

notification procedures in Subpart E of Part 807.

6. In § 888.4230 by revising paragraph (b) to read as follows:

§ 888.4230 Cement ventilation tube.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

7. In § 888.5890 by revising paragraph (b) to read as follows:

§ 888.5890 Noninvasive traction component.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of

Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

8. In § 888.5940 by revising paragraph (b) to read as follows:

§ 888.5940 Cast component.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

9. In § 888.5980 by revising paragraph (b) to read as follows:

§ 888.5980 Manual cast application/removal instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Dated: June 15, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-20195 Filed 9-3-87; 8:45 am]

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Part IV

Department of Defense

Department of the Navy

32 CFR Part 728

Medical and Dental Care for Eligible
Persons at Navy Medical Department
Facilities; Final Rule

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 728

Medical and Dental Care for Eligible Persons at Navy Medical Department Facilities

AGENCY: Naval Medical Command, Navy, DOD.

ACTION: Final rule.

SUMMARY: The Naval Medical Command has promulgated this regulation to describe and publish the policies and procedures for providing medical and dental care to eligible persons at Navy Medical Department facilities. This promulgation enumerates those persons eligible to receive medical and dental care at Navy Medical Department facilities and prescribes the extent and conditions under which medical and dental care may be provided such persons. It updates a Department of the Navy instruction for conformity with Department of Defense directives.

EFFECTIVE DATE: May 14, 1987.

FOR FURTHER INFORMATION CONTACT: Herbert L. Pelham, Program Analyst, Naval Medical Command, Washington, DC 20372-5120, (202) 653-1179.

SUPPLEMENTARY INFORMATION: This revision relates to internal naval management and personnel practices and largely reflects nonsubstantive changes adopted in NAVMEDCOMINST 6320.38. It was determined that invitation of public comment on these changes prior to adoption would be impracticable and is therefore not required under public rulemaking provisions of Parts 296 and 701 of 32 CFR.

List of Subjects in 32 CFR Part 728

Dental health, Government employees, Health care, Military personnel.

Jane M. Virga,

LT, JAGC, USNR, Federal Register Liaison Officer.

Date: August 20, 1987.

Accordingly, 32 CFR Part 728 is revised to read as follows:

PART 728—MEDICAL AND DENTAL CARE FOR ELIGIBLE PERSONS AT NAVY MEDICAL DEPARTMENT FACILITIES**Subpart A—General**

- Sec.
- 728.1 Mission of Navy Medical Department facilities.
- 728.2 Definitions.
- 728.3 General restrictions and priorities.
- 728.4 Policies.

Subpart B—Members of the Uniformed Services on Active Duty

- Sec.
- 728.11 Eligible beneficiaries.
- 728.12 Extent of care.
- 728.13 Application for care.
- 728.14 Pay patients.

Subpart C—Members of Reserve Components, Reserve Officers' Training Corps, Navy and Marine Corps Officer Candidate Programs, and National Guard Personnel

- 728.21 Navy and Marine Corps Reservists.
- 728.22 Members of other reserve components of the uniformed services.
- 728.23 Reserve Officers' Training Corps (ROTC).
- 728.24 Navy and Marine Corps Officer Candidate Programs.
- 728.25 Army and Air Force National Guard personnel.

Subpart D—Retired Members and Dependents of the Uniformed Services

- 728.31 Eligible beneficiaries and health benefits authorized.
- 728.32 Application for care.
- 728.33 Nonavailability statement (DD 1251).
- 728.34 Care beyond the capabilities of a naval MTF.
- 728.35 Coordination of benefits—third party payers.
- 728.36 Pay patients.

Subpart E—Members of Foreign Military Services and Their Dependents

- 728.41 General provisions.
- 728.42 NATO.
- 728.43 Members of other foreign military services and their dependents.
- 728.44 Members of security assistance training programs, foreign military sales, and their ITO authorized dependents.
- 728.45 Civilian components (employees of foreign military services) and their dependents.
- 728.46 Charges and collection.

Subpart F—Beneficiaries of Other Federal Agencies

- 728.51 General provisions—the "Economy Act".
- 728.52 Veterans Administration beneficiaries (VAB).
- 728.53 Department of Labor, Office of Workers' Compensation Programs (OWCP) beneficiaries.
- 728.54 U.S. Public Health Service (USPHS), other than members of the uniformed services.
- 728.55 Department of Justice beneficiaries.
- 728.56 Treasury Department beneficiaries.
- 728.57 Department of State and associated agencies.
- 728.58 Federal Aviation Agency (FAA) beneficiaries.
- 728.59 Peace Corps beneficiaries.
- 728.60 Job Corps and Volunteers in Service to America (VISTA) beneficiaries.
- 728.61 Medicare beneficiaries.

Subpart G—Other Persons

- 728.71 Ex-service maternity care.
- 728.72 Applicants for enrollment in the Senior Reserve Officers' Training Program.

Sec.

- 728.73 Applicants for enlistment or reenlistment in the Armed Forces, and applicants for enlistment in the reserve components.
- 728.74 Applicants for appointment in the regular Navy or Marine Corps and reserve components, including members of the reserve components who apply for active duty.
- 728.75 Applicants for cadetship at service academies and applicants for the Uniformed Services University of Health Sciences (USUHS).
- 728.76 Naval Home residents.
- 728.77 Secretarial designees.
- 728.78 American Red Cross representative and their dependents.
- 728.79 Employees of Federal contractors and subcontractors.
- 728.80 U.S. Government employees.
- 728.81 Other civilians.
- 728.82 Individuals whose military records are being considered for correction.
- 728.83 Persons in military custody and nonmilitary Federal prisoners.

Subpart H—Adjuncts to Medical Care

- 728.91 General.
- 728.92 Policy.
- 728.93 Chart of Adjuncts.

Subpart I—Reservists—Continued Treatment, Return to Limited Duty, Separation, or Retirement for Physical Disability

- 728.101 General.
- 728.102 Care from other than Federal sources.

Subpart J—Initiating Collection Action on Pay Patients

- 728.111 General.
- 728.112 Responsibilities.
- 728.113 Categories of patients.

Authority: 5 U.S.C. 301 and 8101; 10 U.S.C. 1071-1095, 1201-1221, 2104, 2107, 2109, 2110, 5031, 5537, 6011, 6201-6203; 22 U.S.C. 1158, 2357, 2504, 2505, 2507, 2522; 24 U.S.C. 15, 34, 35; 31 U.S.C. 1535; 42 U.S.C. 249, 253; and 32 CFR 700.1202.

Subpart A—General**§ 728.1 Mission of Navy Medical Department facilities.**

The primary mission of Navy Medical Department facilities is to provide medical and dental care for members of the Navy and Marine Corps and for members of the other uniformed services who may be sick, injured, or disabled. In addition, Navy Medical Department facilities may provide medical and dental care to dependents of military personnel, to members not on active duty, and to such other persons as authorized by law, U.S. Navy regulations, and Department of Defense directives. These authorizations also provide that Navy Medical Department facilities may be called upon to furnish medical and dental care, under laws of humanity or principles of international

courtesy, to civilians and to other persons not otherwise entitled to medical and dental care.

§ 728.2 Definitions.

Unless otherwise qualified in this part, the following terms, when used throughout, are defined as follows:

(a) *Active duty.* Full-time duty in the active military service of the United States. This includes full-time training duty; annual training duty; and attendance, while in the active military service, at a school designated as a service school by law or by the Secretary of the military department concerned. It does not include full-time National Guard duty.

(b) *Active duty for training.* A tour of active duty for reserves for training under orders that provide for automatic reversion to non-active status when the specified period of active duty is completed. It includes annual training, special tours, and the initial tour performed by enlistees without prior military service.

(c) *CHAMPUS.* Civilian Health and Medical Program of the Uniformed Services.

(d) *Catchment area.* A specified geographic area surrounding each Uniformed Services Medical Treatment Facility (USMTF) or designated Uniformed Services Treatment Facility (USTF). In the United States, catchment areas are defined by zip codes and are based on an area of approximately 40 miles in radius for inpatient care and 20 miles in radius for ambulatory care. Zip codes designating such areas in the United States are specified in Volumes I and II of the Military Health Services System (MHSS) Catchment Area Directory. Catchment areas for facilities outside the United States are defined in Volume III of the MHSS Catchment Area Directory. These directories exclude certain areas because of geographic barriers.

(e) *Chronic condition.* Any medical or surgical condition marked by long duration or frequent recurrence—or likely to be so marked—which, in light of medical information available, will ordinarily resist efforts to eradicate it completely; a condition which needs health benefits to achieve or maintain stability that can be provided safely only by, or under the supervision of, physicians, nurses, or persons authorized by physicians.

(f) *Civilian employee.* Under 5 U.S.C. 2105, a nonmilitary individual (1) appointed in the civil service, (2) engaged in the performance of a Federal function, or (3) engaged in the performance of his or her duties while subject to the supervision of the

President, a Member or Members of Congress, or the Congress, a member of a uniformed service, an individual who is an employee under 5 U.S.C. 2105, the head of a Government controlled corporation, or an adjutant general designated by the Secretary concerned under section 709c of title 32. Included are justices and judges of the United States, appointed and engaging in the performance of duties per 5 U.S.C. 2104.

(g) *Cooperative care.* Medical services and supplies for which CHAMPUS will share in the cost under circumstances specified in § 728.4 (z), even though the patient remains under the primary control of a USMTF.

(h) *Cooperative care coordinator.* Designated individual in a CHAMPUS contractor's office who serves as the point of contact for health benefits advisors on all matters related to supplemental-cooperative care or services provided or ordered for CHAMPUS-eligible beneficiaries by USMTF providers.

(i) *Dental care.* Treatment which will prevent or remedy diseases, disabilities, and injuries to the teeth, jaws, and related structures and thereby contribute to maintenance or restoration of the dental health of an individual.

(j) *Dependent.* A spouse, an unremarried widow or widower, a child, or a parent who bears that legal relationship to his or her sponsor. For the purpose of rendering care under title 10, U.S.C., chapter 55, this category may also include an unremarried former spouse. However, each beneficiary must also meet the eligibility criteria in § 728.31(b) and § 728.31(c).

(k) *Designated USTFs.* The following former U.S. Public Health Service (USPHS) facilities operate as "designated USTFs" for the purpose of rendering medical and dental care to active duty members and to all CHAMPUS-eligible individuals.

