve performance and/or identify needed training. Individual reviews are not sent to Commandant (CG-1122).
- e. Commandant CG-1122. Commandant (CG-1122) will use data provided from the reports to track enterprise-wide trends and establish benchmarks for improvement.
- f. Findings. Findings determined to warrant a second review will be conducted by HSWL SC per guidance from Commandant (CG-1122).

5. Definitions.

- a. Current Procedural Terminology (CPT). The CPT is an acronym for Current Procedural Terminology. CPT codes are published by the American Medical Association, and the fourth edition, the most current, is used. The purpose of the coding system is to provide uniform language that accurately describes medical, surgical, and diagnostic services.



- b. International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). The ICD-9-CM coding system is used to code signs, symptoms, injuries, diseases, and conditions.
- c. Code on Dental Procedures and Nomenclature (CDT). CDT is an acronym for Code on Dental Procedures and Nomenclature. The American Dental Association's (ADA) Code on Dental Procedures and Nomenclature (CDT) is used to record and report dental procedures. It is the dental equivalent of Current Procedure Terminology (CPT) codes for other-than-dental procedures. Hence the ADA's choice of the official abbreviation CDT rather than CDPN.
- d. Benchmarking. A systematic comparison of products, services, or work processes of similar organizations, departments or practitioners to identify best practices known to date for the purpose of continuous quality improvement.

This page intentionally left blank.

Section J. Infection and Exposure Control Program.

1. Introduction.....	1
2. Policy .....	2
3. Standard Precautions.....	2
4. Precautions for Invasive Procedures.....	5
5. Precautions for Medical Laboratories.....	6
6. Handling Biopsy Specimens .....	6
7. Using and Caring for Sharp Instruments and Needles.....	7
8. Infection Control Procedures for Minor Surgery Areas and Dental Operatories .....	8
9. Sterilizing and Disinfecting .....	14
10. Clinic Attire .....	19
11. Storage and Laundering of Clinic Attire, PPE and Linen.....	19
12. Cleaning and Decontaminating Blood or Other Body Fluid Spills .....	20
13. Infectious Waste.....	20
14. Managing Exposures (Bloodborne Pathogen Exposure Control).....	21
15. Training Personnel for Occupational Exposure.....	26

This page intentionally left blank.

## Section J. Infection Control Program (Exposure Control Plan).

### 1. Introduction.

- a. Standard Precautions. Identifying potentially infectious patients by medical history, physical examination, or readily available laboratory tests is not always possible. Extended periods often exist between the time a person becomes infected with a microbial agent and the time when laboratory tests can detect the associated antigens or antibodies. Consequently, even if a patient tests negative, he or she may still be infectious. Health care personnel must assume that all blood/body fluids and contaminated instruments and materials are infectious and routinely use Standard Precautions to protect themselves and patients.
- b. Safety Procedures. All procedures should be available to minimize the sources and transmission of infections, including adequate surveillance techniques.
- c. Protection. All CG systems must provide for the protection of patients, staff and the environment.
- d. Exposure. While CG health services personnel and emergency medical technicians must be seriously concerned with the risk of exposure to human immunodeficiency virus (HIV), the risk of contracting other infectious diseases, such as hepatitis B virus (HBV), is much greater. HBV infection can result in serious physical debilitation and adversely affect a practitioner's ability to provide health care. Once infected, a person also poses a potential risk to future patients as an HBV infection "carrier." Infection control practices that prevent HBV transmission also prevent HIV transmission. Since 1982 a safe, effective vaccine to prevent Hepatitis B has been available; it stimulates active immunity against HBV infection and provides over 90% protection against the virus for 7 or more years after vaccination.
- e. Occupational Safety and Health Administration (OSHA). The OSHA Blood borne Pathogens (BBP) Standard requires the use of Standard Precautions to protect the healthcare worker from exposure to bloodborne pathogens. The basic principle of Standard Precautions is the assumption that all patients are potentially infectious. Therefore, the risk of exposure to blood or other potentially infectious materials (OPIM) posed by a procedure dictates the level of precautions, rather than the perceived infectivity of the patient. In 1996, the Hospital Infection Control Practices Advisory Committee (HICPAC) issued guidelines for transmission-based precautions in hospitals. In addition to precautions for BBP, airborne, droplet and contact isolation procedures were also included. Under this regime, procedures to protect health services personnel from BBP are referred to as Standard Precautions, previously identified as Universal Precautions. All CG Health Services will adopt the use of standard blood and body fluid precautions as recommended by the CDC and OSHA.

2. Policy.

- a. Health services personnel. Health services personnel will adhere to infection-control principles, general hygiene measures, and the Center for Disease Control and Prevention's (CDC's) "standard precautions" to prevent transmitting infectious disease between themselves and their patients.
- b. Mandatory vaccination. Hepatitis B vaccination is mandatory for all CG active duty and reserve members and all civilian health care providers. The civilian administrative staff is exempt; however, these personnel are encouraged to receive Hepatitis B vaccination. Civilian clinic administrative personnel declining to receive Hepatitis B vaccination must sign this statement on an SF-600, and it shall be retained in the individual's health record:

I understand due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with the hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If, in the future, I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

- c. Emergency Medical Technicians. Emergency Medical Technicians will adhere to the "standard precautions" described in Chapter 13-J-3.
- d. OSHA Blood-Borne Pathogen (BBP) Standard. Under the OSHA Blood-Borne Pathogen (BBP) Standard, all health services administrative and clinical personnel are potentially occupationally exposed. All clinics shall provide the health care professional responsible for vaccinating employees with Hepatitis B vaccine a copy of the OSHA BBP Standard.

3. Standard Precautions.

- a. Background. Since medical history and examination cannot reliably identify all patients infected with HIV or other blood-borne pathogens, health services personnel must consistently use blood and body-fluid precautions with all patients, including those in emergency care settings in which the risk of blood exposure is greater and the patient's infectious status usually is unknown. CDC currently recommends the "standard blood and body-fluid precautions" approach or "standard precautions."
  - (1) All health care workers will routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when anticipating contact with any patient's blood or other body fluids. Personnel will wear gloves to touch patients' blood and body fluids, mucous membranes, or broken skin; to handle

items or surfaces soiled with blood or body fluids; and to perform venipuncture and other vascular access procedures. Personnel will change gloves after contact with each patient. Personnel will wear masks and protective eyewear or face shields during procedures likely to generate blood droplets or other body fluids to prevent exposure to oral, nasal, or optic mucous membranes. Personnel will wear gowns or aprons otherwise identified under Personal Protective Equipment (PPE) during procedures likely to generate blood splashes or other body fluids. All protective clothing must be removed before leaving the work area.

(2) Hand Hygiene

- (a) During the delivery of healthcare, avoid unnecessary touching of surfaces in close proximity to the patient to prevent both contamination of clean hands from environmental surfaces and transmission of pathogens from contaminated hands to surfaces.
- (b) When hands are visibly dirty, contaminated with proteinaceous material, or visibly soiled with blood or body fluids, wash hands with either a nonantimicrobial soap and water or an antimicrobial soap and water.
- (c) If hands are not visibly soiled, or after removing visible material with nonantimicrobial soap and water, decontaminate hands in the clinical situations described in 2.c.1-6. The preferred method of hand decontamination is with an alcohol-based hand rub. Alternatively, hands may be washed with an antimicrobial soap and water. Frequent use of alcohol-based hand rub immediately following handwashing with nonantimicrobial soap may increase the frequency of dermatitis. Perform hand hygiene:
  - (1) Before having direct contact with patients.
  - (2) After contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings.
  - (3) After contact with a patient's intact skin (e.g., when taking a pulse or blood pressure or lifting a patient).
  - (4) If hands will be moving from a contaminated-body site to a clean-body site during patient care.
  - (5) After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient.
  - (6) After removing gloves.

- (3) All health services personnel will take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures or when cleaning used instruments, disposing of used needles, and handling sharp instruments after procedures. To prevent needle stick injuries, personnel will not by hand directly recap needles, purposely bend or break them, remove them from disposable syringes, or otherwise manipulate them. After using disposable syringes and needles, scalpel blades, and other sharp items, personnel will dispose of them by placing them in puncture-resistant containers located as close to the use area as practical. The CG prohibits the use of reusable needles.
- (4) Per CFR 1910.1030 Subpart Z (2001), OSHA requires: a) the use of sharps protection devices with engineered sharps injury protection, b) evaluation by employers with input from non-managerial employees involved in the use of the devices, and c) documentation of efforts to implement requirements. Employers must consider, and where appropriate, use effective engineering controls. Effective being defined as a device, that based on reasonable judgment, will make an exposure incident less likely to occur in the application in which it is used. The evaluation and documentation shall include the following:
  - (a) Methods of evaluation.
  - (b) Results of evaluation.
  - (c) Justification for selection decision.
- (5) Although research has not definitively implicated saliva in HIV transmission, it is prudent to use appropriate protective barriers such as mouthpieces, resuscitation bags, or other ventilation devices instead of direct mouth-to-mouth resuscitation. These devices must be available for use in areas where the need for resuscitation is predictable.
- (6) Health care workers who have exuding lesions or weeping dermatitis will not provide any direct patient care or handle patient care equipment until the condition resolves.
- (7) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas with a reasonable likelihood of occupational exposure to BBP.
- (8) Personnel shall not keep food and drink in refrigerators, freezers, shelves, drug storage areas, or cabinets or on counter tops or bench tops where blood or other potentially infectious materials are present.



- (9) Personnel shall perform all procedures involving blood or other potentially infectious materials in a manner that prevents droplets of these substances from splashing, spraying, and splattering.
  - (10) Pregnant health care workers apparently do not face greater risk of contracting HIV infection than non-pregnant health care workers; however, if a health care worker develops HIV infection during pregnancy, the infant risks infection due to prenatal or perinatal transmission. Therefore, pregnant health care workers will thoroughly learn and strictly adhere to standard precautions to minimize the risk of HIV transmission.
- b. Implementation. Implementing standard blood and body fluid precautions for all patients eliminates the need for the “Blood and Body Fluid Precautions” isolation category CDC previously recommended for patients known or suspected to be infected with blood-borne pathogens. Personnel will use isolation precautions as necessary if they diagnose or suspect associated conditions, such as infectious diarrhea or tuberculosis.
4. Precautions for Invasive Procedures.
- a. Aseptic techniques. Acceptable aseptic techniques are to be used by all persons in the surgical area. Environmental controls are implemented to ensure a safe and sanitary environment.
  - b. When to use standard precautions. The standard blood and body fluid precautions listed above and those listed below shall be the minimum precautions for all invasive procedures, defined as surgical entry into tissues, cavities, or organs; repair of major traumatic injuries in an operating or delivery room, emergency department, or out-patient setting, including both physicians’ and dentists’ offices; a vaginal delivery; manipulating, cutting, or removing any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists.
  - c. Types of precautions. All health care workers who routinely participate in invasive procedures shall take appropriate barrier precautions to prevent skin and mucous membrane contact with all patients’ blood and other body fluids. Personnel shall wear gloves and surgical masks for procedures that commonly generate droplets, splash blood or other body fluids, or generate bone chips, such as those using rotary dental instrumentation. Personnel shall wear gowns or aprons made of materials that provide an effective barrier during invasive procedures likely to splash blood or other body fluids.
  - d. Accidents. If a glove is torn, cut, or punctured, the wearer will remove it, re-  
scrub, and put on a new glove as promptly as patient safety permits. The needle or instrument involved in the incident shall also be removed from the sterile field.