(1) *Sisters of Charity of the Incarnate Word Health Care System.* 6400 Lawndale, Houston, TX 77058 (713) 928-2931 operates the following facilities:

(i) St. John Hospital, 2050 Space Park Drive, Nassau Bay, TX 77058, telephone (713) 333-5503. Inpatient and outpatient services.

(ii) St. Mary's Hospital Outpatient Clinic, 404 St. Mary's Boulevard, Galveston, TX 77550, telephone (409) 763-5301. Outpatient services only.

(iii) St. Joseph Hospital Ambulatory Care Center, 1919 La Branch, Houston, TX 77002, telephone (713) 757-1000. Outpatient services only.

(iv) St. Mary's Hospital Ambulatory Care Center, 3600 Gates Boulevard, Port Arthur, TX 77640 (409) 985-7431. Outpatient services only.

(2) *Inpatient and outpatient services.*

(i) Wyman Park Health System, Inc., 3100 Wyman Park Drive, Baltimore, MD 21211, telephone (301) 338-3693.

(ii) Alston-Brighton Aid and Health Group, Inc., Brighton Marine Public Health Center, 77 Warren Street, Boston, MA 02135, telephone (617) 782-3400.

(iii) Bayley Seton Hospital, Bay Street and Vanderbilt Avenue, Staten Island, NY 10304, telephone (718) 390-5547 or 6007.

(iv) Pacific Medical Center, 1200 12th Avenue South, Seattle, WA 98144, telephone (206) 326-4100.

(3) *Outpatient services only.* (i) Coastal Health Service, 331 Veranda Street, Portland, ME 04103, telephone (207) 774-5805.

(ii) Lutheran Medical Center, Downtown Health Care Services, 1313 Superior Avenue, Cleveland, OH 44113, telephone (216) 363-2065.

(l) *Disability retirement or separation.* Temporary or permanent retirement or separation for physical disability as provided in title 10, U.S.C., 1201-1221.

(m) *Elective care.* Medical, surgical, or dental care desired or requested by the individual or recommended by the physician or dentist which, in the opinion of other cognizant professional authority, can be performed at another place or time without jeopardizing life, limb, health, or well-being of the patient, e.g., surgery for cosmetic purposes and nonessential dental prosthetic appliances.

(n) *Emergency care.* Medical treatment of patients with severe, life-threatening, or potentially disabling conditions that require immediate intervention to prevent undue suffering or loss of life or limb and dental treatment of painful or acute conditions.

(o) *Health benefits advisors (HBA).* Designated individuals at naval facilities who are responsible for advising and assisting beneficiaries covered in this part concerning medical and dental benefits in uniformed services facilities and under CHAMPUS. They also provide information regarding Veterans' Administration, Medicare, MEDICAID, and such other local health programs known to be available to beneficiaries (see § 728.4(n)).

(p) *Hospitalization.* Inpatient care in a medical treatment facility.

(q) *Inactive duty training.* Duty prescribed for Reserves by the Secretary concerned under section 206 of title 37, U.S.C. or any other provision of law. Also includes special additional duties authorized for Reserves by an authority designated by the Secretary concerned and performed on a voluntary basis in connection with the prescribed training

or maintenance activities of the units to which they are assigned. It includes those duties when performed by Reserves in their status as members of the National Guard.

(r) *Legitimate care.* Those medical and dental services under the cooperative/supplemental care program of CHAMPUS that are legally performed and not contrary to governing statutes.

(s) *Maximum hospital benefit.* That point during inpatient treatment when the patient's progress appears to have stabilized and it can be anticipated that additional hospitalization will not directly contribute to any further substantial recovery. A patient who will continue to improve slowly over a long period without specific therapy or medical supervision, or with only a moderate amount of treatment on an outpatient basis, may be considered as having attained maximum hospital benefit.

(t) *Medical care.* Treatment required to maintain or restore the health of an individual. Medical care may include, but is not limited to, the furnishing of inpatient treatment, outpatient treatment, nursing service, medical examinations, immunizations, drugs, subsistence, transportation, and other adjuncts such as prosthetic devices, spectacles, hearing aids, orthopedic footwear, and other medically indicated appliances or services.

(u) *Medically inappropriate.* A situation arising when denial of a Nonavailability Statement could result in significant risk to the health of a patient or significant limitation to the patient's reasonable access to needed health care.

(v) *Medically necessary.* The level of services and supplies (i.e., frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury, including maternity care. Medically necessary, includes the concept of appropriate medical care.

(w) *Medical treatment facility (MTF).* Any duly authorized medical department center, hospital, clinic, or other facility that provides medical, surgical, or dental care.

(x) *Member or former member.*

Includes:

(1) Members of the uniformed services ordered to active duty for more than 30 days.

(2) Retired members as defined in § 728.2(bb).

(3) Members of a uniformed service ordered to active duty for more than 30 days who died while on that duty.

(4) Deceased retired members.

(y) *Military patient.* A member of a United States uniformed service on active duty, active duty for training, or inactive duty training, or an active duty member of the armed forces of a foreign government who is receiving inpatient or outpatient care.

(z) *Occupational health services.* Includes medical examinations and tests related to preemployment, preplacement, periodic, and pretermination; tests required for protecting the health and safety of naval personnel; job-related immunizations and chemoprophylaxis; education and training related to occupational health; and other services provided to avoid lost time or to improve effectiveness of employees. The latter will include the furnishing of emergency treatment of illnesses or injuries occurring at work. Furnish such health services to both active duty military personnel and naval civilian employees per current directives.

(aa) *Retired member.* A member or former member of a uniformed service who is entitled to retired or retainer pay, or equivalent pay, as a result of service in a uniformed service. This includes a member or former member who is: (1) Retired for length of service; (2) permanently or temporarily retired for physical disability; (3) on the emergency officers' retired list and is entitled to retired pay for physical disability; or (4) otherwise in receipt of retired pay under chapter 67 of title 10.

(bb) *Routine care.* Medical and dental care necessary to maintain health or dental functions other than care of an emergency or elective nature.

(cc) *Supplemental care or services.* When medical or dental management is retained by a naval MTF and required care is not available at the facility retaining management, any additional material, professional diagnostic or consultative services, or other personal services ordered by qualified uniformed service providers, and obtained for the care of that patient are supplemental. See § 728.12 concerning the management of active duty member patients.

(dd) *Uniformed services.* The Navy, Marine Corps, Air Force, Army, Coast Guard, Commissioned Corps of the Public Health Service, and the Commissioned Corps of the National Oceanic and Atmospheric Administration.

(ee) *USMTF.* Uniformed services medical treatment facility.

(ff) *Visit, outpatient.* Appearance by an eligible beneficiary at a separate, organized clinic or specialty service for: Examination, diagnosis, treatment, evaluation, consultation, counseling, or medical advice; or treatment of an eligible beneficiary in quarters; and a signed and dated entry is made in the patient's health record. Specifically excluded are personnel in an inpatient status at the time of such a visit.

§ 728.3 General restrictions and priorities.

(a) *Restrictions.* (1) Naval MTFs provide care to all eligible beneficiaries subject to the capabilities of the professional staff and the availability of space and facilities.

(2) Hospitalization and outpatient services may be provided outside the continental limits of the United States and in Alaska to officers and employees of any department or agency of the Federal Government, to employees of a contractor with the United States or the contractor's subcontractor, to accompanying dependents of such persons, and in emergencies to such other persons as the Secretary of the Navy may prescribe: *Provided*, such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities. Hospitalization of such individuals in a naval MTF is limited to the treatment of acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care. Routine dental care, other than dental prosthesis or orthodontia, may be rendered on a space available basis outside the continental limits of the United States and in Alaska, *Provided*, such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(b) *Priorities.* When care cannot be rendered to all eligible beneficiaries, the priorities in the following chart will prevail. Make no distinction as to the sponsoring uniformed service when providing care or deciding priorities.

PRIORITIES FOR THE VARIOUS CATEGORIES OF PERSONNEL ELIGIBLE FOR CARE IN NAVY MEDICAL DEPARTMENT FACILITIES

Priority	Category	Degree of entitlement
1	A. Members of the uniformed services on active duty (including active duty for training and inactive duty training) and comparable personnel of the NATO nations meeting the conditions prescribed in this part. B. Members of a Reserve Component of the Armed Forces and National Guard personnel under orders.	See Subpart B. See Subpart C.
2	Dependents of active duty members of the uniformed services, dependents of persons who died while in such a status, and the dependents of active duty members of NATO nations meeting the conditions prescribed in subpart E of this part.	See Subparts D and E.
3	Members of the Senior Reserve Officers' Training Corps of the Armed Forces.....	See § 728.23.
4	Retired members of the uniformed services and their dependents and dependents of deceased retired members.	See Subpart D.
5	Civilian employees of the Federal Government under the limited circumstances covered by the Federal Employees' Health Service program.	See § 728.80.
6	All others, including ex-service maternity eligibles	See Subparts F and G.

§ 728.4 Policies.

(a) *Admissions to closed psychiatric wards.* Admit patients to closed psychiatric wards only when they have a psychiatric or emotional disorder which renders them dangerous to themselves or others, or when a period of careful closed psychiatric observation is necessary to determine whether such a condition exists. When a patient is admitted to a closed psychiatric ward, the reason for admission must be clearly stated in the patient's clinical record by the physician admitting the patient to the ward. These same policies apply equally in those instances when it becomes necessary to place a patient under constant surveillance while in an open ward.

(b) *Absence from the sick list.* See § 728.4 (d), (x), and (y).

(c) *Charges and collection.* Charges for services rendered vary and are set by the Office of the Assistant Secretary of Defense (Comptroller) and published in a yearly NAVMEDCOMNOTE 6320. (Cost elements of medical, dental, subsistence rates, and hospitalization bills). Billing and collection actions also vary according to entitlement or eligibility and are governed by the provisions of NAVMED P-5020, Resource Management Handbook. See subpart J on the initiation of collection action on pay patients.

(d) *Convalescent leave.* Convalescent leave, a period of authorized absence of active duty members under medical care when such persons are not yet fit for duty, may be granted by a member's commanding officer (CO) or the hospital's CO per the following:

(1) Unless otherwise indicated, grant such leave only when recommended by COMNAVMEDCOM through action taken upon a report by a medical board,

or the recommended findings of a physical evaluation board or higher authority.