5. Precautions for Medical Laboratories. Blood and other body fluids from all patients will be considered infectious. To supplement the standard precautions listed above; the following precautions are recommended for health care workers in clinical laboratories.
  - a. Blood and body fluid specimens. All blood and body fluid specimens shall be placed in a well-constructed, labeled container with a secure lid to prevent leaking during transport, taking care when collecting each specimen to avoid contaminating the container's exterior or the laboratory form accompanying the specimen.
  - b. Equipment. All persons obtaining or processing blood and body fluid specimens (e.g., removing tops from vacuum tubes) shall wear gloves. Personnel shall wear masks and protective eyewear if they anticipate contact with mucous membrane with blood or body fluids, change gloves, and wash hands after completing specimen processing.
  - c. Routine procedures. For routine procedures such as histological and pathologic studies or microbiologic culturing, a biological safety cabinet is not necessary. However, personnel shall use biological safety cabinets (Class I or II) whenever performing procedures with a high potential for generating droplets, including activities such as blending, sonicating, and vigorous mixing.
  - d. Pipetting. Use mechanical pipetting devices to manipulate all liquids in the laboratory. Never pipette by mouth.
  - e. Needles. When using needles and syringes, personnel will follow the recommended standard precautions to prevent needle injuries.
  - f. Decontamination. Decontaminate laboratory work surfaces with an appropriate chemical germicide after spilling blood or other body fluids and completing work activities. Decontaminate contaminated materials used in laboratory tests before reprocessing or place such materials in bags and dispose of them according to institutional policies for disposing of infectious waste. Decontaminate scientific equipment contaminated with blood or other body fluids with an appropriate chemical germicide and clean such equipment before repairing it in the laboratory or transporting it to the manufacturer.
  - g. Hand washing. All persons shall wash their hands after completing laboratory activities and remove protective clothing before leaving the laboratory.
6. Handling Biopsy Specimens. Generally, personnel must put each specimen in a sturdy container with a secure lid to prevent leaking during transport and take care when collecting specimens to avoid contaminating the container's exterior. If the outside of the container is visibly contaminated, clean and disinfect it or place it in an impermeable bag before delivery to the appropriate destination for examination.
7. Using and Caring for Sharp Instruments and Needles.

- a. Sharps. Personnel will consider sharp items (needles, scalpel blades, dental burs, and other sharp instruments) potentially infectious and handle them with extreme care to prevent unintentional injuries.
- b. Disposal items. All generating personnel must place disposable syringes, tube holders, needles, scalpel blades, anesthetic carpules and other sharp items in closable, leak-proof, puncture-resistant containers. Cardboard containers are not appropriate for this purpose. To prevent unintentional needle stick injuries, personnel will not directly recap disposable needles by hand, purposefully bend or break needles, remove them from disposable syringes or tube holders, or otherwise manipulate them after use.
  - (1) At the discretion of the Clinic Administrator, a clinic may elect to receive sharps from patients for proper disposal. If so, then the following criteria must be met.
    - (a) The sharps container must be:
      - (1) Installed in a non-sensitive area to allow for disposal by patients.
      - (2) Accessible by wheelchair bound patients.
      - (3) Out of the reach of children.
      - (4) Maintained regularly and replaced when  $\frac{3}{4}$  full.
    - (b) Patients must dispose of their own sharps into an appropriate sharps container.
    - (c) Patients will be instructed to maintain lancets, needles, and other sharps in a leak-proof, puncture-resistant container such as a bleach container or 2-liter soda bottle.
  - (2) The Clinic Administrator must maintain policies and procedures for the handling of sharps brought into the clinic.
- c. Recapping needles. If multiple injections of anesthetic or other medications from a single syringe are required, personnel may use these techniques in lieu of directly recapping by hand:
  - (1) Use an approved shielding device specifically designed to recap safely (e.g., “On-Guard”).
  - (2) Use the “scoop” recapping technique. Affix the empty needle sheath to a flat surface and “scoop” it onto the exposed needle. A hand does not touch the sheath until the needle is securely inside.

- (3) Use a hemostat to recap by securing the empty sheath well away from the health care worker's hand.
      - d. Needle sticks protocol. All CG Health Care Units shall establish a needle stick protocol; see Section 13-J-14. If a needle stick occurs, the affected person shall report the accident to his or her immediate supervisor, who will document the incident in a memorandum to the SHSO or health services department head, with a copy to the affected person. The memorandum will detail the needle stick's time, date, and circumstances and any medical treatment received. The SHSO or health services department head shall ensure the established needle stick protocol is observed in all cases.
8. Infection Control Procedures for Minor Surgery Areas and Dental Operatories.
  - a. Medical History. Always obtain a thorough medical history. For dental procedures, have the patient complete a Dental Health Questionnaire, CG-5605. Amplify this information by asking the patient specific questions about medications, current illnesses, hepatitis, recurrent illness, unintentional weight loss, lymphadenopathy, oral soft tissue lesions, results of last HIV test, or other infections. Completely review the individual's health record or consult with a physician if the history reveals active infection or systemic disease.
  - b. Using Personal Protective Equipment and Barrier Techniques.
    - (1) Health services personnel (HCW) in CG medical/dental treatment facilities must comply fully with 29 CFR, Part 1910, OSHA Occupational Exposure to Blood Borne Pathogens. OSHA has determined that health care workers face a significant health risk as a result of occupational exposure to blood and "other potentially infectious materials" (OPIM) that may contain potentially harmful blood borne pathogens. This risk can be minimized or eliminated by the practice of standard precautions including the use of PPE.
    - (2) PPE is defined in CFR 1910.1030 as specialized clothing worn by an employee for protection against a blood borne hazard. PPE must be removed daily, when visibly soiled, or when leaving the work area and must be commercially laundered at the unit's expense. Under no circumstances shall employees take PPE or contaminated clinic attire from the workplace for self-laundering.
    - (3) Health services personnel will consider all patients' blood, saliva, and other body fluids infectious. To protect themselves and patients, personnel must always wear gloves when touching:
      - (a) Blood.
      - (b) Saliva.
      - (c) Body fluids or secretions.
      - (d) Items or surfaces contaminated by the above.

(e) Mucous membranes.

- (4) Further, personnel must completely treat one patient, if possible, and wash and re-glove hands before performing procedures on another patient. Repeatedly using a single pair of gloves is not allowed; such use can produce defects in the glove material, which reduce its effectiveness as a barrier to microorganisms. Additionally, when gloves are torn, cut, or punctured, the wearer immediately must remove them, thoroughly wash his or her hands, and put on new gloves before completing minor surgical or dental procedures.
- (5) Personnel shall wear surgical masks and protective eyewear or a chin-length plastic face shield. Personnel shall change masks after lengthy examinations or procedures, most especially after any, which produce spatter. Patient protective eyewear shall be provided during all treatment procedures likely to splash or spatter blood, saliva, gingival fluids, or foreign objects. Personnel will use rubber dams, pre-procedural mouth rinsing, high-speed evacuation, and proper patient positioning, when appropriate, to minimize droplet generation and spatter in the dental operator.
- (6) Clinic attire is defined in section 10.

c. Hand Hygiene.

- (1) Hand hygiene includes hand washing, alcohol-based hand rubs, and surgical/aseptic hand washing. Wearing gloves does not replace the need for hand hygiene.
- (2) Indications for hand hygiene are: before and after treating patients (e.g. before glove placement and after glove removal), after barehanded touching of inanimate objects likely to be contaminated by blood or saliva, before regloving after removing gloves that are torn, cut, or punctured, and before leaving the dental operator.
- (3) At the beginning of the day, hand washing with plain soap is adequate, since soap and water will remove transient microorganisms. Wet hands with water, apply product, rub hands together for at least 15 seconds, rinse and dry with a disposable towel. Whenever possible wash hands at sinks that provide hot and cold water through a single mixing valve.
- (4) During the rest of the day, for routine dental procedures, alcohol-based hand rubs are recommended. Apply product to palm of one hand, rub hands together covering all surfaces until dry. The appropriate volume of product is based on manufacturer. Alcohol based hand rubs should NOT be used if hands are visibly soiled or contaminated.

- (5) For surgical procedures, personnel must use an antimicrobial surgical hand scrub. Scrub hands and forearms for the length of time recommended by manufacturer (2-6 minutes). Clinics may need to stock non-allergenic soap and sterile gloves for allergic individuals.
  - (6) Health services personnel who have exuding lesions or weeping dermatitis must refrain from all direct patient care and handling patient-care equipment until the condition resolves.
  - (7) Health services personnel should avoid wearing artificial nails and keep natural nails short as to minimize harboring bacterial growth.
- d. Dental equipment. Sterilizing and Disinfecting Dental Hand Pieces, Ultrasonic Scalers, Dental Units, and Dental Laboratory equipment by the following procedures:
- (1) After each use with each patient, personnel will sterilize dental hand pieces (including high-speed, low-speed components used intra-orally and ultrasonic scalers) because the device may aspirate a patient's blood, saliva, or gingival fluid into the hand piece or waterline. Clinics should purchase sufficient numbers of autoclavable hand pieces to meet this requirement. Dry heat is the recommended method of sterilizing dental burs.
  - (2) Disinfect all dental unit surfaces with a suitable chemical germicide between patients or cover such surfaces during use. Use impervious backed paper, aluminum foil, or clear plastic wrap to cover surfaces difficult or impossible to disinfect (e.g., light handles or x-ray tube heads). Remove the covering while gloved, discard the covering, remove used and don fresh gloves, and then recover with clean material after each patient.
  - (3) Dental laboratory personnel will observe infection control protocols. They will thoroughly, carefully clean blood and saliva from material used in the mouth (e.g., impression materials, occlusal registrations), especially before polishing and grinding intra-oral devices. They will clean and disinfect contaminated materials, impressions, and intra-oral devices before handling them in the dental laboratory and before putting them in a patient's mouth. They will disinfect laboratory instruments (e.g. spatulas, knives, and wax carvers), plastic benches, chucks, handles, switches, tubing, air hoses, and lab hand pieces every day. Rubber mixing bowls require overnight immersion to disinfect. Workstations, including exposed equipment, drawers, work surfaces, and sinks, require weekly surface disinfecting. Because of the increasing variety of dental materials used intra-orally, dental providers should consult with manufacturers about specific materials' stability in disinfecting procedures.
- e. Dental Unit Waterlines.