(2) Member's commanding officer (upon advice of attending physician); commanding officers of Navy, Army, or Air Force medical facilities; commanders of regional medical commands for persons hospitalized in designated USTFs or in civilian facilities within their respective areas of authority; and managers of Veterans Administration hospitals within the 50 United States or in Puerto Rico may grant convalescent leave to active duty naval patients, with or without reference to a medical board, physical evaluation board, or higher authority provided the:

(i) Convalescent leave is being granted subsequent to a period of hospitalization.

(ii) Member is not awaiting disciplinary action or separation from the service for medical or administrative reasons.

(iii) Medical officer in charge:

(A) Considers the convalescent leave beneficial to the patient's health.

(B) Certifies that the patient is not fit for duty, will not need hospital treatment during the contemplated convalescent leave period, and that such leave will not delay final disposition of the patient.

(3) When considered necessary by the attending physician and approved on an individual basis by the commander of the respective geographic regional medical command, convalescent leave in excess of 30 days may be granted. The authority to grant convalescent leave in excess of 30 days may not be redelegated to hospital commanding officers. Member's permanent command must be notified of such extensions (see MILPERSMAN 3020360).

(4) Exercise care in granting convalescent leave to limit the duration of such leave to that which is essential in relation to diagnosis, prognosis, estimated duration of treatment, and patient's probable final disposition.

(5) Upon return from convalescent leave;

(i) Forward one copy of original orders of officers, bearing all endorsements, to the Commander, Naval Military Personnel Command (COMNAVMILPERSCOM) (NMPC-4) or the Commandant of the Marine Corps (CMC), as appropriate.

(ii) Make an entry on the administrative remarks page (page 13 for Navy personnel) of the service records of enlisted personnel indicating that convalescent leave was granted and the dates of departure and return.

(6) If considered beneficial to the patient's health, commanding officers of hospitals may grant convalescent leave as a delay in reporting back to the parent command.

(e) *Cosmetic surgery.* (1) Defined as that surgery which is done to revise or change the texture, configuration, or relationship of contiguous structures of any feature of the human body which would be considered by the average prudent observer to be within the broad range of "normal" and acceptable variation for age or ethnic origin, and in addition, is performed for a condition which is judged by competent medical opinion to be without potential for jeopardy to physical or mental health of an individual.

(2) Commanding officers will monitor, control, and assure compliance with the following cosmetic surgery policy:

(i) Certain cosmetic procedures are a necessary part of training and retention

of skills to meet the requirements of certification and recertification.

(ii) Insofar as they meet minimum requirements and serve to improve the skills and techniques needed for reconstructive surgery, the following cosmetic procedures may be performed as low priority surgery on active duty members only when time and space are available.

(A) Cosmetic facial rhytidectomies (face lifts) will be a part of all training programs required by certifying boards.

(B) Cosmetic augmentation mammoplasties will be done only by properly credentialed surgeons and residents within surgical training programs to meet requirements of certifying boards.

(f) *Cross-utilization of uniformed services facilities.* To provide effective cross-utilization of medical and dental facilities of the uniformed services, eligible persons, regardless of service affiliation, will be given equal opportunity for health benefits. Catchment areas have been established by the Department of Defense for each USMTF (see § 728.2(d)). Eligible beneficiaries residing within such a catchment area are expected to use that inpatient facility for care. Make provisions to assure that:

(1) Eligible beneficiaries residing in a catchment area served by a USMTF not of the sponsor's own service may obtain care at that facility or at a facility of the sponsor's service located in another catchment area.

(2) If the facility to which an eligible beneficiary applies cannot furnish needed care, the other facility or facilities in overlapping catchment areas are contacted to determine whether care can be provided thereat.

(g) *Disengagement.* Discontinuance of medical management by a naval MTF for only a specific episode of care.

(1) *General.* Disengagement is accomplished only after alternative sources of care (i.e., transfer to another USMTF, a USTF, or other Federal source via the aeromedical evacuation system, if appropriate) and attendant costs, if applicable, have been fully explained to patient or responsible family member. Counselors may arrange for counseling by other appropriate sources when the patient is or may be eligible for VA, Medicare, MEDICAID, etc. benefits. With the individual's permission, counselors may also contact State programs, local health organizations, or health foundations to determine if care is available for the condition upon which disengagement is based. After the disengagement decision is made, the patient to be disengaged or the responsible family member should be

advised to return to the naval MTF for any care required subsequent to receiving the care that necessitated disengagement.

(2) *CHAMPUS-eligible individuals.* (i) Issue a Nonavailability Statement (DD 1251) per § 728.33, when appropriate, to patients released to civilian sources for total care (disengaged) under CHAMPUS. CHAMPUS-eligible patients disengaged for total care, who do not otherwise require a DD 1251 (released for outpatient care or those released whose residence is outside the inpatient catchment area of all USMTFs and USTFs) will be given the original of a properly completed DD 2161, Referral For Civilian Medical Care, which clearly indicates that the patient is released for total care under CHAMPUS. CHAMPUS-eligible beneficiaries will be disengaged for services under CHAMPUS when:

(A) Required services are beyond your capability and these services cannot be appropriately provided through one of the alternatives listed in § 728.4(z), or

(B) You cannot effectively provide required services or manage the overall course of care even if augmented by services procured from other Government or civilian sources using naval MTF operation and maintenance funds as authorized in subpart § 728.4(z).

(ii) When a decision is made to disengage a CHAMPUS-eligible individual, commanding officers (CO) or officers-in-charge (OIC) are responsible for assuring that counseling and documentation of counseling are appropriately accomplished. Complete a NAVMED 6320/30, Disengagement for Civilian Medical Care, to document that all appropriate disengagement procedures have been accomplished.

(iii) After obtaining the signature of the patient or responsible family member, the counselor will file a copy of the DD 2161 and the original of the NAVMED 6320/30 in the patient's Health Record.

(3) *Patients other than active duty or CHAMPUS-eligible individuals—* (i) *Categories of patients.* The following are categories of individuals who also may be disengaged:

(A) Medicare-eligible individuals.

(B) MEDICAID-eligible individuals.

(C) Civilians (U.S. and foreign) admitted or treated as civilian humanitarians.

(D) Secretarial designees.

(E) All other individuals, with or without private insurance, who are not eligible for care at the expense of the Government.

(ii) *Disengagement decision.* Disengage such individuals when:

(A) Required services are beyond the capability of the MTF, and services necessary for continued treatment in the MTF cannot be appropriately provided by another USMTF, a USTF, or another Federal source. (Explore alternative sources, for individuals eligible for care from these sources, before making the disengagement decision.)

(B) The MTF cannot, within the facility's capability, effectively provide required care or manage the overall course of treatment even if augmented by services procured from other Government sources or through procurement from civilian sources using supplemental care funding.

(iii) *Counseling.* The initial step in the disengagement process is appropriate counseling and documentation. In an emergency, or when the individual cannot be appropriately counseled prior to leaving the MTF, establish procedures to ensure counseling and documentation are accomplished during the next working day. Such "follow-up" counseling may be in person or via a witnessed telephone conversation. In either instance, the counselor will document counseling on a NAVMED 6320/30, Disengagement for Civilian Medical Care. The disengagement decision making authority must assure the accomplishment of counseling by personally initiating this service or by referring the patient or responsible family member to the HBA for counseling. As a minimum, counseling will consist of:

(A) Explaining that the patient is being disengaged from treatment at the facility and the reason therefor. Assure that the individual understands the meaning of "disengagement" by explaining that the MTF is unable to provide for the patient's present needs and must therefore relinquish medical management of the patient to a health care provider of the individual's choice.

(B) Assuring the individual that the disengagement action is taken to provide for the patient's immediate medical needs. Also assure that the individual understands that the disengagement is not indicative of whether care is or will be available in the MTF for other aspects of past, current, or future medical conditions.

(C) Explaining Medicare, MEDICAID, or other known programs as they relate to the particular circumstance of the patient, including cost-sharing, deductibles, allowable charges, participating and authorized providers, physicians accepting assignment, claim filing procedures, etc. Explain that once disengagement is accomplished, the Navy, is not responsible for any costs

for care received from a health care provider of the patient's or responsible family member's choice.

(iv) *Documentation.* Commanding officers are responsible for ensuring that proper documentation procedures are started and that providers and counselors under their commands are apprised of their individual responsibilities for counseling and documenting each disengagement. Failure to properly counsel and document counseling may result in the naval MTF having to absorb the cost of the entire episode of care. Document counseling on a NAVMED 6320/30. Disengagement for Civilian Medical Care. Completion of all items on the form assures documentation and written acknowledgement of appropriate disengagement and counseling. If the patient or responsible family member refuses to acknowledge receipt of counseling by signing the form, state this fact on the bottom of the form and have it witnessed by an officer. Give the patient or responsible family member a copy and immediately file the original in the patient's Health Record.

(4) *Active duty members.* When an active duty member seeks care at a USMTF, that USMTF retains some responsibility (e.g., notification, medical cognizance, supplemental care, etc.) for that member even when the member must be transferred to another facility for care. Therefore, relinquishment of total management of an active duty member (disengagement) cannot be accomplished.

(h) *Domiciliary/custodial care.* The type of care designed essentially to assist an individual in meeting the normal activities of daily living, i.e., services which constitute personal care such as help in walking and getting in or out of bed, help in bathing, dressing, feeding, preparation of special diets, and supervision over medications which can usually be self-administered and which does not entail or require the continuing attention of trained medical or paramedical personnel. The essential characteristics to be considered are the level of care and medical supervision that the patient requires, rather than such factors as diagnosis, type of condition, or the degree of functional limitation. Such care will not be provided in naval MTFs except when required for active duty members of the uniformed services.

(i) *Emergency care.* Treat patients authorized only emergency care and those admitted as civilian emergencies only during the period of the emergency. Initiate action to effect appropriate disposition of such patients as soon as the emergency period ends.

(j) *Evaluation after admission.* Evaluate each patient as soon as possible after admission and continue reevaluation until disposition is made. Anticipate each patient's probable type and date of disposition. Necessary processing by the various medical and administrative entities will take place concurrently with treatment of the patient. Make the medical disposition decision as early as possible for U.S. military patients inasmuch as immediate transfer to a specialized VA center or to a VA spinal cord injury center may be in their best interest (see NAVMEDCOMINST 6320.1.2). Make disposition decisions for military personnel of NATO nations in conformance with § 728.42(d).

(k) *Extent of care.* Subject to the restrictions and priorities in § 728.3, eligible persons will be provided medical and dental care to the extent authorized, required, and available. When an individual is accepted for care, all care and adjuncts thereto, such as nonstandard supplies, as determined by the CO to be necessary, will be provided from resources available to the CO unless specifically prohibited elsewhere in this part. When a patient has been accepted and required care is beyond the capability of the accepting MTF, the CO thereof will arrange for the required care by one of the means shown below. The method of choice will be based upon professional considerations and travel economy.

(1) Transfer the patient per § 728.4(bb).

(2) Procure from civilian sources the necessary material or professional personal services required for the patient's proper care and treatment.

(3) Care authorized in § 728.4(k)(2) will normally be accomplished in the naval MTF. However, when such action is not feasible, supplementation may be obtained outside the facility. Patients may be sent to other Federal or civilian facilities for specific treatment or services under § 728.4(k)(3) provided they remain under medical management of the CO of the sending facility during the entire period of care.

(l) *Family planning services.* Provide family planning services following the provisions of SECNAVINST 6300.2A.

(m) *Grouping of patients.* Group hospitalized patients according to their requirements for housing, medical, or dental care. Provide gender identified quarters, facilities, and professional supervision on that basis when appropriate. Individuals who must be retained under limited medical supervision (medical hold) solely for administrative reasons or for medical conditions which can be treated on a

clinic basis will be provided quarters and messing facilities, where practicable, separately from those hospitalized. Provide medical care for such patients on a periodic clinic appointment basis (see § 728.4(p) for handling enlisted convalescent patients). Make maximum use of administrative versus medical personnel in the supervision of such patients.

(n) *Health benefits advising—(1) General.* A Health Benefits Advising program must be started at all shore commands having one or more medical officers. While health benefits advisors are not required aboard every ship with a medical officer, the medical department representative can usually provide services to personnel requiring help. The number of health benefits advisors (HBAs) of a command will be commensurate with counseling and assistance requirements. The program provides health benefits information and counseling to beneficiaries of the Uniformed Services Health Benefits Program (USHBP) and to others who may or may not qualify for care in USMTFs. Office location of HBAs, their names, and telephone numbers will be widely publicized locally. If additional help is required, contact MEDCOM-333 on AUTOVON 294-1127 or commercial (202) 653-1127. In addition to the duties described in § 728.4(n)(2), HBAs will:

(i) Maintain a depository of up-to-date officially supplied health benefits information for availability to all beneficiaries.

(ii) Provide information and guidance to beneficiaries and generally support the medical and dental staff by providing help to eligible beneficiaries seeking or obtaining services from USMTFs, civilian facilities, VA facilities, Medicare, MEDICAID, and other health programs.

(iii) Assure that when a referral or disengagement is required, patients or responsible family members are:

(A) Fully informed that such action is taken to provide for their immediate medical or dental requirements and that the disengagement or referral has no bearing on whether care may be available in the naval MTF for other aspects of current or other future medical conditions.

(B) Provided the services and counseling outlined in § 728.4(n)(2) or § 728.3(g)(3)(ii), as appropriate, prior to their departure from the facility when such beneficiaries are referred or disengaged because care required is beyond the naval MTF's capability. In an emergency, or when the patient or sponsor cannot be seen by the HBA

prior to leaving, provide these benefits as soon thereafter as possible.

(2) *Counseling and Assisting CHAMPUS-Eligible Individuals.* HBAs, as a minimum, will:

(i) Explain alternatives available to the patient.

(ii) If appropriate, explain CHAMPUS as it relates to the particular circumstance, including the cost-sharing provisions applicable to the patient, allowable charges, provider participation, and claim filing procedures. Fully inform the patient or responsible family member that when a patient is disengaged for care under CHAMPUS or when cooperative care is to be considered for payment under the provisions of § 728.4(z) (5) and (6), the naval MTF is not responsible for monetary amounts above the CHAMPUS-determined allowable charge or for charges CHAMPUS does not allow.

(iii) Explain why the naval MTF is paying for the supplemental care, if appropriate (see § 728.4(z) (3) and (4)), and how the bill will be handled. Then:

(A) Complete a DD 2161, Referral For Civilian Medical Care, marking the appropriate source of payment with the concurrence of the naval MTF commanding officer or CO's designee.

(B) If referred for a specified procedure with a consultation report to be returned to the naval MTF retaining medical management, annotate the DD 2161 in the consultation report section to state this requirement. Advise patient or responsible family member to arrange for a completed copy of the DD 2161 to be returned to the naval MTF for payment, if appropriate, and inclusion in patient's medical record.

(iv) Brief patient or responsible family member on the use of the DD 2161 in USMTF payment procedures and CHAMPUS claims processing, as appropriate. Provide sufficient copies of DD 2161 and explain that CHAMPUS contractors will return claims submitted without a required DD 2161. Obtain signature of patient or responsible family member on the form.

(v) Arrange for counseling from appropriate sources when the patient is eligible for VA, Medicare, or MEDICAID benefits.

(vi) Serve as liaison between civilian providers and naval MTF on administrative matters related to the referral and disengagement process.

(vii) Serve as liaison between naval MTF and cooperative care coordinators on matters relating to care provided or recommended by naval MTF providers, as appropriate.

(viii) Explain why the patient is being disengaged and, per § 728.4(g)(2),

provide a DD 1251, Nonavailability Statement, or DD 2161, Referral For Civilian Medical Care, as appropriate.

(o) *Immunizations.* Administer immunizations per BUMED INST 6230.1H.

(p) *Medical holding companies.* Medical holding companies (MHC) have been established at certain activities to facilitate handling of enlisted convalescent patients whose medical conditions are such that, although they cannot be returned to full duty, they can perform light duty ashore commensurate with their condition while completing their medical care on an outpatient basis. Where feasible, process such patients for transfer.

(q) *Notifications.* The interests of the Navy, Marine Corps, and DOD have been adversely affected by past procedures which emphasized making notifications only when an active duty member's condition was classed as either seriously ill or injured or classed as very seriously ill or injured. However, even temporary disabilities which preclude communication with the next of kin have generated understandable concern and criticism, especially when emergency hospitalization has resulted. Accordingly, naval MTFs will effect procedures to make notifications required in § 728.4(q) (2), (3), and (4) upon admission or diagnosis of individuals specified. The provisions of § 728.4(q) supplement articles 1810520 and 4210100 of the Naval Military Personnel Manual and chapter 1 of Marine Corps Order P3040.4B, Marine Corps Casualty Procedures Manual; they do not supersede them.

(1) *Privacy Act.* The right to privacy of individuals for whom hospitalization reports and other notifications are made will be safeguarded as required by the Privacy Act, implemented in the Department of the Navy by SECNAVINST 5211.5C, U.S. Navy Regulations, the Manual of the Judge Advocate General, the Marine Corps Casualty Procedures Manual, and the Manual of the Medical Department.

(2) *Active duty flag or general officers and retired Marine Corps general officers.* Upon admission of subject officers, make telephonic contact with MEDCOM-33 on AUTOVON 294-1179 or commercial (202) 653-1179 (after duty hours, contact the command duty officer on AUTOVON 294-1327 or commercial (202) 653-1327) to provide the following information:

(i) *Initial.* Include in the initial report: (A) Officer's name, grade, social security number, and designator.

(B) Duty assignment in ship or station, or other status.

(C) Date of admission.

(D) Present condition, stating if serious or very serious.

(E) Diagnosis, prognosis, and estimated period of hospitalization. To prevent possible invasion of privacy, report the diagnosis only in International Classification of Diseases—9th Edition (ICD-9-CM) code designator.

(ii) *Progress reports.* Call frequency and content will be at the discretion of the commanding officer. However, promptly report changes in condition or status.

(iii) *Termination report.* Make a termination of hospitalization report to provide appropriate details for informational purposes.

(iv) *Additional commands to apprise.* The geographic naval medical region serving the hospital and, if different, the one serving the officer's command will also be apprised of such admissions.

(3) *Active duty members—(i) Notification of member's command.* The commanding officer of naval medical treatment facilities has responsibility for notifying each member's commanding officer under the conditions listed below. Make COMNAVILPERS COM or CMC, as appropriate, information addressees on their respective personnel:

(A) *Direct admissions.* Upon direct admission of an active duty member, with or without orders regardless of expected length of stay. The patient administration department (administrative watch officer after hours) is responsible for preparation, per § 728.4(q)(4), and release of these messages. If the patient is attached to a local command (CO's determination), initial notification may be made telephonically. Record the name, grade or rate, and position of the person receiving the call at the member's command on the back of the NAVMED 6300/5, Inpatient Admission/Disposition Record and include the name and telephone number of the MTF's point of contact as given to the patient's command.

(B) *Change in medical condition.* Upon becoming aware of any medical condition, including pregnancy, which will now or in the foreseeable future result in the loss of a member's full duty services in excess of 72 hours. Transmit this information in a message, prepared per § 728.4(q)(4), marked "Commanding Officer's Eyes Only."

(ii) *Notification of Next of Kin (NOK)—(A) Admitted members.* As part of the admission procedure, encourage all patients to communicate expeditiously and regularly with their NOK. When an active duty member's

incapacity makes timely personal communication impractical, i.e., fractures, burns, eye pathology, psychiatric or emotional disorders, etc., MTF personnel will initiate the notification process. Do not start the process if the patient specifically declines such notification or it is clear that the NOK already has knowledge of the admission (commands should develop a local form for such patients to sign attesting their desire or refusal to have their NOK notified). Once notification has been made, the facility will make progress reports, at least weekly, until the patient is again able to communicate with the NOK.

(1) *Navy personnel.* Upon admission of Navy personnel, effect the following notification procedures.

(i) *In the contiguous 48 States.* Patient administration department personnel will notify the NOK in person, by telephone, telegraph, or by other expeditious means. Included are notifications of the NOK upon arrival of all Navy patients received in the medical air- evacuation system.