- (1) Background: Studies have demonstrated that dental unit waterlines are colonized with a wide variety of microorganisms including bacteria, fungi, and protozoa. Microorganisms colonize and multiply on the interior surfaces of the waterlines resulting in the formation of biofilms. Although oral flora may enter and colonize dental water systems, the public water system is the primary source of the microorganisms found in waterline biofilms.
- (2) Discussion: Current dental water systems cannot deliver water of optimal microbiologic quality without some form of intervention by the user. The literature supports the need for improvement in dental unit water quality. Improving the microbiologic quality of water used in dental treatment shows commitment to high-quality patient care. All CG dental clinics should take prudent measures to provide quality water for dental treatment and to ensure a safe and healthy environment for their patients and employees.
- (3) All CG dental clinics shall follow the Centers for Disease Control and Prevention (CDC) recommendation that only sterile solutions be used for surgical procedures that involve the cutting of bone.
- (4) The number of colony forming units (CFU) in water used as a coolant or irrigant for non-surgical dental treatment should be as low as reasonably achievable. The ceiling limit for acceptable dental water quality is  $\leq 500$  CFU/mL of heterotrophic plate count bacteria, the regulatory standard for safe drinking water. Non-surgical procedures include most subgingival scaling or restorative procedures and for initial access into the dental pulp.
- (5) Water Quality Improvement: There are several options for improving dental unit water quality. They are:
  - (a) Flushing: Flush waterlines for 2-3 minutes at the beginning of the day, 20-30 seconds between patients to eliminate any retracted oral fluids, and 3 minutes at the end of the day. Mechanical flushing is an interim measure and has no effect on biofilms. However, flushing between patients will remove patient material potentially retracted during treatment, and should be continued even when other methods to control biofilms are used.
  - (b) All water lines should be completely drained and air purged at the end of the day. This procedure will remove all existing water, dry the lines and discourage the re-growth of microorganisms.
  - (c) An independent water reservoir will eliminate the inflow of municipal water into the dental unit and provides better control over the quality of source water for patient care. Independent water reservoirs are available as optional equipment on most new dental units and can be

retrofitted to existing equipment. Use of independent reservoirs when used with a routine disinfection protocol, can virtually eliminate bacterial and fungal contamination.

- (d) Periodic monitoring should be performed to assess compliance with recommended protocols and to identify technique errors or non compliance. Dental staff should be trained regarding water quality, biofilm formation, water treatment methods, and appropriate maintenance protocols for water delivery systems. Clinical monitoring of water quality can ensure that procedures are correctly performed and that devices are working in accordance with the manufacturer's previously validated protocol. Dentists should consult with the manufacturer of their dental unit or water delivery system to determine the best method for maintaining acceptable water quality (i.e.,  $\leq 500$  CFU/mL) and the recommended frequency of monitoring.
  - (e) If the dental unit manufacturer does not provide a recommendation for frequency of monitoring then monthly testing on a semi-random basis is recommended, (e.g. daily, weekly, monthly so it is easy to remember to perform the testing). Water should be tested at each exit point of the unit. If a unit fails to test  $\leq 500$  CFU/mL, the unit shall be re-treated (under supervision if need be). This does not preclude the continued use of the dental unit.
  - (f) Monitoring of dental water quality can be performed by using commercial self-contained test kits or commercial water-testing laboratories. Because methods used to treat dental water systems target the entire biofilm, no rationale exists for routine testing for such specific organisms as *Legionella* or *Pseudomonas*, except when investigating a suspected waterborne disease outbreak.
- f. Dental Radiology Sterilization and Disinfecting Procedures.
- (1) Film-Holding and Aiming Devices. Film-holding and aiming devices will be heat-sterilized.
  - (2) Panoramic Unit Bite Blocks. Use disposable bite block covers between patients. If disposable covers are not available, treat bite blocks similarly to film-holding devices.
  - (3) The use of film with barriers is highly recommended. The following outlines the protocol of film handling with barriers:
    - (a) Place paper towel on work surface in darkroom.
    - (b) Place container with contaminated films next to paper towel.
    - (c) Put on gloves.
    - (d) Take one contaminated film out of container.



- (e) Tear open barrier.
  - (f) Allow film to drop onto paper towel.
  - (g) Do not touch film with gloved hands.
  - (h) Dispose of barrier.
  - (i) After removing all barriers, dispose of container.
  - (j) Remove gloves, wash hands or use alcohol-based hand rub.
  - (k) Secure door, turn out darkroom lights.
  - (l) Unwrap/process films.
- (4) The following outlines the protocol of film handling without barriers:
- (a) Place paper towel on work surface in darkroom.
  - (b) Place container with contaminated films next to paper towel.
  - (c) Secure door, turn out darkroom lights.
  - (d) Put on gloves.
  - (e) Take one contaminated film out of container.
  - (f) Open film packet tab and slide out lead foil backing and black paper.
  - (g) Discard film packet wrapping.
  - (h) Rotate foil away from black paper and discard.
  - (i) Open black paper wrapping without touching film.
  - (j) Allow film to drop onto paper towel.
  - (k) Do not touch film with gloved hands.
  - (l) Discard black paper wrapping.
  - (m) After all film packets have been opened, dispose container.
  - (n) Remove gloves, wash hands or use alcohol-based hand rub.
  - (o) Process films – handle by edges.
- (5) X-ray Chair. Between patients wipe arm- and headrests with a chemical surface disinfecting solution. If using paper or plastic headrest covers, replace them after each patient.
- (6) Intra-oral X-ray Tubehead and Exposure Buttons. Wipe these items with a surface disinfectant or cover them after each patient visit. Do not allow disinfectant liquid to leak into the tubehead seams or the exposure button switch.
- (7) Digital Sensors. Digital sensors will be covered with a disposable plastic sleeve.

9. Sterilizing and Disinfecting.

- a. Background. The rationale for sterilization is to kill all microbes remaining on the instruments and help assure patient safety.
- b. Instrument Categories (Spaulding Classification). The Spaulding Classification defines as critical instruments that normally penetrate soft tissue, teeth, or bone (e.g., forceps, scalpels, bone chisels, scalers, surgical burs, etc.). They must be heat-sterilized after each use. Instruments not intended to penetrate soft or hard tissues (e.g., amalgam carvers, plastic instruments, etc.) but which may come into contact with tissues are semi-critical and also should be heat-sterilized after each use. If heat sterilization is not possible, semi-critical instruments must receive chemical sterilization. Non-critical instruments never contact tissue. Sterilization is recommended for non-critical instruments, but high-level disinfection is acceptable.
- c. Instrument Processing.
  - (1) Designate a central processing area and divide into:
    - (a) Receiving, cleaning, and decontamination.
    - (b) Preparation and packaging.
    - (c) Sterilization.
    - (d) Storage.
  - (2) Cleansing Instruments. Instruments must be cleansed for sterilization to be effective. Use automated cleaning equipment (ultrasonic cleaner, instrument washer). Use a container or wrapping material compatible with then type of sterilization process. Hand-scrubbing instruments is prohibited. Persons who cleanse instruments must wear heavy-duty (“Nitrile”) rubber utility gloves to reduce the risk of injury. Inspect instruments for cleanliness before preparing them for packaging. Use only FDA-cleared medical devices for sterilization.
  - (3) Packaging and Wrapping Instruments. Depending on intended use, wrap or package most instruments individually or in sets. Packaging in metal or plastic trays reduces set-up time; instruments and other materials arranged systematically are more convenient. Package size and sterilization method generally determine the best wrapping material, most commonly paper/plastic peel pouches, nylon plastic tubing, cloth, sterilization wrap, or wrapped cassettes. Seal packages by heat, tape, and self-sealing methods. Wrap instruments loosely to allow the sterilizing agent to circulate freely throughout the pack. Pack scissors, hemostats, and hinged instruments in the open position so the sterilizing agent can reach all parts. When

wrapping in an easily punctured material, cover the tips of sharp instruments with 2 x 2 gauze or cotton roll. If using plastic or nylon sterilization tubing, the pack should be approximately 20% larger than the longest instrument to allow the inside air to expand when heated. Clear tubing is relatively puncture-resistant and enables rapid identification of contents. When using cloth to wrap critical items, use a double thickness. Package instruments/cassettes with microbial barriers. Allow packages to dry in the sterilizer before they are handled to avoid contamination. Do not use liquid chemical sterilants for surface disinfection or as holding solutions.

- d. Heat Sterilization. The best way to minimize cross-contamination is to sterilize all instruments that can withstand sterilizing conditions. The most practical, dependable sterilization method, heat, when appropriate, is preferable to chemical means. These are the most common heat sterilization techniques:
- (1) Steam Vapor under Pressure Sterilizer (Autoclave). Steam vapor under pressure is an excellent sterilization method. Moist heat kills the bacteria by causing their proteins to denature and coagulate within the microbial cell. The steam's high temperature, not the pressure, kills the microorganisms. Steam can rust cutting edges made of carbon steel; however, antirust agents reduce this process.
  - (2) Chemical Vapor under Pressure Sterilizer (Chemiclave). This sterilizer uses chemical vapor under pressure and kills bacteria in much the same manner as the steam sterilizer. It is an excellent sterilization method. Because chemical vapors are less corrosive than steam, they do not dull sharpened instruments. Chemical vapor sterilizers use a specific mixture of formaldehyde, alcohols, ketone, acetone, and water. If the manufacturer's recommended chemical solution is not available, distilled water may be used for a short time. Chemical solutions shall be used only once. A disadvantage of the chemical vapor sterilizer is the residual chemical vapor that escapes into the air when the chamber door is opened. While non-toxic and non-mutagenic, its odor can be objectionable. Allowing the sterilizer to cool for at least 20 minutes before opening will significantly reduce the residual vapor level. A commercial purging system that reduces residual vapor levels is available.
  - (3) Dry Heat Sterilizer. Dry heat kills bacteria by an oxidation process. Dry heat sterilization will not corrode instruments, but dry heat sterilizers can destroy metal instruments' temper and melt solder joints if not monitored properly. Some dry heat units are not able to sterilize large trays and require special wrapping and bagging materials. For these reasons, dry heat sterilization is not recommended for critical instruments, and should be monitored carefully and used judiciously with semi-critical and non-critical instruments. Because sterility is destroyed as soon as items are touched or

left open to the environment, do not place loose instruments in dry heat sterilizers. Wrap and bag all instruments; they must remain wrapped or bagged until used.

e. Sterilization Monitoring.

- (1) All sterilization procedures must be monitored and recorded in a log book for compliance.
- (2) Mechanical Monitoring. Correct time, temperature and pressure is monitored to demonstrate that the physical parameters of the sterilization process have been achieved with every load. Use mechanical monitoring with each load.
- (3) Chemical Monitoring. Chemical indicators show that every package has been exposed to sterilizing conditions in a heat sterilizer. They do not guarantee the instruments are sterile. External chemical indicators (autoclave tape or sterilizing bags with heat-sensitive printing) identify at a glance which instruments have been processed but show that only the outside of the pack was exposed to an elevated temperature. An external chemical indicator must be on every pack processed. If using see-through packages, a chemical indicator placed inside the pouch is acceptable. Internal chemical indicators, available in strips, cards, or labels, react to time/temperature/ sterilizing agent combinations – use an internal chemical indicator inside each package. Do not use instrument packages if mechanical or chemical indicators suggest inadequate processing.
- (4) Biological Monitoring (Spore testing). Bacterial spores are used to demonstrate that the sterilization procedure kills highly resistant microbes (bacterial spores). Place them in the most challenging area of the load being tested and wrap the pack in the usual fashion. Monitor all chemical vapor, water vapor, and dry heat sterilizers with a spore test either weekly or each cycle, whichever is less frequent.
  - (a) These systems require either a medical laboratory service or an in-house incubator to incubate the test spore. Dry heat sterilizers require an alternate system using a glassine envelope with enclosed spore strips. Regardless of the system used, document spore monitoring, including identification test date, test results, and operator, and maintain the records for two years.
  - (b) In the case of a positive spore test, take the sterilizer out of service and review procedures to determine if operator error could be responsible. Re-test the sterilizer using biological, chemical, and mechanical indicators after correcting any procedural problems. If repeat test is negative and the chemical and mechanical tests are normal, put the sterilizer back in service. If the repeat spore test is positive do not use the sterilizer until it has been inspected or repaired or the problem identified. Recall and reprocess items from the suspect loads. Re-test

the sterilizer with spore tests in three consecutive empty chamber sterilization cycles after the cause of the failure has been determined and corrected before putting it back into service.

- (5) Storage and Shelf Life. Implement practices based on date- or event-related shelf life for the storage of wrapped, sterilized items. Materials are considered indefinitely sterile unless packaging is torn, ripped, punctured or exposed to water. At a minimum, place the date of sterilization and which sterilizer was used on the package. Examine wrapped sterilized packages before opening them to ensure the barrier wrap is in tact. Re-clean, re-pack and re-sterilize packages that are compromised. Store sterile packages in dry closed cabinets.

f. Chemical Sterilization and High-Level Disinfection.

- (1) Although heat is the preferred sterilization method, certain instruments and plastics will not tolerate heat sterilization and require chemical sterilization or high-level disinfection. These disinfectants destroy microorganisms by damaging their proteins and nucleic acids. Most formulae contain 2% glutaraldehyde and come in two containers. Mixing the proper amounts from each container activates the solution. Sterilization monitors cannot verify glutaraldehyde sterilization. The solution is caustic to the skin, so use forceps or rubber gloves to handle instruments immersed in glutaraldehyde and *always* follow manufacturer's directions *carefully*. Label each container of fresh solution with an expiration date.
- (2) Uninterrupted immersion for 7 to 10 hours in a fresh glutaraldehyde solution usually will achieve sterilization; uninterrupted immersion for 10 minutes will kill most pathogenic organisms, but not spores. Heavily soiled or contaminated instruments render glutaraldehydes ineffective. Debride instruments thoroughly to disinfect effectively. Glutaraldehydes are not recommended for surface disinfection.

g. Surface Disinfection.

- (1) Extraordinary efforts to disinfect or sterilize environmental surfaces such as walls, floors, and ceilings generally are not required because these surfaces generally do not transmit infections to patients or health care workers. However, routinely clean and remove soil from them.
- (2) After contamination, wipe all other treatment room surfaces such as countertops, dental chairs, light units, exam tables, and non-sterile objects in the operating field with absorbent toweling to remove any extraneous organic material, and then disinfect them with a suitable chemical germicide. Personnel shall wear heavy-duty ("Nitrile") rubber utility gloves when applying surface disinfectants. Many different chemical disinfectants possessing varying degrees of effectiveness are available. The following three surface disinfectants are recommended.

- (a) Iodophor. Iodophor compounds contain 0.05 to 1.6% iodine and surface-active agents, usually detergents, which carry and release free iodine. Iodophor's antimicrobial activity is greater than that of iodine alone: 10 to 30 minutes of contact produces intermediate levels of disinfection. Iodophors are EPA-approved as effective when diluted 1:213 with water. Because iodine's vapor pressure is reduced in iodophor, its odor is not as offensive. In addition, iodophors do not stain as readily as iodine.
  - (b) Phenolics. In high concentrations, phenolic compounds are protoplasmic poisons. In low concentrations, they deactivate essential enzyme systems. As disinfectants, phenolics are usually combined with a detergent; 10 to 20 minutes of contact produces disinfection. Phenolics are less corrosive to treated surfaces.
  - (c) Sodium Hypochlorite. Sodium hypochlorite is thought to oxidize microbial enzymes and cell wall components. A 1:10 dilution of 5.25% sodium hypochlorite in water produces a solution which disinfects at an intermediate level in 10 minutes. Sodium hypochlorite solution tends to be unstable, so prepare a fresh solution daily. It possesses a strong odor and can harm eyes, skin, clothing, upholstery, and metals (especially aluminum).
- (3) Chemical Disinfectants Not Recommended For Use.
- (a) Alcohol. Alcohol is bactericidal against bacterial vegetative forms by denaturing cellular proteins. Diluted in water, a 70 to 90% solution is more effective than a more concentrated solution. Alcohol's disadvantages are: (1) rapid evaporation, (2) lack of sporicidal or viricidal activity, and (3) rapid inactivation by organic material. Since alcohol interferes with proper surface cleansing, it has no place in the disinfection protocol.
  - (b) Quaternary Ammonium Compounds. In the past, benzalkonium chlorides and other "quats" were used as disinfectants because they were thought to be safe and inexpensive and have low surface tension. Their biocidal activity breaks down the bacterial cell membrane, producing an altered cellular permeability. As a group, these compounds have serious deficiencies. Being positively charged, they are attracted to not only bacteria but also to glass, cotton, and proteins, which decrease their biocidal activity. Common cleaners, soaps, and other compounds negatively charged ions neutralize "quats." Research has shown some "quats" support the growth of gram-negative organisms. Quats are ineffective against most spore formers, the Hepatitis B virus, and the tubercle bacillus.

10. Clinic Attire.

- a. Definition. Clothing ensembles worn during routine direct patient encounters when not anticipating exposure to blood or OPIM is considered clinic attire.
- b. Approved clinic attire. Approved clinic attire is defined as military uniforms or surgical scrubs only. Clinical attire is NOT intended to be PPE and must be supplemented by PPE whenever exposure to blood or OPIM is reasonably anticipated. Surgical scrubs worn as clinic attire shall be worn in designated direct patient care work areas of the clinic, only when engaged in direct patient care activities and shall not be worn outside the clinic. Undergarments worn under scrubs will be the same as those required to be worn under military uniforms. Under no circumstances should long-sleeve undergarments be worn. When arms need to be covered when performing procedures, long sleeve PPE should be worn. The work area is defined in OSHA BBP plan as the area where potential blood borne exposure exists, including corridors or passageways in direct patient care areas.
- c. Soiled Clinic attire. Clinic attire that is visibly soiled with blood, OPIM or that had been exposed to contaminated spray or splatter is considered contaminated. PPE is always considered contaminated even if no visible evidence of contamination is present. At no time shall PPE or contaminated clinic attire be worn in administrative areas, break areas, or areas where food or potable drink are stored, prepared or consumed.
- d. PPE or contaminated clinic attire. Except for commercial laundering, PPE or contaminated clinic attire shall not be removed from the clinic's direct patient care area, nor shall it be stored in personal clothing lockers nor removed from the clinic.
- e. Name tags. When wearing surgical scrubs, military uniforms and civilian clothing as clinical attire, HCWs must also wear a name tag that includes name, rank and occupation (i.e. Physician, Dentist, Physician Assistant, Nurse Practitioner, and Health Service Technician) clearly visible to all patients.

#### 11. Storage and Laundering of Clinic Attire, PPE and Linen.

- a. Laundering clinic attire and PPE. Military uniforms and civilian clothing worn as clinic attire that is visibly soiled with blood or OPIM or have been exposed to contaminating spray and spatter is considered contaminated laundry and shall be commercially laundered only at the expense of the unit. PPE is considered contaminated even if no visibly evidence of contamination is present and shall be commercially laundered at the expense of the unit. All linen shall be commercially laundered at the expense of the unit. All surgical scrubs, even if not contaminated will not be taken home for self-laundering and shall be commercially laundered only at the expense of the unit.

- b. Handling contaminated laundry. Contaminated laundry, including scrubs, shall be placed and transported in bags labeled or color-coded in accordance with OSHA Regulation, Bloodborne Pathogens Standards, 1910.1030(g)(1)(i). (If contaminated laundry is wet, bags or containers must prevent leakage or soak-through). Gloves and other appropriate PPE will be worn when handling contaminated laundry.
    - c. Linens. Although research has identified soiled linens as a source of large numbers of certain pathogenic microorganisms, the risk of linens actually transmitting disease is negligible. When handling soiled linen, it is recommended to always wear gloves. Handle it as little as possible and with minimum agitation to prevent gross microbial contamination of the air and persons handling the linen. Carefully check linen for sharps objects and remove them before washing. Bag all soiled linen where used; do not sort or rinse it in patient care areas.
12. Cleaning and Decontaminating Blood or Other Body Fluid Spills. Use an EPA-approved germicide or recommended surface disinfectant agent to promptly clean all blood and blood-contaminated fluid spills. Health care workers must wear gloves. First remove visible material with disposable towels or other appropriate means that prevent direct contact with blood. If anticipating splashing, wear protective eyewear and an impervious gown or apron that provides an effective barrier to splashes. Next decontaminate the area with disinfectant solution or an appropriate EPA-approved germicide. Clean and decontaminate soiled cleaning equipment or put it in an appropriate container and dispose of it according to clinic policy. Use plastic bags clearly labeled as containing infectious waste to remove contaminated items from the spill site. Remove gloves; then wash hands.
13. Infectious Waste.
  - a. Medical waste. Epidemiological evidence does not suggest most clinic waste is any more infectious than residential waste. However, public concern about the risk of medical wastes must not be ignored. Identifying wastes for which special precautions are necessary include those wastes which potentially cause infection during handling and disposal and for which special precautions appear prudent, including sharps, microbiology laboratory waste, pathology waste, and blood specimens or products. While any item that has touched blood, exudates, or secretions potentially may be infectious, it is usually not considered practical or necessary to treat all such waste as infectious. Materials containing small amounts of blood, saliva, or other secretions such as tainted gauze pads, sanitary napkins, or facial tissues are not considered infectious waste. Generally, autoclave or incinerate infectious waste before disposing of it in a sanitary landfill. Infectious waste autoclaving standards are different from normal sterilization standards. Carefully pour bulk blood, suctioned fluids, excretions, and secretions down a drain connected to a sanitary sewer. Or for materials



capable of it, grind and flush such items into sanitary sewers (some states prohibit this practice).

- b. Environmental Protection Agency classification. The Environmental Protection Agency classifies health care facilities as generators of infectious waste based on the weight of waste generated. CG classification is based on facility type. All CG clinics are considered generators. Each CG health care facility must have a written infectious waste management protocol consistent with state and local regulations in the unit's area.
- c. Biohazard. Biohazard warning labels shall be affixed to regulated waste containers; refrigerators, and freezers containing blood or other potentially infectious material; and other containers used to store, transport, or ship blood or other potentially infectious materials with these exceptions:
  - (1) Substitute red bags for labels on regulated waste bags or containers. OSHA believes red bags protect personnel because they must comply with OSHA BBP Standard Paragraph (g)(2)(iv)(M), which requires training personnel to understand the meaning of all color-coding.
  - (2) Individual containers of blood or other potentially infectious materials placed in a labeled container during storage, transport, shipment or disposal.

#### 14. Managing Exposures (Bloodborne Pathogen Exposure Control).

- a. Exposure.
  - (1) An exposure occurs if a health care worker comes in contact with blood or other body fluids in one of these ways:
    - (a) Parenteral—through a needle stick or cut;
    - (b) Mucous membrane—from a splash to the eye or mouth;
    - (c) Cutaneous—contact with large amounts of blood or prolonged contact with blood when the health care worker's exposed skin is chapped, abraded, or afflicted with dermatitis.
  - (2) After an exposure, if the source of the exposure is known, obtain the source person's consent (if applicable), making sure to follow local laws governing consent for testing non-active duty source persons and incompetent or unconscious persons.
  - (3) The treating healthcare provider will perform an initial screening of the exposure incident to determine if the "source" is known to be HIV positive. This should be done within 15 minutes of the exposure. If the "source" is known to be HIV positive, the treating physician will contact the nearest

hospital with infectious disease services, notify them of the exposure and arrange a time for the exposed worker to be seen ASAP.