(ii) *Outside the contiguous 48 States.* If the next of kin has accompanied the patient on the tour of duty and is in the immediate area, hospital personnel will notify the next of kin in person, by telephone, telegraph, or by other expeditious means. If the next of kin is located in the 48 contiguous United States, use telegraphic means to notify COMNAV MILPERSCOM who will provide notification to the NOK.

(2) *Marine Corps personnel.* When Marine Corps personnel are admitted, effect the following notification procedures.

(i) *In the Contiguous 48 States.* The commander of the unit or activity to which the casualty member is assigned is responsible for initiating notification procedures to the NOK of seriously or very seriously ill or injured Marine Corps personnel. Patient administration department personnel will assure that liaison is established with the appropriate command or activity when such personnel are admitted. Patient administration personnel will notify the Marine's command by telephone and request that cognizance be assumed for in-person initial notification of the NOK of Marine Corps patients admitted with an incapacity that makes personal and timely communication impractical and for those arriving via the medical air- evacuation system. If a member's command is unknown or cannot be contacted, inform CMC (MHP-10) on AUTOVON 224-1787 or commercial (202) 694-1787.

(ii) *Outside the contiguous 48 States.* Make casualty notification for Marine

Corps personnel hospitalized in naval MTFs outside the contiguous 48 States to the individual's command. If the command is unknown or not located in close proximity to the MTF, notify CMC (MHP-10). When initial notification to the individual's command is made via message, make CMC (MHP-10) an information addressee.

(iii) *In and outside the United States.* In life-threatening situations, the Commandant of the Marine Corps desires and encourages medical officers to communicate with the next of kin. In other circumstances, request that the Marine Corps member communicate with the NOK if able. If unable, the medical officer should communicate with the NOK after personal notification has been effected.

(B) *Terminally ill patients.* As soon as a diagnosis is made and confirmed (on inpatients or outpatients) that a Navy member is terminally ill, MILPERSMAN 4210100 requires notification of the primary and secondary next of kin. Accomplish notification the same as for Navy members admitted as seriously or very seriously ill or injured, i.e., by priority message to the Commander, Naval Military Personnel Command and to the Casualty Assistance Calls/ Funeral Honors Support Program Coordinator, as appropriate, who has cognizance over the geographical area in which the primary and secondary NOK resides (see OPNAVINST 1770.1). Submit followup reports when appropriate. See MILPERSMAN 4210100 for further amplification and for information addressees.

(1) *In the contiguous 48 States.* Notification responsibility is assigned to the USMTF making the diagnosis and to the member's duty station if diagnosed in a civilian facility.

(2) *Outside the contiguous 48 States.* Notification responsibility is assigned to the naval medical facility making the diagnosis. When diagnosed in nonnaval facilities or aboard deployed naval vessels, notification responsibility belongs to the Commander, Naval Military Personnel Command.

(C) *Other uniformed services patients.* Establish liaison with other uniformed services to assure proper notification upon admission or diagnosis of active duty members of other services.

(D) *Nonactive duty patients.* At the discretion of individual commanding officers, the provisions of § 728.4(q)(3)(ii) on providing notification to the NOK may be extended to admissions or diagnosis of nonactive duty patients; e.g., admission of dependents of members on duty overseas.

(4) *Messages—* (i) *Content.* Phrase contents of messages (and telephonic

notifications) in lay terms and provide sufficient details concerning the patient's condition, prognosis, and diagnosis. Messages will also contain the name and telephone number of the facility's point of contact. When appropriate for addressal, psychiatric and other sensitive diagnoses will be related with discretion. When indicated, also include specific comment as to whether the presence of the next of kin is medically warranted. **Note:** In making notification to the NOK of patients diagnosed as having Acquired Immune Deficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV), use one of the symptoms of the disease as the diagnosis (e.g., pneumonia) rather than "HIV", "AIDS", or the diagnostic code for AIDS.

(ii) *Information addressees.* Make the commander of the geographic naval medical region servicing the member's command and the one servicing the hospital, if different, information addressees on all messages. For Marine Corps personnel, also include CMC (MHP-10) and the appropriate Marine Corps district headquarters as information addressees, COMNAV MEDCOM WASHINGTON DC requires information copies of messages *only* when a patient has been placed on the seriously ill or injured or very seriously ill or injured list or diagnosed as terminally ill.

(r) *Outpatient care.* Whenever possible, perform diagnostic procedures and provide preoperative and post operative care, surgical care, convalescence, and followup observations and treatment on an outpatient basis.

(s) *Performance of duties while in an inpatient status.* U.S. military patients may be assigned duties in and around naval MTFs when such duties will be, in the judgement of the attending physician, of a therapeutic value. Physical condition, past training, and other acquired skills must all be considered before assigning any patient a given task. Do not assign patients duties which are not within their capabilities or which require more than a very brief period of orientation.

(t) *Prolonged definitive medical care.* Prolonged definitive medical care in naval MTFs will not be provided for U.S. military patients who are unlikely to return to duty. The time at which a patient should be processed for disability separation must be determined on an individual basis, taking into consideration the interests of the patient as well as those of the Government. A long-term patient roster will be maintained and updated at least

once monthly to enable commanding officers and other appropriate staff members to monitor the progress of all patients with 30 or more continuous days of hospitalization. Include on the roster basic patient identification data (name, grade or rate, register number, ward or absent status, clinic service, and whether assigned to a medical holding company), projected disposition (date, type, and profile), diagnosis, and cumulative hospital days (present facility and total).

(u) *Remediable physical defects of active duty members*—(1) *General*. When a medical evaluation reveals that a Navy or Marine Corps patient on active duty has developed a remediable defect while on active duty, the patient will be offered the opportunity of operative repair or other appropriate remediable treatment, if medically indicated.

(2) *Refusal of treatment*. Per MANMED art. 18-15, when a member refuses to submit to recommended therapeutic measures for a remediable defect or condition which has interfered with the member's performance of duty and following prescribed therapy, the member is expected to be fit for full duty, the following procedures will apply:

(i) Transfer the member to a naval MTF for further evaluation and appearance before a medical board. After counseling per MANMED art. 18-15, any member of the naval service who refuses to submit to recommended medical, surgical, dental, or diagnostic measures, other than routine treatment for minor or temporary disabilities, will be asked to sign a completed NAVMED 6100/4, Medical Board Certificate Relative to Counseling on Refusal of Surgery and/or Treatment, attesting to the counseling.

(ii) The board will study all pertinent information, inquire into the merits of the individual's refusal to submit to treatment, and report the facts with appropriate recommendations.

(iii) As a general rule, refusal of minor surgery should be considered unreasonable in the absence of substantial contraindications. Refusal of major surgical operations may be reasonable or unreasonable, according to the circumstances. The age of the patient, previous unsuccessful operations, existing physical or mental contraindications, and any special risks should all be taken into consideration.

(iv) Where surgical procedures are involved, the board's report will contain answers to the following questions:

(A) Is surgical treatment required to relieve the incapacity and restore the

individual to a duty status, and may it be expected to do so?

(B) Is the proposed surgery an established procedure that qualified and experienced surgeons ordinarily would recommend and undertake?

(C) Considering the risks ordinarily associated with surgical treatment, the patient's age and general physical condition, and the member's reason for refusing treatment, is the refusal reasonable or unreasonable? (Fear of surgery or religious scruples may be considered, along with all the other evidence, for whatever weight may appear appropriate.)

(v) If a member needing surgery is mentally competent, do not perform surgery over the member's protestation.

(vi) In medical, dental, or diagnostic situations, the board should show the need and risk of the recommended procedure(s).

(vii) If a medical board decides that a diagnostic, medical, dental, or surgical procedure is indicated, these findings must be made known to the patient. The board's report will show that the patient was afforded an opportunity to submit a written statement explaining the grounds for refusal. Forward any statement with the board's report. Advise the patient that even if the disability originally arose in line of duty, its continuance may be attributable to the member's unreasonable refusal to cooperate in its correction; and that the continuance of the disability might, therefore, result in the member's separation without benefits.

(viii) Also advise the patient that:

(A) Title 10 U.S.C. 1207 precludes disposition under chapter 61 of 10 U.S.C. if such a member's disability is due to intentional misconduct, willful neglect, or if it was incurred during a period of unauthorized absence. A member's refusal to complete a recommended therapy regimen or diagnostic procedure may be interpreted as willful neglect.

(B) Benefits from the Veterans Administration will be dependent upon a finding that the disability was incurred in line of duty and is not due to the member's willful misconduct.

(ix) The Social Security Act contains special provisions relating to benefits for "disabled" persons and certain provisions relating to persons disabled "in line of duty" during service in the Armed Forces. In many instances persons deemed to have "remediable" disorders have been held not "disabled" within the meaning of that term as used in the statute, and Federal courts have upheld that interpretation. One who is deemed unreasonably to have refused to undergo available surgical procedures may be deemed both "not disabled" and

to have incurred the condition "not in the line of duty."

(x) Forward the board's report directly to the Central Physical Evaluation Board with a copy to MEDCOM-25 except in those instances when the convening authority desires referral of the medical board report for Departmental review.

(xi) Per MANMED art. 18-15, a member who refuses medical, dental, or surgical treatment for a condition that existed prior to entry into the service (EPTE defect), not aggravated by a period of active service but which interferes with the performance of duties, should be processed for reason of physical disability, convenience to the Government, or enlisted in error rather than under the refusal of treatment provisions. Procedures are delineated in BUMEDINST 1910.2G and SECNAVINST 1910.4A.

(3) *Other uniformed services patients*. When a patient of another service is found to have a remediable physical defect developed in the military service, refer the matter to the nearest headquarters of the service concerned.

(v) *Responsibilities of the commanding officer*. In connection with the provisions of this part, commanding officers of naval MTFs will:

(1) Determine which persons within the various categories authorized care in a facility will receive treatment in, be admitted to, and be discharged from that specific facility.

(2) Supervise care and treatment, including the employment of recognized professional procedures.

(3) Provide each patient with the best possible care in keeping with accepted professional standards and the assigned primary mission of the facility.

(4) Provide for counseling patients and naval MTF providers when care required is beyond the naval MTF's capability. This includes:

(i) Establishing training programs to acquaint naval MTF providers and HBAs with the uniformed services' referral for supplemental/cooperative care or services policy outlined in § 728.4(z).

(ii) Implementing control measures to ensure that:

(A) Providers requesting care under the provisions § 728.4(z) are qualified to maintain physician case management when required.

(B) Care requested under the supplemental/cooperative care criteria is medically necessary, legitimate, and otherwise permissible under the terms of that part of the USHBP under which it will be considered for payment.

(C) Providers explain to patients the reason for a referral and the type of referral being made.

(D) Attending physicians properly refer beneficiaries to the HBA for counseling and services per § 728.4(n).

(E) Uniform criteria are applied in determining cooperative care situations without consideration of rate, grade, or uniformed service affiliation.

(F) All DD 2161's are properly completed and approved by the commanding officer or designee.

(G) A copy of the completed DD 2161 is returned to the naval MTF for inclusion in the medical record of the patient.

(w) *Sick call.* A regularly scheduled assembly of sick and injured military personnel established to provide routine medical care. Subsequent to examination, personnel medically unfit for duty will be admitted to an MTF or placed sick in quarters; personnel not admitted or placed sick in quarters will be given such treatment as is deemed necessary. When excused from duty for medical reasons which do not require hospitalization, military personnel may be authorized to remain in quarters, not to exceed 72 hours.

(x) *Sicklist—authorized absence from.* Commanding officers of naval MTFs may authorize absences of up to 72 hours for dependents and retired personnel without formal discharge from the sicklist. When absences are authorized in excess of 24 hours, subsistence charges or dependent's rate, as applicable, for that period will not be collected and the number of reportable occupied bed days will be appropriately reduced. Prior to authorizing such absences, the attending physician will advise patients of their physical limitations and of any necessary safety precautions, and will annotate the clinical record that patients have been so advised. For treatment under the Medical Care Recovery Act, make reporting consistent with § 728.4(aa).

(y) *Subsisting out.* A category in which officer and enlisted patients on the sicklist of a naval MTF may be placed when their daily presence is not required for treatment nor examination, but who are not yet ready for return to duty. As a general rule, patients placed in this category should reside in the area of the facility and should be examined by the attending physician at least weekly. Enlisted personnel in a subsisting out status should be granted commuted rations.

(1) Granting of subsisting out privileges is one of many disposition alternatives; however, recommend that other avenues (medical holding company, convalescent leave, limited

duty, etc.) be considered before granting this privilege.

(2) Naval MTF patients in a subsisting out status should not be confused with those enlisted personnel in a rehabilitation program who are granted liberty and are drawing commuted rations, but are required to be present at the treating facility during normal working hours. These personnel are not subsisting out and must have a bed assigned at the naval MTF.

(3) Naval MTF patients who are required to report for examinations or treatment more often than every 48 hours should not be placed in a subsisting out status.

(z) *Supplemental/cooperative care or services—(1) General.* When such services as defined in § 728.2(cc) are rendered to other than CHAMPUS-eligible individuals, the cost thereof is chargeable to operation and maintenance funds available for operation of the facility requesting care or services. Cooperative care applies to CHAMPUS-eligible patients receiving inpatient or outpatient care in a USMTF who require care or services beyond the capability of that USMTF. The following general principles apply to such CHAMPUS-eligible patients:

(i) *Cooperation of uniformed services physicians.* USMTF physicians are required to cooperate in providing CHAMPUS contractors and OCHAMPUS additional medical information. SECNAVINST 5211.5C delineates policies, conditions, and procedures that govern safeguarding, using, accessing, and disseminating personal information kept in a system of records. Providing information to CHAMPUS contractors and OCHAMPUS will be governed thereby.

(ii) *Physician case management.* Where required by NAVMEDCOMINST 6320.18 (CHAMPUS Regulation; implementation of), uniformed services physicians are required to provide case management (oversight) as would an attending or supervising civilian physician.

(iii) *CHAMPUS-authorized providers.* CHAMPUS contractors are responsible for determining whether a civilian provider is CHAMPUS-authorized and for providing such information, upon request, to USMTFs.

(iv) *Psychiatric or psychotherapeutic services.* If psychiatric care is being rendered by a psychiatric or clinical social worker, a psychiatric nurse, or a marriage and family counselor, and the uniformed services facility has made a determination that it does not have the professional staff competent to provide required physician case management, the patient may be (partially)

disengaged for the psychiatric or psychotherapeutic service, yet have the remainder of required medical care provided by the naval MTF.

(v) *Forms and documentation.* A DD 2161, Referral For Civilian Medical Care, will be provided to each patient who is to receive supplemental or cooperative care or services. When supplemental care is required under the provisions of § 728.4(z) (3) and (4), the provisions of § 728.4(z)(3)(iii) apply. When cooperative care or services are required under the provisions of § 728.4(z) (5) and (6), the provisions of § 728.4(z)(5)(iv) apply.

(vi) *Clarification of unusual circumstances.* Commanding officers of naval MTFs will submit requests for clarification of unusual circumstances to OCHAMPUS or CHAMPUS contractors via the Commander, Naval Medical Command (MEDCOM-33) for consideration.

(2) *Care beyond a naval MTF's capability.* When, either during initial evaluation or during the course of treatment of CHAMPUS-eligible beneficiaries, required services are beyond the capability of the naval MTF, the commanding officer will arrange for the services from an alternate source in the following order, subject to restrictions specified. The provisions of § 728.4(z)(2)(i) through (iii) must be followed before either supplemental care, authorized in § 728.4(z)(4), is considered for payment from Navy Operations and Maintenance funds, or cooperative care, authorized in § 728.4(z)(6), is to be considered for payment under the terms of CHAMPUS.

(i) Obtain from another USMTF or other Federal MTF the authorized care necessary for continued treatment of the patient within the naval MTF, when such action is medically feasible and economically advantageous to the Government.

(ii) When the patient is a retired member or dependent, transfer per § 728.4(bb)(3) (i), (ii), (iii), or (iv), in that order. When the patient is a dependent of a member of a NATO nation, transfer per § 728.4(bb)(4) (i), (ii), or (iii), in that order.

(iii) With the patient's permission, the naval MTF may contact State programs, local health agencies, or health foundations to determine if benefits are available.

(iv) Obtain such supplemental care or services as delineated in § 728.4(z)(4) from a civilian source using local operation and maintenance funds, or

(v) Obtain such cooperative care or services as delineated in § 728.4(z)(6)

from a civilian source under the terms of CHAMPUS.

(3) *Operation and maintenance funds.* When local operation and maintenance funds are to be used to obtain supplemental care or services, the following guidelines are applicable:

(i) Care or services must be legitimate, medically necessary, and ordered by a qualified USMTF provider.

(ii) The naval MTF must make the necessary arrangements for obtaining required care or services from a specific source of care.

(iii) Upon approval of the naval MTF commanding officer or designee, provide the patient or sponsor with a properly completed DD 2161, Referral For Civilian Medical Care. The DD 2161 will be marked by the health benefits advisor or other designated individual to show the naval MTF as the source of payment. Forward a copy to the MTF's contracting or supply officer who is the point of contact for coordinating obligations with the comptroller and thus is responsible for assuring proper processing for payment.

(iv) Authorize care on an inpatient or outpatient basis for the minimum period necessary for the civilian provider to perform the specific test, procedure, treatment, or consultation requested. Patients receiving inpatient services in civilian medical facilities will not be counted as an occupied bed in the naval MTF, but will be continued on the naval MTF's inpatient census. Continue to charge pay patients the USMTF inpatient rate appropriate for their patient category.

(v) Naval MTF physicians will maintain professional contact with civilian providers.

(4) *Care and services authorized.* Use local operation and maintenance funds to defray the cost of the following when CHAMPUS-eligible patients are referred to civilian sources for the following types of care or services:

(i) All specialty consultations for the purpose of establishing or confirming diagnoses or recommending a course of treatment.

(ii) All diagnostic tests, diagnostic examinations, and diagnostic procedures (including genetic tests and CAT scans), ordered by qualified USMTF providers.

(iii) Prescription drugs and medical supplies.

(iv) Civilian ambulance service ordered by USMTF personnel.

(5) *CHAMPUS funds.* When payment is to be considered under the terms of CHAMPUS for cooperative care, even though the beneficiary remains under naval MTF control, the following guidelines are applicable:

(i) Process charges for care under the terms of CHAMPUS.

(A) If the charge for a covered service or supply is above the CHAMPUS-determined reasonable charge, the direct care system will not assume any liability on behalf of the patient where a civilian provider is concerned, although a USMTF physician recommended or prescribed the service or supply.

(B) Payment consideration for all care or services meeting cooperative care criteria will be under the terms of CHAMPUS and payment for such care or services will not be made from naval MTF funds. Conversely, any care or services meeting naval MTF supplemental care or services payment criteria will not be considered under the terms of CHAMPUS.

(ii) Care must be legitimate and otherwise permissible under the terms of CHAMPUS and must be ordered by a qualified USMTF provider.

(iii) Provide assistance to beneficiaries referred or disengaged under CHAMPUS. Although USMTF personnel are not authorized to refer beneficiaries to a specific civilian provider for care under CHAMPUS, health benefits advisors are authorized to contact the cooperative care coordinator of the appropriate CHAMPUS contractor for aid in determining authorized providers with the capability of rendering required services. Such information may be given to beneficiaries. Also encourage beneficiaries to obtain required services only from providers willing to participate in CHAMPUS. Subject to the availability of space, facilities, and capabilities of the staff, USMTFs may provide consultative and such other ancillary aid as required by the civilian provider selected by the beneficiary.

(iv) Provide a properly completed DD 2161, Referral For Civilian Medical Care, to patients who are referred (versus disengaged) to civilian sources under the terms of CHAMPUS for cooperative care. (A Nonavailability Statement (DD 1251) may also be required. Provide this form when required under § 728.33.) The DD 2161 will be marked by the health benefits advisor, or other designated individual, to show CHAMPUS as the source of payment consideration. All such DD 2161's must be approved by the commanding officer or designee. Give the patient sufficient copies to ensure a copy of the DD 2161 accompanies each CHAMPUS claim. Advise patients that CHAMPUS contractors will return claims received without the DD 2161. Also advise patients to arrange for return of a completed copy of the DD 2161 to the naval MTF for inclusion in their medical record.

(v) Such patients receiving inpatient or outpatient care or services will pay the patient's share of the costs as specified under the terms of CHAMPUS for their beneficiary category. Patients receiving inpatient services will not be continued on the naval MTF's census and will not be charged the USMTF inpatient rate.