- (4) Post-exposure prophylaxis (PEP) should be initiated as soon as possible, preferably within hours rather than days of exposure. If a question exists concerning which antiretroviral drugs to use, or whether to use a basic or expanded regimen, the basic regimen should be started immediately rather than delay PEP administration. The optimal duration of PEP is unknown, however the CDC recommends a 4 week period for PEP. The nearest local hospital with infectious disease services should be consulted for additional guidance.
- (5) If the HIV status of the source is not known, a rapid HIV antibody test should be performed on the source at the nearest local hospital or USMTF (protocol for clinic use of rapid HIV antibody testing will be developed soon). Each clinic should have a local hospital point of contact who can assist with obtaining stat HIV results. Viomed should not be utilized for stat testing because the results will not be available until 48 hours post-exposure. If the test is positive, the treating physician should prescribe HIV PEP based on CDC guidelines.
- (6) In addition to determining the HIV status of the source, a blood sample should be drawn and tested for, Hepatitis B Surface Antigen, Hepatitis C Antibody, and for the ALT status of the source person. Provide the source person post-test counseling and treatment referrals. Inform the exposed person of the source person's test results and applicable laws and regulations on disclosing the source person's identity and infectious status. It is extremely important all persons who seek consultation for any HIV-related concerns receive appropriate counseling from a USMTF or other medical facility capable of providing this service.
- (7) After an exposure, any worker (active duty, civilian, or contractor) incurring an exposure to blood/body fluids will wash or flush the area for at least 5 minutes, and then report the exposure immediately to their supervisor. The exposed individual is to then seek medical attention immediately. Workers reporting to an outside facility initially should follow-up at a CG clinic on the next day (during regular business hours).
- (8) Recommendations for Hepatitis B PEP and HIV PEP are located in paragraphs (b) and (c). Currently, there is no recommendation for Hepatitis C PEP. Both active duty and civilian workers will be followed by the local CG clinic. Contract workers will be contacted by a healthcare provider to educate them on their need to follow-up with their private physician and to provide them the results on the "source".
- (9) All clinics shall ensure the health care professional evaluating a worker after an exposure incident has this information:

- (a) A copy of the OSHA BBP Standard;
  - (b) A description of the exposed employee's duties as they relate to the exposure incident;
  - (c) Documentation of the route(s) of exposure and circumstances under which exposure occurred; and
  - (d) Results of the source individual's blood tests, if available; and all records on the employee's appropriate treatment, including vaccination.
- (10) The SME shall obtain and give the exposed person a copy of the evaluating health care professional's written opinion within 15 days after the evaluation is complete. The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following:
- (a) Written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.
  - (b) The employee has been informed of the results of the evaluation.
  - (c) The employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.
- (11) A copy of the SME's written opinion will also be provided to the SHSO or health services department head. The QI coordinator or his or her designee also will retain a copy and ensure all required follow-up treatment and testing is documented. The SHSO or health services department head shall ensure that the following this management protocol is adhered.
- (12) Utilize CG-6201, Bloodborne Pathogen Exposure Guidelines.
- b. Hepatitis B Virus Post-exposure Management.
- (1) For a worker exposed to a source individual found to be positive for HbsAg:
- (a) The exposed worker who has not previously received Hepatitis B vaccine will receive the vaccine series. A single dose of Hepatitis B immune globulin (HBIG) if it can be given within 7 days of exposure is also recommended.
  - (b) Test the exposed worker who has previously received Hepatitis B vaccine for antibody to Hepatitis B surface antigen (anti-HBs). If the antibody level in the worker's blood sample is inadequate (i.e., less

than 10 SRU by RIA, negative by EIA) give the exposed employee one dose of vaccine and one dose of HBIG.

- (2) If the source individual is negative for HbsAg and the worker has not been vaccinated, the worker shall receive Hepatitis B vaccination.
- (3) If the source individual refuses testing or cannot be identified, the unvaccinated worker should receive the Hepatitis B vaccine series. Consider administering HBIG on an individual basis if the source individual is known or suspected to be at high risk of HBV infection. At his or her discretion the responsible Medical Officer will manage and treat as needed previously vaccinated workers who are exposed to a source who refuses testing or is not identifiable.
- (4) Additional guidance on Hepatitis B PEP be found at the CDC Updated USPHS Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis, MMWR, June 29, 2001 / 50(RR11):1-42 – <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

c. Human Immunodeficiency Virus Post-exposure Management.

- (1) Workers who have an occupational exposure to HIV should receive follow-up counseling, post-exposure testing, and medical evaluation regardless of whether they receive PEP. In view of the evolving nature of HIV post-exposure management, the health care provider must be well informed of current CDC guidelines on this subject. The basic regimen includes:
  - (a) Zidovudine (Retrovir, ZDV, AZT) plus lamivudine (Epivir, 3TC) which is available as Combivir. The preferred dosing is - ZDV: 300 mg twice daily or 200 mg three times daily, with food; total: 600 mg daily plus 3TC: 300 mg once daily or 150 mg twice daily or as Combivir: one tablet twice daily (300 mg ZDV + 150 mg 3TC ); OR
  - (b) Zidovudine (Retrovir, ZDV, AZT) plus emtricitabine (Emtriva, FTC). The preferred dosing is - ZDV: 300 mg twice daily or 200 mg three times daily, with food; total: 600 mg/day, in 2-3 divided doses plus FTC: 200 mg (one capsule) once daily; OR
  - (c) Tenofovir (Viread, TDF) plus lamivudine (Epivir, 3TC). The preferred dosing is - TDF: 300 mg once daily plus 3TC: 300 mg once daily or 150 mg twice daily; OR
  - (d) Tenofovir (Viread, TDF) plus emtricitabine (Emtriva, FTC) which is available as Truvada. The preferred dosing is - TDF: 300 mg once daily plus FTC: 200 mg once daily or as Truvada: one tablet daily.

- (2) For alternate basic regimens, consult an infectious disease physician or refer to the CDC Updated USPHS Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis, MMWR, September 30, 2005 / 54(RR09):1-17 - <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>. If a provider prescribes Lopinavir/ritonavir (Kaletra) – the preferred dosing listed in the CDC reference is erroneous. The correct dosing is LPV/RTV: 400/100 mg.
- (3) The Bloodborne Pathogen Exposure Control Plan Instruction, COMDINST M6220.8 (series), offers additional guidance on HIV PEP. If PEP is used, workers should be monitored for drug toxicity by testing at baseline and again 2 weeks after starting PEP. The scope of testing should be based on medical conditions in the exposed person and the toxicity of drugs included in the PEP regimen. Minimally, laboratory monitoring for toxicity should include a complete blood count and renal and hepatic function tests. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies might be indicated.
- (4) Exposed workers who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided about potential drug interactions and drugs that should not be taken with PEP, side effects of prescribed drugs, measures to minimize side effects, and methods of clinical monitoring for toxicity during the follow-up period. Evaluation of certain symptoms (e.g., rash, fever, back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia (e.g., increased thirst or frequent urination) should not be delayed.
- (5) After the initial test at the time of exposure, retest seronegative workers 6 weeks, 12 weeks, and 6 months after exposure to determine whether HIV transmission has occurred. Extended HIV follow-up (e.g., for 12 months) is recommended for workers who become infected with the HCV after exposure to a source coinfecting with HIV and HCV. During this follow-up period (especially the first 6 to 12 weeks after exposure, when most infected persons seroconvert), exposed workers must follow CDC recommendations to prevent transmitting HIV, including refraining from blood donation, informing health care workers rendering treatment of his or her status, and using appropriate protection during sexual intercourse. During all phases of follow-up, it is vital to protect worker confidentiality.
- (6) Advise the exposed worker to report and seek medical evaluation for any acute febrile illness occurring within 12 weeks after exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may indicate recent HIV infection. HIV testing should be performed on any exposed worker who has an illness compatible with an acute retroviral syndrome, regardless of the interval since exposure. A person in whom

HIV infection is identified should be referred for medical management to a specialist with expertise in HIV treatment and counseling.

- (7) If the source individual's tests are seronegative, perform a baseline testing of the exposed worker with optional follow-up testing 12 weeks later if the worker desires or the health care provider recommends it. After the initial test at the time of exposure, at the responsible Medical Officer's discretion, retest consenting seronegative source individuals at 12 weeks and 6 months afterward.
  - (8) If the source individual cannot be identified, decide appropriate follow-up on an individual basis. All workers concerned they have been infected with HIV through an occupational exposure should undergo serologic testing.
  - (9) Follow CDC recommendations for preventing HIV and HBV transmission to patients during exposure-prone procedures, defined as those invasive procedures with a recognized risk of percutaneous injury to health care workers.
  - (10) All health care workers shall adhere to standard precautions. Health care workers with exuding lesions or weeping dermatitis shall refrain from all direct patient care. Health care workers shall comply with current CDC guidelines for disinfecting and sterilizing equipment and supplies.
  - (11) All health care workers performing exposure-prone procedures shall know their HIV and HBV status.
  - (12) All health care workers who are HIV or HBV positive shall refrain from performing exposure-prone procedures.
15. Training Personnel for Occupational Exposure. All Health Services Divisions or Branches will inform and train personnel in occupational exposure initially on assignment and annually thereafter. Personnel who have taken appropriate training within the past year need to receive additional training only on subjects not previously covered. The training program shall contain at least these elements:
- a. An accessible copy and explanation of the regulatory text of this standard (Federal Register 56 (235): 64175, December 6, 1991 [29 USC 1910.1030]).
  - b. A general explanation of the epidemiology and symptoms of bloodborne diseases.
  - c. An explanation of bloodborne pathogen transmission modes.
  - d. An explanation of the exposure control plan outlined in Section 13-J.

- e. An explanation of the appropriate methods to recognize tasks and other activities that may involve exposure to blood and other potentially infectious materials.
- f. An explanation of methods to reduce or prevent exposure, such as barrier techniques, and their limitations.
- g. Information on the types and properly using, locating, removing, handling, decontaminating, and disposing of personal protective equipment.
- h. An explanation of the basis for selecting personal protective equipment.
- i. Hepatitis B vaccine. Information on the Hepatitis B vaccine, including efficacy, safety, administration, and benefits. This vaccination is mandatory for active duty and reserve personnel.
- j. Information on appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.
- k. Explanation of the procedures. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and available medical follow-up described in Section 13-J-13.
- l. Information on the post-exposure evaluation and follow-up the Senior Medical Officer (SMO) or designee is required to provide for the employee after an exposure incident.
- m. An explanation of the signs, labels, and/or color coding required for sharps and biohazardous materials.
- n. A question-and-answer period with the person conducting the training session.

This page intentionally left blank.



Section K. Patient Safety and Risk Management Program.

1. Purpose.....	1
2. Informed Consent.....	1
3. Adverse Event Monitoring and Reporting.....	4
4. Patient Safety Training .....	8

This page intentionally left blank.

K. Patient Safety and Risk Management Program.

1. Purpose.

- a. Background. The patient safety and risk management program supports quality medical care by identifying, analyzing, and preventing actual and potential risks to patients and staff. The program provides mechanisms to detect and prevent medical errors, accidents and injuries and reduces the cost of claims and loss of other resources. Patient safety involves a variety of clinical and administrative activities that identify, evaluate and reduce the potential for harm to beneficiaries and to improve the quality of health care.
- b. Responsibilities. Patient safety and risk management programs are most effective if they are prospective, preventive, and comprehensive. All staff members, beneficiaries, contract providers, and volunteers shall be aware of risks in the clinical environment and act safely and responsibly to implement program requirements. Patient safety and risk management activities are not limited to claims activities but examine all instances of actual and potential risk or loss. Successful patient safety programs facilitate a non-punitive, interdisciplinary approach to decrease unanticipated adverse health care outcomes. The organizational focus is on continued learning about risks and risk management strategies and reengineering systems/processes to reduce the chance of human error.

2. Informed Consent.

- a. Background. Every person, with a few exceptions, has the right to be examined and treated only in the manner they authorize. This individual prerogative is based on the concept a competent patient has the right to make informed decisions about health care. Consent for health care must be informed, voluntary, competent, and specific, and is clearly an important issue in quality patient care. The objective of informed consent is improved patient-provider communication in non-emergent situations, which should result in patients' realistic expectations about the nature of treatment and the expected outcome, and reduced liability for the government. Clear documentation demonstrating the patient was properly informed is necessary to protect the patient, the provider, and the government. Although patients must be informed of treatment options, military members who refuse treatment necessary to render them fit for duty (including immunization) are subject to separation and/or disciplinary action (see Chapter 2-Section A. 4. b.).
- b. Responsibilities.
  - (1) SHSO: The SHSO must publish facility-specific implementing instructions that ensure providers carry out the spirit and intent of this Section. The SHSO and HSWL SC should monitor compliance with consent policies and procedures as a regular part of medical and dental records review.

- (2) Health Care Providers: Responsible health care providers must counsel patients before treatment and document receiving the patient's informed consent.

c. Types of Consent.

- (1) Expressed Consent: This type of consent is obtained by open discussion between the provider and patient and must include a statement the patient consents to the proposed procedure. Expressed consent may be oral or written.
  - (2) Oral Consent. Except where this regulation specifically requires written consent, oral consent is sufficient authorization for treatment. However, oral consent is difficult to prove. If a health care provider receives oral consent to treatment, he or she must document it by an entry in the treatment record. Consent received from competent authority by telephone is a form of oral expressed consent; a person not directly involved in the patient's care should witness such consent; and it must be documented by an entry in the treatment record.
  - (3) Conditions Requiring Written Consent. Document written consent by having the patient sign forms authorizing treatment and including an entry in the treatment record that discusses the requirements outlined in Paragraph 13-K-4. Except in emergencies, written consent is required for these situations:
    - (a) All surgical procedures (including, among others, placing sutures, incision and drainage, removing a foreign body(s), cauterizing, removing wart(s), injecting medications into a joint(s), etc.)
    - (b) Invasive tests and procedures to diagnose and treat disease or remove tissue specimens (e.g., biopsies), except routine phlebotomy.
    - (c) Anesthesia, including local dental anesthesia.
    - (d) All dental procedures.
    - (e) Genitourinary procedures including vasectomies, IUD insertion or removal, etc.
- d. Implied Consent. Implied consent is derived from the patient's conduct even if he or she does not communicate specific words of consent. Assume implied consent only if one can reasonably presume the patient knows the risks, benefits, and alternatives to treatment. For example, a patient's presence at dental sick call is implied consent for a dental exam. Never accept implied consent to treatment involving surgical therapy or invasive diagnostic procedures except in emergencies.

- e. Emergencies. Consent before treatment is not necessary when immediate treatment is required to preserve the patient's life or limb. The provider will document the existence and scope of the emergency and describe the events precluding obtaining consent.
- f. Who May Consent. Generally, competent adult patients who have the capacity to manage their own affairs who present themselves for treatment have the authority to consent. If a patient is incompetent due either to statutory incompetence (e.g., a minor) or mental impairment, then it must be determined who the individual with legal capacity to consent and obtain his or her consent before examining or treating the patient. Laws defining minors and to what they may legally consent differ by state. The law of the state where the facility is located governs legal capacity to consent. Each clinic will develop a policy for treating minors.
- g. Information to Provide. The provider must advise the patient of the nature of his or her condition; describe the proposed treatment in terms the patient can understand; and explain the material risks and expected benefits of the proposed treatment course, available alternative health care options, and the option of non-treatment. A material risk is one a reasonable person likely would consider significant in deciding whether to undertake therapy and is a function of the likelihood of occurrence, the severity of the injury it threatens to cause, and existing reasonable alternatives. A provider is not required to explain risk that are considered extremely remote unless the patient requests an explanation or the potential adverse consequences are so grave a reasonable person in the patient's particular circumstances would consider the risk important.
- h. Informing the Patient. Health care providers will provide information in a manner that allows a patient of ordinary understanding to intelligently weigh the risks and benefits when faced with the choice of selecting among the alternatives or refusing treatment altogether. Health care providers must communicate in language one can reasonably expect the patient to understand. Although open discussions between the responsible health care provider and the patient should be the standard, each department may develop internal methods to acquaint patients with the benefits, risks, and alternatives to procedures requiring consent. In some departments, prepared pamphlets or information sheets may be desirable.
- i. Documentation. Regardless of the method used to inform the patient or the form of consent (oral or written), the provider must document the disclosure and the patient's reactions in the medical or dental record. It is highly recommended to document this in progress notes even if the patient has signed a preprinted "consent" form. Progress notes written to document disclosing information to the patient will be specific about the information provided. The notes must specifically enumerate risks, alternative forms of treatment, and expected benefits the provider discussed with the patient. Use the Request for Administration of Anesthesia and for Performance of Operations and Other

Procedures, SF-522 to document consent in all surgical, anesthetic and reproductive procedures.

- j. Witness to Consent. All consent forms require a witness's signature. The witness may be a health care facility member who is not participating in the procedure or treatment. Patients' relatives are not acceptable as witnesses. The witness confirms the patient signed the form, not that he or she received all relevant information.
- k. Duration of Consent. Consent is valid as long as no material change in circumstances occurs between the date the patient consented and the procedure or treatment date. Obtain new consent if a material change in circumstances occurs, for example the provisional diagnosis changes. If more than seven (7) days elapse between the date the patient signed the consent and the date treatment begins, provider and patient must re-sign, re-initial, and re-date the consent form. A new consent is not required for each stage in a series of treatments for a specific medical condition (e.g., repeated application of liquid nitrogen to warts).

3. Adverse Event Monitoring and Reporting.

a. Definitions.

- (1) Action Plan: The end product of a Root Cause Analysis that identifies the risk reduction strategies to prevent the recurrence of similar adverse events.
- (2) Adverse Event: An occurrence or condition associated with the provision of health care or services that may result in harm or permanent effect. Adverse events may be due to acts of omission or commission. Incidents such as falls or erroneous administration of medications are also considered adverse events even if there is no harm or permanent effect.
- (3) Contributing Factors: Additional reasons for an event or series of events that may result in harm, which could apply to individuals, systems operations or the organization.
- (4) Near Miss: An event or situation that could have resulted in harm but did not either by chance or timely intervention.
- (5) Root Cause: The most basic reason that a situation or treatment did not turn out as planned or as expected.
- (6) Root Cause Analysis: A process for identifying the basic or contributing causal factor(s) associated with a sentinel event, an adverse event or close call. The review is interdisciplinary and includes those who are closest to the process, and focuses on systems and processes, not individual performance. An ad hoc Root Cause Analysis Team, with membership as

necessary depending on the event, is identified by the patient safety official to develop the Root Cause Analysis and Action Plan.

- (7) **Safety Assessment Code:** A risk assessment tool that considers the severity of an adverse or near miss event together with the probability of the event’s recurrence. The score, or Safety Assessment Code, assigned to the event determines the type of action that should be taken, e.g., Root Cause Analysis (score 3), intense analysis (score 2 or 1) or no action. Severity is divided into four categories – catastrophic, major, moderate, and minor. Probability is divided into three categories – high, medium, and low. This provides a standardized process for prioritizing actions and applying resources where there is the greatest opportunity to improve safety.

**SAC Scoring**

• What is the SAC Score?

Severity Frequency	Catastrophic	Major	Moderate	Minor
High	3	3	2	1
Medium	3	2	1	1
Low	3	2	1	1

Slide 8 of 31

Table 13-K-1

- (8) **Sentinel Event:** An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof that is not related to the natural course of an individual’s illnesses or underlying condition. Such events signal the need for immediate investigation and proactive response on the part of the organization.
- b. **Significant Events.** Events are not reviewed to place blame or discipline those involved, but rather to assess the health care process (es) and systems involved and identify potential areas for improvements in patient safety. The CG Health Care Program uses the resulting recommendations to determine health care policy, personnel, equipment and training needs to prevent future adverse health care outcomes or patient injuries. A significant event may result in initiating a Mishap Board as the Safety and Environmental Health Manual, COMDTINST M5100.47 (series), requires and a legal investigation conducted concurrently with a medical incident review of the same event (e.g., a vessel collision with

injuries). In most cases however, an adverse event review will occur solely within a CG health care facility or the CG Health Care Program.

- c. Responsibilities.
  - (1) SHSO: The SHSO must publish facility-specific implementing instructions that ensure providers carry out the spirit and intent of this Section.
  - (2) Health Care Providers: Identification and reporting of near misses and adverse events must be encouraged as an expectation of everyday practice by CG health care. Prevention of harm to patients and reporting all potential and/or adverse events is a performance expectation for all CG health care program staff.
- d. Immediate Actions. Upon identification of a patient safety event, the staff member will immediately perform necessary health care interventions to protect and support the patient(s). Practitioners will be contacted as soon as possible to report the incident and provide an update. The staff member/practitioner will take all necessary health care interventions to contain risk and to present event-related materials that may be needed for analysis or investigation.
- e. Reporting Procedure. Within 24 hours after an adverse event occurs, the command shall submit copy(s) of Emergency Care and Treatment Report, SF-558 and/or Chronological Record of Care, SF-600 for events occurring within the clinic and/or Emergency Medical Treatment Report, CG-5214 for events occurring outside the clinic to the HSWL SC. Clearly mark "Patient Safety Report" in large print across the top of these forms. Stamp or print this statement on the top of each document: "This is a medical quality assurance document. It is protected by Federal law." HSWL SC shall send copies of the documents to Commandant (CG-112) within three days of receipt.
- f. Review Procedure. On receiving one of the three forms, HSWL SC conferring with Commandant (CG-112), shall review the document(s); verify the event meets the Paragraph 13-K-3 criteria for an adverse event or near miss; determine whether an on-site medical review or Root Cause Analysis shall be conducted; and designate a single point of contact at Commandant (CG-112). A Root Cause Analysis must be conducted and an Action Plan completed for all adverse events with Severity Assessment Code 3.
  - (1) If HSWL SC after conferring with Commandant (CG-112), determines a medical incident review is unnecessary, they shall notify the command by letter within 10 working days of the event and send a copy of the letter to Commandant (CG-112).
  - (2) If an on-site medical incident review or Root Cause Analysis is indicated, HSWL SC shall notify the involved command as soon as possible and designate a clinic professional staff member to conduct a review or convene a panel of qualified professional staff members from the involved facility,



to review all aspects of the incident. To ensure confidentiality, the panel shall consist of only the designated facility point of contact and the persons HSWL SC appoint.