(vi) Certain ancillary services authorized under CHAMPUS require physician case management during the course of treatment. USMTF physicians will manage the provision of ancillary services by civilian providers when such services are obtained under the terms of CHAMPUS. Examples include physical therapy, private duty (special) nursing, rental or lease/purchase of durable medical equipment, and services under the CHAMPUS Program for the Handicapped. USMTF providers exercising physician case management responsibility for ancillary services under CHAMPUS are subject to the same benefit limitations and certification of need requirements applicable to civilian providers under the terms of CHAMPUS for the same types of care. USMTF physicians exercising physician case management responsibility will maintain professional contact with civilian providers of care.

(6) *Care and services authorized.* Refer CHAMPUS-eligible patients to civilian sources for the following under the terms of CHAMPUS:

(i) Authorized nondiagnostic medical services such as physical therapy, speech therapy, radiation therapy, and private duty (special) nursing.

(ii) Preauthorized (by OCHAMPUS) adjunctive dental care, including orthodontia related to surgical correction of cleft palate.

(iii) Durable medical equipment. (CHAMPUS payment will be considered only if the equipment is not available on a loan basis from the naval MTF.)

(iv) Prosthetic devices (limited benefit), orthopedic braces and appliances.

(v) Optical devices (limited benefit).

(vi) Civilian ambulance service to a USMTF when service is ordered by other than direct care personnel.

(vii) All CHAMPUS Program for the Handicapped care.

(viii) Psychotherapeutic or psychiatric care.

(ix) Except for those types of care or services delineated in § 728.4(z)(4), all other CHAMPUS authorized medical services not available in the naval MTF (for example, neonatal intensive care).

(aa) *Third party liability case.* Per chapter 24, section 2403, JAG Manual, use the following guidelines to complete

and submit a NAVJAG 5890/12, Hospital and Medical Care, 3rd Party Liability Case, when a third party may be liable for the injury or disease being treated:

(1) *Preparation.* All naval MTFs will use the front of NAVJAG 5890/12 to report the value of medical care furnished to any patient when (i) a third party may be legally liable for causing the injury or disease, or (ii) when a Government claim is possible under workmen's compensation, no-fault insurance (see responsibilities for apprising the insurance carrier in § 728.4(aa)(5)), uninsured motorist insurance, or under medical payments insurance (e.g., in all automobile accident cases). Block 4 of this form requires an appended statement of the patient or an accident report, if available. Prior to requesting such a statement from a patient, the person preparing the front side of NAVJAG 5890/12 will show the patient the Privacy Act statement printed at the bottom of the form and have the patient sign his or her name beneath the statement.

(2) *Submission*—(i) *Naval patients.* For naval patients, submit the completed front side of the NAVJAG 5890/12 to the appropriate action JAG designee listed in section 2401 of the JAG Manual at the following times:

(A) *Initial.* Make an initial submission as soon as practicable after a patient is admitted for any period of inpatient care, or if it appears that more than 7 outpatient treatments will be furnished. This submission should not be delayed pending the accumulation of all potential charges from the treating facility. This submission need not be based upon an extensive investigation of the cause of the injury or disease, but it should include all known facts. Statements by the patient, police reports, and similar information (if available), should be appended to the form.

(B) *Interim.* Make an interim submission every 4 months after the initial submission until the patient is transferred or released from the facility, or changed from an inpatient status to an outpatient status.

(C) *Final.* Make a final submission upon completion of treatment or upon transfer of the patient to another facility. The facility to which the patient is transferred should be noted on the form. Report control symbol NAVJAG 5890-1 is assigned to this report.

(ii) *Nonnaval patients.* When care is provided to personnel of another Federal agency or department, that agency or department generally will assert any claim in behalf of the United States. In such instances, submit the

NAVJAG 5890/12's (initial, interim, and final) directly to the appropriate of the following:

(A) *U.S. Army.* Commanding general of the Army or comparable area commander in which the incident occurred.

(B) *U.S. Air Force.* Staff judge advocate of the Air Force installation nearest the location where the initial medical care was provided.

(C) *U.S. Coast Guard.* Commandant (G-K-2), U.S. Coast Guard, Washington, DC 20593-0001.

(D) *Department of Labor.* The appropriate Office of Workers' Compensation Programs (OWCP).

(E) *Veterans Administration.* Director of the Veterans Administration hospital responsible for medical care of the patient being provided treatment.

(F) *Department of Health and Human Services (DHHS).* Regional attorney's office in the area where the incident occurred.

(3) *Supplementary documents.* An SF 502 should accompany the final submission in all cases involving inpatient care. Additionally, when Government care exceeds \$1,000, inpatient facilities should complete and submit the back side of NAVJAG 5890/12 to the action JAG designee. On this side of the form, the determination of "patient status" may be used on local hospital usage.

(4) *Health record entries.* Retain copies of all NAVJAG 5890/12's in the Health Record of the patient. Immediately notify action JAG designees when a patient receives additional treatment subsequent to the issuance of a final NAVJAG 5890/12 if the subsequent treatment is related to the condition which gave rise to the claim.

(5) *No-fault insurance.* When no-fault insurance is or may be involved, the naval legal service office at which the JAG designee is located is responsible for apprising the insurance carrier that the Federal payment for the benefits of this part is secondary to any no-fault insurance coverage available to the injured individual.

(6) *Additional guidance.* Chapter 24 of the JAG Manual and BUMEDINST 5890.1A contain supplemental information.

(bb) *Transfer of patients*—(1) *General.* Treat all patients at the lowest echelon equipped and staffed to provide necessary care; however, when transfer to another MTF is considered necessary, use Government transportation when available. Accomplish medical regulating per the provisions of OPNAVINST 4630.25B and BUMEDINST 6320.1D.

(2) *U.S. military patients.* Do not retain U.S. military patients in acute care MTFs longer than the minimum time necessary to attain the mental or physical state required for return to duty or separation from the service. When required care is not available at the facility providing area inpatient care, transfer patients to the most readily accessible USMTF or designated USTF possessing the required capability. Transportation of the patient and a medical attendant or attendants, if required, is authorized at Government expense. Since the VA is staffed and equipped to provide care in the most expeditious manner, follow the administrative procedures outlined in NAVMEDCOMINST 6320.12 when:

(i) A patient has received the maximum benefit of hospitalization in a naval MTF but requires a protracted period of nursing home type care. The VA can provide this type care or arrange for it from a civilian source for individuals so entitled.

(ii) Determined that there is or may be spinal cord injury necessitating immediate medical and psychological attention.

(iii) A patient has sustained an apparently severe head injury or has been blinded necessitating immediate intervention beyond the capabilities of naval MTFs.

(iv) A determination has been made by the Secretary concerned that a member on active duty has an alcohol or drug dependency or drug abuse disability.

(3) *Retired members and dependents.* When a retired member of a dependent requires care beyond the capabilities of a facility and a transfer is necessary, the commanding officer of that facility may:

(i) Arrange for transfer to another USMTF or designated USTF located in an overlapping inpatient catchment area of the transferring facility if either has the required capability.

(ii) If the patient or sponsor agrees, arrange for transfer to the nearest USMTF or designated USTF with required capability, regardless of its location.

(iii) Arrange for transfer of retired members to the Veterans Administration MTF nearest the patient's residence.

(iv) Provide aid in releasing the patient to a civilian provider of the patient's choice under the terms of Medicare, if the patient is entitled. Beneficiaries entitled to Medicare, Part A, because they are 65 years of age or older or because of a disability or chronic renal disease, lose CHAMPUS

eligibility but remain eligible for care in USMTFs and designated USTFs.

(v) If the patient is authorized benefits under CHAMPUS, disengage from medical management and issue a Non-availability Statement (DD 1251) per the provisions of § 728.33, for care under CHAMPUS. This step should only be taken after due consideration is made of the supplemental/cooperative care policy addressed in § 728.4(z).

(4) *Dependents of members of NATO nations.* When a dependent, as defined in § 728.41, of a member of a NATO nation requires care beyond the capabilities of a facility and a transfer is necessary, the commanding officer of that facility may:

(i) Arrange for transfer to another USMTF or designated USTF with required capability if either is located in an overlapping inpatient catchment area of the transferring facility.

(ii) If the patient or sponsor agrees, arrange for transfer to the nearest USMTF or designated USTF with required capability, regardless of its location.

(iii) Effect disposition per § 728.42(d).

(5) *Others—(i) Medical care.* Section 34 of title 24, United States Code, provides that hospitalization and outpatient services may be provided outside the continental limits of the United States and in Alaska to officers and employees of any department or agency of the Federal Government, to employees of a contractor with the United States or the contractor's subcontractor, to dependents of such persons, and in emergencies to such other persons as the Secretary of the Navy may prescribe: *Provided*, such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities. Hospitalization of such persons in a naval MTF is further limited by 24 U.S.C. 35 to the treatment of acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care.

(ii) *Dental care.* Section 35 of title 24 provides for space available routine dental care, other than dental prosthesis and orthodontia, for the categories of individuals enumerated in § 728.4(bb)(5)(i): *Provided*, that such services are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(iii) *Transfer.* Accomplish transfer and subsequent treatment of individuals in § 728.4(bb)(5)(i) per the provisions of law enumerated in § 728.4(bb)(5) (i) and (ii).

(cc) *Verification of patient eligibility—(1) DEERS.* (i) The Defense Enrollment Eligibility Reporting System

(DEERS) was implemented by OPNAVINST 1750.2. Where DEERS has been started at naval medical and dental treatment facilities, commanding officers will appoint, in writing, a DEERS project officer to perform at the base level. The project officer's responsibilities and functions include coordinating, executing, and maintaining base-level DEERS policies and procedures; providing liaison with line activities, base-level personnel project officers, and base-level public affairs project officers; meeting and helping the contractor field representative on site visits to each facility under the project officer's cognizance; and compiling and submitting reports required within the command and by higher authority.

(ii) Commanding officers of afloat and deployable units are encouraged to appoint a unit DEERS medical project officer as a liaison with the hospital project officer providing services to local medical and dental treatment facilities. Distribute notice of such appointments to all concerned facilities.

(iii) When a DEERS project officer has been appointed by a naval MTF or DTF, submit a message (report control symbol MED 6320-42) to COMNAVMEDCOM, with information copies to appropriate chain of command activities, no later than 10 October annually, and situationally when changes occur. As a minimum, the report will provide:

(A) Name of reporting facility. If the project officer is responsible for more than one facility, list all such facilities.