- (3) If a patient safety event is an intentional unsafe act that results from gross negligence or possible criminal activity, the event shall be reported to the appropriate authorities for investigation.
- g. Incident review officer or Root Cause Analysis Team. The incident review officer or Root Cause Analysis Team shall request and review all relevant documents and reports, interview personnel as required, and when the review is complete, submit a written letter report with this information on the incident to Commandant (CG-112) through the HSWL SC:
- (1) Synopsis. A brief summary of the incident and injuries and/or fatalities involved.
  - (2) Factual Information. Factual information and data about the incident and personnel involved shall consist of at least these topics:
    - (a) History. The chronological order of any significant event preceding, during, and after the incident, including any written logs or transcripts of radio logs substantiating this chronology, such as the Emergency Care and Treatment, SF-558, the Emergency Medical Treatment Report, CG-5214, or the Chronological Record of Care, SF-600.
    - (b) Injuries. Describe each injury, or in the case of fatalities, the cause of death. Include autopsy findings when available.
    - (c) Professional qualifications of all persons who delivered health care, if relevant, including all recent applicable training and certificates (e.g., ACLS, BLS, EMT, HS, etc.).
    - (d) Equipment Performance. List all pertinent medical equipment used during the incident and any failures due to mechanical malfunction, operator error, inadequate training, or other factors. Describe whether equipment involved was maintained or serviced according to manufacturers' specifications.
    - (e) Applicable Medical and/or Dental Guidelines.
  - (3) Analysis and Conclusions. The analysis and conclusion should contain the individual's or panel's hypothesis of the circumstances surrounding the event, emphasizing the health care aspect, including a brief conclusion about the health care rendered and how it contributed to the event's outcome.

- (4) Action Plan. The action plan comprises recommended modifications and risk reduction strategies in policy, staffing, equipment, training, or other health care delivery system aspects that need improvement to avoid similar incidents in the future. The action plan should address responsibility for implementation, oversight, pilot testing (if appropriate), timelines and the metrics to be used in evaluating the effectiveness of the actions taken.

h. Routing Patient Safety Review Reports.

- (1) The completed root cause analysis report will be sent from the clinic to Commandant (CG-112) thru HSWL SC for review and appropriate action.
- (2) Staff members who submit patient safety event reports shall receive timely feedback on the actions being taken as a result of their report. Management efforts and activities shall focus on improving the systems and processes that may have contributed to the patient safety event.
- (3) In cases involving an unanticipated outcome of care, a qualified health care provider shall inform the patient. QI-protected information shall not be released or provided to the patient. During the communication, at least one other health care program staff member should be present. The provider shall document in the patient's record what was communicated.

4. Patient Safety Training.

- a. All health care program staff shall receive patient safety, risk management and teamwork education during their initial orientation and on an as-needed basis.
- b. Patient safety topics shall include an overview of the patient safety and risk management program, roles and responsibilities in reporting patient safety events, patient education in safety and effective communication strategies.

Section L. Training and Professional Development.

1. Definitions..	1
2. Unit Health Services Training Plan (In-Service Training).	1
3. Emergency Medical Training Requirements.	3
4. Health Services Technician "A" School.	4
5. Health Services Technician "C" Schools.	4
6. Continuing Education Programs.	5
7. Long-Term Training Programs.	6

This page intentionally left blank.

## Section L. Training and Professional Development.

### 1. Definitions.

- a. ACLS (Advanced Cardiac Life Support). Sponsored by the American Heart Association (AHA) and American Safety and Health Institute (ASHI), this 16-hour program (8 hours for recertification) emphasizes cardiac-related diagnostic and therapeutic techniques and grants a completion certificate valid for two years on completion. An ACLS certificate of completion recognizes a person completed the course and does not in any way authorize him or her to perform skills taught there. ACLS also sometimes refers to the cardiac component of Advanced Life Support. Online ACLS courses without hands-on skills proficiency testing are not accepted substitutes for the ACLS courses noted above.
- b. Advanced Life Support (ALS). A general term applied to pre-hospital skills beyond the basic life support level including, among others, EKG interpretation, medication administration, and advanced airway techniques.
- c. Basic Life Support (BLS) for the Health Care Provider. Health care providers must successfully complete and maintain proficiency in a program sponsored by any of the following: The Military Training Network, American Heart Association (AHA), American Red Cross (ARC), American Safety & Health Institute (ASHI) or the American College of Emergency Physicians (ACEP). (The Military Training Network is the preferred choice). Successful completion grants certification for 2 years. The course curriculum of all programs includes basic skills (e.g. airway maintenance, cardiac compression and use of the automatic external defibrillator) necessary to sustain heart and brain function until advanced skills can be administered.
- d. Emergency Medical Technician (EMT). A general term referring to the certification of pre-hospital care providers. Three skill levels (EMT-Basic, EMT-Intermediate, EMT-Paramedic) are recognized, but functions performed at each level vary significantly by jurisdiction. When the term EMT is used alone, it refers to EMT-Basic, which performs BLS skills. The term EMT applies to all CG personnel with EMT training and certification regardless of rating.
- e. Paramedic. An individual certified by the National Registry of Emergency Medical Technicians as an Emergency Medical Technician-Paramedic (NREMTP) or certified by a local governing body to perform ALS procedures under a physician's license.

### 2. Unit Health Services Training Plan (In-Service Training).

- a. Health Services Units. These personnel must have an on-going in-service training program aimed at all providers with emphasis on the Health Services Technicians' professional development. It is expected of clinic staff members attending outside training to share new information with other staff members.

In-service training sessions allow clinics to ensure issues of clinical significance are presented to their staff.

- b. Clinic Training Program must include these topics, among others.
- (1) Quality Improvement Implementation Guide Exercises.
  - (2) Annual review of clinic protocols on suicide, sexual assault, and family violence.
  - (3) Patient satisfaction issues.
  - (4) Patient sensitivity.
  - (5) Patient confidentiality to include HIPAA guidelines.
  - (6) Emergency I.V. therapy.
  - (7) Emergency airway management.
  - (8) Cardiac monitor and defibrillator familiarization.
  - (9) Cervical spine immobilization and patient transport equipment.
  - (10) Emergency vehicle operator's training (where operated).
  - (11) Section 13-J: Infection and Exposure Control Program.
- c. Health Services Training Coordinator (HSTC). The SHSO must designate in writing a Health Services Training Coordinator (HSTC) who coordinates clinic in-service training, distributes a quarterly training schedule, and maintains the unit's health services training record. The HSTC's responsibilities include these:
- (1) Establishes and maintains a Health Services Training Record to document all training conducted within the clinic. Records should include presentation outline, title, program date, name of presenter, and list of attendees. Maintain training records for 3 years from the date on which training occurred.
  - (2) Ensures all emergency medical training is documented in the individual's CG Training Record, CG-5285 for credit toward the 48-hour National Registry EMT continuing education requirement.
  - (3) Maintains a Training Record section that records personnel certifications including CPR, ACLS, EMT, and flight qualifications, including expiration dates and copies of the current certificate. The HSTC should ensure assigned personnel obtain recertification before current certificates expire.

3. Emergency Medical Training Requirements.
- a. BLS Certification. All active duty, civilian, and contract civilian personnel working in CG clinics and sick bays shall maintain current BLS certification at the health care provider level (AHA "C" Course or equivalent).
  - b. SAR or MEDEVAC. Every Health Services Technician, or other CG EMT (eg Rescue Swimmer), who participates in SAR or MEDEVAC operations must be a currently certified EMT by NREMT or equivalent state organization. The Flight Surgeon may authorize, in writing, EMTs to perform BLS and ALS skills in the course of their assigned SAR/MEDEVAC duties.
  - c. Emergency Vehicles. At least one currently certified EMT will staff CG Emergency Vehicles. CG Emergency Vehicles will, at a minimum, meet standards established under Federal Specification KKK-A-1822E and as defined under CFR 42 Part 410 Section 41. Unit CO shall ensure HS's are trained in sufficient numbers under Section 13-L-3.h to meet this requirement. This staffing requirement does not apply to general-purpose vehicles used by the medical department. However, general-purpose vehicles shall not be equipped with emergency warning lights and/or sirens nor shall they display a "star of life" insignia or other emblem implying emergency medical capabilities. Emergency vehicles shall be equipped to provide basic life support (BLS) only. The clinic shall maintain equipment (monitor-defibrillator, advanced airway kit etc.) and medications to provide ALS services in a reserve status and add them when necessary if authorized ALS providers are available.
  - d. ACLS Certification. All Medical Officers serving in clinical assignments will maintain current ACLS certification. Only licensed or certified physicians, nurse practitioners, physician assistants, or nationally registered advanced life support providers (EMT-P and EMT-I) will perform ALS procedures, except as Section 13-L-3.e stipulates. Paramedics may perform functions authorized by their certifying jurisdiction's protocols with written Medical Officer authority. Other than those described this section, persons who have completed an ACLS course should note certification means only they have completed the course and does not convey a license to perform any skill. Individuals completing ACLS courses shall serve as a clinic resource on current standards for pre-hospital care in training and equipment areas. ACLS classes that are electronic only (e-ACLS) do not satisfy this certification requirement. Individuals with documented training and demonstrated proficiency may request and obtain written authorization by a local CG Medical Officer to perform emergency medical procedures not normally associated with EMT-B skill sets (e.g. use of Combitube).
  - e. EMT training (basic course or recertification). Commands shall use local military sources if available. Usually most public service training agencies or community colleges offering training can accept CG personnel. If the required training is not available from a civilian or military source within a 50-mile

radius, commands may use other cost-effective training sources. Submit requests through the chain of command to Commandant (CG-112) with these items:

- (1) Short-Term Resident Training Request, CG-5223;
- (2) Request, Authorization, Agreement and Certification of Training, SF-182;
- (3) Requests for training outside a 50-mile radius which incur per diem expense require the unit CO's or officer-in-charge's statement local training sources are unavailable.

4. Health Services Technician "A" School.

- a. The Office of Personnel and Training operates the 14-week introductory course for Health Services Technicians, including the Emergency Medical Technician (EMT) course, at TRACEN Petaluma. As program manager, Commandant (CG-1121) provides professional comments to the TRACEN on curriculum and qualifying requirements. Commandant (CG-132) controls HS "A" School personnel quotas. The Training and Education Manual, COMDTINST M1500.1(series), outlines selection requirements and procedures.
- b. All HS "A" School students must successfully pass the NREMT-B examination in order to advance to HS3 upon graduation.

5. Health Services Technician "C" Schools.

- a. Training. Due to the specialized nature of health care, the CG requires some Health Services Technicians to complete training in medical specialty fields such as aviation medicine, preventive medicine, medical and dental equipment repair, physical therapy, laboratory, radiology, pharmacy, and independent-duty specialties. The usual sources are Department of Defense training programs and through IDHS training which is conducted at CG Training Center Petaluma.
- b. Selection for HS "C" Schools. Selection for HS "C" Schools is based on qualification code requirements for HS billets at clinics and independent duty sites as specified in personnel allowance lists. Secondary selection criteria include command requests, personnel requests, and deficiencies noted on HSWL SC Quality Improvement Site Surveys.
- c. Training Request. HS personnel should submit a Short-Term Resident Training Request CG-5223, with Command endorsement to Commandant (CG-1121) through the appropriate chain of command. Commandant (CG-1121) must receive this request at least 45 days before the training convening date. HS personnel wishing to pursue "C" school training in courses of 20 weeks or longer require a permanent change of duty station coordinated by Commander, Personnel Service Center (PSC-epm-2).



6. Continuing Education Programs.

- a. Licensing. All PHS and CG Physician Assistants must maintain active professional licenses and/or certification to practice their professional specialty while assigned to the CG. Licensing and/or recertification requirements often demand continuing professional education, which enhances the practitioner's skills and professional credentials.
- b. Funding. The Director of Health and Safety encourages one continuing education course annually for all licensed health services professionals. The funding command using HSC 30 funds will approve the Short Term Training Requests. This program is in addition to the operational medicine (AFC 56) training program (see Medical Manual Chapter 1. Section C). Generally training should provide at least six documented continuing education credits per day pertinent to the applicant's CG billet. Personnel should obtain training at the nearest possible geographic location.
- c. Licensing and Certification Exams. Medical and Dental Officers' licensing and certification exams will not be funded as continuing education. CG-sponsored Physician Assistant (PA) programs' graduates may request funding for examination fees (primary care only), travel to the testing site nearest their current duty station, and per diem associated with obtaining initial certification from the National Commission on Certification of Physician Assistants. The CG funds this one-time exception because it sponsors the PA training program and requires certification for employment. PA's may take the recertification examination in conjunction with the annual physician assistant conference. Travel and per diem will be authorized as annual CME. The member pays recertification examination fees.
- d. Healthcare Provider Training. There are several required medical, dental, leadership, CBRNE, and Disaster training courses. These are listed at <http://www.uscg.mil/hq/cg112/cg1121/medtraining.asp>.
- e. Procedures. Except for Health Service Technician "C" School applicants, Health and Safety Program personnel requesting continuing education must follow these procedures:
  - (1) Each person requesting training must complete Short-Term Resident Training Request, CG-5223 with proper endorsements.
  - (2) Accompany each training request with course literature (e.g., a descriptive brochure) or a brief written description.
  - (3) Submit Request, Authorization, Agreement and Certification of Training, SF 182 (10 parts) with proper endorsements if using a government purchase order to pay tuition or fees.
  - (4) Send all completed forms to Commandant (CG-112) for processing. Send one information copy of the Short Term Training Request, CG-5223 to the

appropriate Maintenance and Logistics Command, Quality Assurance Branch.

- (5) Training requests must arrive at Commandant (CG-112) 8 weeks before the anticipated training convening date. Coast Guard Training Quota Management Center (TQC), Portsmouth, VA, processes approved requests and issues orders.

7. Long-Term Training Programs.

- a. Long-Term Post-graduate Training. Long-Term Post-graduate Training for Medical Officers (Physicians, Physician Assistants, and Nurse Practitioners). This 1- to 2-year program for Medical Officers principally emphasizes primary care (family practice, general internal medicine). Consideration may be given for non-primary care specialties such as sports medicine, occupational health, public health, and preventive medicine. Training in orthopedics is a potential option for mid-level practitioners only. The Health Services Program Manager will consider non-primary care post-graduate medical training only when needed. Applicants also must have applied to their chosen training program and meet its requirements before requesting training. Applicants should have served with the CG Health Services Program for at least 2 years for each year of training received. For physician applicants, highest consideration will be given first to those who have not completed an initial medical residency. Commandant (CG-112) has more information.
- b. Comprehensive Dental Residency. This 2-year program provides Dental Officers advanced training in general dentistry, enabling them to give more effective, comprehensive dental care to CG beneficiaries. The Naval Postgraduate Dental School, National Naval Medical Center, Bethesda, MD, conducts the training, designed to qualify Dental Officers to meet the American Dental Association and the American Board of General Dentistry requirements for specialty board examination. Dental Officers chosen for this program are expected to pursue board certification. For program prerequisites and applications procedures, see the Training and Education Manual, COMDTINST M1500.1 (series).
- c. Health Services Administration. This program provides instruction in facility and personnel management, program planning, cost containment, quality assurance, third-party payment and liability, and medical-legal issues. The program provides training at the undergraduate (bachelor's degree) level for Chief Warrant Officers and senior enlisted HS personnel (Medical Administrators) and post-graduate (master's degree) level for officers in grades O-2, O-3, and O-4. See the Training and Education Manual, COMDTINST M1500.1 (series) for eligibility requirements, prerequisites, and application procedures.
- d. Physician Assistant Program. Conducted at the U.S. Inter-service Physician Assistant Program, Fort Sam Houston TX, this program trains CG personnel

interested in becoming Physician Assistants. Program graduates receive a baccalaureate degree from the University of Nebraska. If they meet eligibility requirements, graduates are offered a direct commission as ensigns as described in the Personnel Manual, COMDTINST M1000.6 (series), Article 1.A.7. Each year, up to three Coast Guard students are selected for training based on Service needs. Training at other institutions is not authorized. See the Training and Education Manual, COMDTINST M1500.1 (series) for eligibility requirements, prerequisites, and application procedures.

This page intentionally left blank.

Section M. Patient Affairs Program.

1. Patient Sensitivity .....	1
2. Patient Advisory Committee (PAC) .....	1
3. Patient Satisfaction Assessment.....	2
4. Patient Grievance Protocol .....	2
5. Congressional Inquiries .....	3
6. Patient Bill of Rights and Responsibilities .....	3

This page intentionally left blank.

M. Patient Affairs Program.

1. Patient Sensitivity.

- a. The importance of patient sensitivity. The CG considers patient sensitivity issues of paramount importance in delivering health care. Important issues in this area include medical record confidentiality, appropriate privacy during medical examination and treatment, respect for patient concerns and cultural backgrounds, and enhancing the patient's perception of the quality of services delivered. Patients are always treated with respect, consideration and dignity.
- b. Training. All clinics shall conduct continuing patient sensitivity training.

2. Patient Advisory Committee (PAC).

- a. Purpose of the PAC. The CG's health services program provides primary health care to a wide array of beneficiaries authorized by law and regulation. Medical Treatment Facilities (MTFs) often are unaware of their population's health problems until patients voice complaints or criticisms to the command. To enable beneficiaries to express their concerns, a PAC must be available to open lines of communication between health care providers and care recipients.
- b. Each CG MTF shall establish a PAC and specify criteria for committee functions. PACs shall include one officer and one enlisted member not assigned to the clinic; an active duty representative from each CG command in the clinic's service area; an active duty representative from each of the other uniformed services using the MTF; a retired representative; and an active duty dependent representative from both officer and enlisted communities.
- c. Meeting Frequency. MTF shall conduct PAC meetings at least quarterly.
- d. The SHSO or his or her designee shall chair the meeting. Meeting minutes shall include recommended actions and an attendance list; and will be forwarded to the CO with a copy to each PAC member. Specific PAC objectives include:
  - (1) Advise the SHSO on the range of services the beneficiary population requires.
  - (2) Serve as a communications link between the MTF and the beneficiaries the members represent.
  - (3) Serve as patient advocacy groups to assure all patients are accorded their rights as described in the Commandant's Patient Bill of Rights and Responsibilities.
  - (4) Patients are provided, to the degree known, complete information concerning their diagnosis, evaluation, treatment and prognosis. When it is medically inadvisable to give such information to a patient, the information

ids provided to a person designated by the patient or to a legally authorized person.

- (5) Patients are given the opportunity to participate in decisions involving their healthcare, except when such participation is contraindicated for medical reasons.
- (6) Assist the SHSO in advising patients of their responsibilities as described in the Commandant's Patient Bill of Rights and Responsibilities. Patients are informed about procedures for expressing suggestions to the organization and policies regarding grievance procedures and appeals.
- (7) Assist the SHSO in establishing patient education programs.
- (8) Advise the SHSO on the acceptability and convenience of the services provided.

3. Patient Satisfaction Assessment.

- a. Patient satisfaction. Assessing patient satisfaction through patient satisfaction surveys has become an effective, efficient method to investigate and measure the quality of the CG health care delivery system from the patient's perspective.
- b. Satisfaction Form Availability. A patient satisfaction survey form shall be available to every patient who receives care at a CG facility. Locally prepared patient satisfaction surveys are authorized for use.
- c. Survey Frequency. Satisfaction surveys will be conducted at least annually for all patient visits during a randomly selected one-week period.
- d. Patient satisfaction survey results. Patient satisfaction survey results shall be provided to the quality improvement focus group for discussion and action and will be documented in meeting minutes. Survey results shall be reported and actions for improvement recommended to the unit CO, HSWL SC, and Commandant (CG-1122).
- e. Care received from civilian providers. Persons distant from a CG clinic can comment about care received from civilian providers by sending a mail-in HSWL SC survey form available from unit Health Services Technicians.

4. Patient Grievance Protocol.

- a. Overview. The CG expects health services personnel to maintain a professional attitude at all times. Our goal to provide the highest quality health care within allotted resources to all beneficiaries with the least personal inconvenience. Despite our best efforts, occasionally a patient will be dissatisfied with the care received.



- b. Individuals with grievances. Whenever possible individuals with grievances should seek out or be referred to the clinic supervisor, health benefits advisor (HBA), or Clinic Administrator (CA) for complaint resolution before leaving the clinic. Refer written or telephone complaints to the appropriate clinic staff member. At a minimum, the complainant shall be given the name of his or her unit Patient Advisory Committee representative, and advise the complainant of the time and place of the next PAC meeting.
  - c. Chain of command. If the clinic supervisor, HBA, or CA cannot resolve the complaint, he or she shall refer the complainant to the senior medical or dental officer as appropriate.
  - d. Unresolved complaint. Refer the complainant to the CO or higher authority only if the patient believes the clinic or PAC has not resolved the complaint.
  - e. Review of complaint. HSWL SC shall review concerns reported on forms mailed to the HSWL SC for quality improvement purposes, action, or referral to an appropriate level for resolution and follow up.
5. Congressional Inquiries.
- a. Congressional liaison staff. Occasionally, circumstances arise in which beneficiaries exercise their right to solicit assistance from their elected Congressional Representative to resolve their complaint with the CG health care system. The CG maintains a Congressional liaison staff to direct inquiries to the appropriate Headquarters office that can best address the issue and respond satisfactorily. Normally Commandant (CG-11) replies to health care problems.
  - b. Investigation. Congressional inquiries require a complete investigation of the circumstances surrounding the issues the beneficiary addresses. To this end, the command, health care facility, and individuals involved must supply supporting documentation and/or statements to assist in the investigation.
6. Patient Bill of Rights and Responsibilities.
- a. Posting the Bill of Rights. Each CG health care facility shall conspicuously display the Commandant's "Patient Bill of Rights and Responsibilities."
  - b. Clinic administrator's responsibility. The "Patient Bill of Rights and Responsibilities" is periodically reviewed and updated by Commandant (CG-1122). The clinic administrator shall assure that the most recent edition of the "Patient Bill of Rights and Responsibilities" is displayed in the clinic.

This page intentionally left blank