(B) Mailing address including complete zip code (zip + 4) and unit identification code (UIC). Include this information for all facilities listed in § 728.4(cc)(1)(iii)(A).

(C) Name, grade, and corps of the DEERS project officer designated.

(D) Position title within parent facility.

(E) AUTOVON and commercial telephone numbers.

(2) *DEERS and the identification card.* This subpart includes DEERS procedures for eligibility verification checks to be used in conjunction with the identification card system as a basis for verifying eligibility for medical and dental care in USMTFs and uniformed services dental treatment facilities (USDTFs). For other than emergency care, certain patients are required to have a valid ID card in their possession and, under the circumstances described in § 728.4(cc)(3), are also required to meet DEERS criteria before treatment or services are rendered. Although DEERS and the ID card system are interrelated, there will be instances where a beneficiary is in possession of an apparently valid ID card and the DEERS verification check shows that eligibility

has terminated or vice versa. Eligibility verification via an ID card does not override an indication of ineligibility in DEERS without some other collateral documentation. Dependents (in possession of or without ID cards) who undergo DEERS checking will be considered ineligible for the reasons stated in § 728.4(cc)(4)(v) (A) through (G). For problem resolution, refer dependents of active duty members to the personnel support detachment (PSD) servicing the sponsor's command; refer retirees, their dependents, and survivors to the local PSD.

(3) *Identification cards and procedures.* All individuals, including members of uniformed services in uniform, must provide valid identification when requesting health benefits. Although the most widely recognized and acceptable forms of identification are DD 1173, DD 2, Form PHS-1866-1, and Form PHS-1866-3 (Ret), individuals presenting for care without such identification may be rendered care upon presentation of other identification as outlined in this part. Under the circumstances indicated, the following procedures will be followed when individuals present without the required ID card.

(i) *Children Under 10.* Although a DD 1173 (Uniformed Services Identification and Privilege Card) may be issued to children under 10 years of age, under normal circumstances they are not. Accordingly, certification and identification of children under 10 years of age are the responsibility of the member, retired member, accompanying parent, legal guardian, or acting guardian. Either the DD 1173 issued the spouse of a member or former member or the identification card of the member or former member (DD 2, DD 2 (Ret), Form PHS-1866-1, or Form PHS-1866-3 (Ret)) is acceptable for the purpose of verifying eligibility of a child under 10 years of age.

(ii) *Indefinite expiration.* The fact that the word "indefinite" may appear in the space for the expiration date on a member's card does not lessen its acceptability for identification of a child. See § 728.4(cc)(3)(iii) for dependent's cards with an indefinite expiration date.

(iii) *Expiration date.* To be valid, a dependent's DD 1173 must have an expiration date. Do not honor a dependent's DD 1173 with an expiration date of "indefinite". Furthermore, such a card should be confiscated, per NAVMILPERSCOMINST 1750.1A, and forwarded to the local PSD. The PSD may then forward it to the Commander, Naval Military Personnel Command,

(NMPC (641D)/Pers 7312), Department of the Navy, Washington, DC 20370-5000 for investigation and final disposition. Render necessary emergency treatment to such a person. The patient administration department must determine such a patient's beneficiary status within 30 calendar days and forward such determination to the fiscal department. If indicated, billing action for treatment will then proceed following NAVMED P-5020.

(iv) *Without cards or with expired cards.* (A) When parents or parents-in-law (including step-parents and step-parents-in-law) request care in naval MTFs or DTFs without a DD 1173 in their possession or with expired DD 1173's, render care if they or their sponsor sign a statement that the individual requiring care has a valid ID card or that an application has been submitted for a renewal DD 1173. In the latter instance, include in the statement the allegation that: (1) The beneficiary is dependent upon the service member for over one-half of his or her support, and (2) that there has been no material change in the beneficiary's circumstances since the previous determination of dependency and issuance of the expired card. Place the statement in the beneficiary's medical record. Inform the patient or sponsor that if eligibility is not verified by presentation of a valid ID card to the patient administration department within 30 calendar days, the facility will initiate action to recoup the cost of care. If indicated, billing action for the cost of treatment will then proceed following NAVMED P-5020.

(B) When recent accessions, National Guard, reservists, or Reserve units are called to active duty for a period greater than 30 days and neither the members nor their dependents are at yet in receipt of their identification cards, satisfactory collateral identification may be accepted in lieu thereof, i.e., official documents such as orders, along with a marriage license, or birth certificate which establish the individual's status as a dependent of a member called to duty for a period which is not specified as 30 days or less. For a child, the collateral documentation must include satisfactory evidence that the child is within the age limiting criteria outlined in § 728.31(b)(4). An eligible dependent's entitlement, under the provisions of this subpart, starts on the first day of the sponsor's active service and ends as of midnight on the last day of active service.

(4) *DEERS checking.* Unless otherwise indicated, all DEERS verification procedures will be accomplished in

conjunction with possession of a valid ID card.

(i) *Prospective DEERS processing—*
(A) *Appointments.* To minimize difficulties for MTFs, DTFs, and patients, DEERS checks are necessary for prospective patients with future appointments made through a central or clinic appointment desk. Without advance DEERS checking, patients could arrive at a facility with valid ID cards but may fail the DEERS check, or may arrive without ID cards but be identified by the DEERS check as eligible. Records, including full social security numbers, of central and clinic appointment systems will be passed daily to the DEERS representative for a prospective DEERS check. This enables appointment clerks to notify individuals with appointments of any apparent problem with the DEERS or ID card system and refer those with problems to appropriate authorities prior to the appointment.

(B) *Prescriptions.* Minimum checking requirements of the program require prospective DEERS checks on all individuals presenting prescriptions of civilian providers (see § 728.4(cc)(4)(iv)(D)).

(ii) *Retrospective DEERS processing.* Pass daily logs (for walk-in patients, patients presenting in emergencies, or patients replacing last minute appointment cancellations) to the DEERS representative for retrospective batch processing if necessary for the facility to meet the minimum checking requirements in § 728.4(cc)(4)(iv). For DEERS processing, the last four digits of a social security number are insufficient. Accordingly, when retrospective processing is necessary, the full social security number of each patient must be included on daily logs.

(iii) *Priorities.* With the following initial priorities, conduct DEERS eligibility checks using a CRT terminal, single-number dialer telephone, or 800 number access provided for the specific purpose of DEERS checking to:

(A) Determine whether a beneficiary is enrolled.

(B) Verify beneficiary eligibility. Establishment of eligibility is under the cognizance of personnel support activities and detachments.

(C) Identify any errors on the data base.

(iv) *Minimum checking requirements.* Process patients presenting at USMTFs and DTFs in the 50 States for DEERS eligibility verification per the following minimum checking requirements.

(A) Twenty five percent of all outpatient visits.

(B) One hundred percent of all admissions.

(C) One hundred percent of all dental visits at all DTFs for other than active duty members, retired members, and dependent.

(1) Active duty members are exempt from DEERS eligibility verification checking at DTFs.

(2) Retired members will receive a DEERS verification check at the initial visit to any DTF and annually thereafter at time of treatment at the same facility. To qualify for care as a result of the annually performed verification check, the individual performing the eligibility check will make a notation to this effect on an SF 603, Health Record—Dental. Include in the notation the date and result of the check.

(3) Dependents will have a DEERS eligibility verification check upon initial presentation for evaluation or treatment. This check will be valid for up to 30 days if, when the check is conducted, the period of eligibility requested is 30 days. A 30-day eligibility check may be accomplished online or via telephone by filling in or requesting the operator to fill in a 30 day period in the requested treatment dates on the DEERS eligibility inquiry screen. Each service or clinic is expected to establish auditable procedures to trace the date of the last eligibility verification on a particular dependent.

(D) One hundred percent of pharmacy outpatients presenting new prescriptions written by a civilian provider. Prospective DEERS checks are required for all patients presenting prescriptions of civilian providers. A DEERS check is not required upon presentation of a request for refill of a prescription of a civilian provider if the original prescription was filled by a USMTF within the past 120 days.

(E) One hundred percent of all individuals requesting treatment without a valid ID card if they represent themselves as individuals who are eligible to be included in the DEERS data base.

(v) *Ineligibility determinations.* When a DEERS verification check is performed and eligibility cannot be verified for any of the following reasons, deny routine nonemergency care unless the beneficiary meets the criteria for a DEERS eligibility override as noted in § 728.4(cc)(4)(viii).

(A) Sponsor not enrolled in DEERS.

(B) Dependent not enrolled in DEERS.

(C) "End eligibility date" has passed. Each individual in the DEERS data base has a date assigned on which eligibility is scheduled to end.

(D) Sponsor has separated from active duty and is no longer entitled to benefits.

(E) Spouse has a final divorce decree from sponsor and is not entitled to continued eligibility as a former spouse.

(F) Dependent child is married.

(G) Dependent becomes an active duty member of a uniformed service. (Applies only to CHAMPUS benefits since the former dependent becomes entitled to direct care benefits in his or her own right as an active duty member and must enroll in DEERS.)

(vi) *Emergency situations.* When a physician determines that emergency care is necessary, initiate treatment. If admitted after emergency treatment has been provided, a retrospective DEERS check is required. If an emergency admission or emergency outpatient treatment is accomplished for an individual whose proof of eligibility is in question, the patient administration department must determine the individual's beneficiary status within 30 calendar days of treatment and forward such determination to the fiscal department. Eligibility verifications will normally consist of presentation of a valid ID card along with either a positive DEERS check or a DEERS override as noted in § 728.4(cc)(4)(viii). If indicated, billing action for treatment will then proceed per NAVMED P-5020.

(vii) *Eligibility verification for nonemergency care.* When a prospective patient presents without a valid ID card and:

(A) DEERS does not verify eligibility, deny nonemergency care. Care denial will only be accomplished by supervisory personnel designated by the commanding officer.

(B) The individual is on the DEERS data base, do not provide nonemergency care until a NAVMED 6320/9, Dependent's Eligibility for Medical Care, is signed by the member, patient, patient's parent, or patient's legal or acting guardian. This form attests the fact that eligibility has been established per appropriate directives and includes the reason a valid ID card is not in the prospective patient's possession. Apprise the aforementioned responsible individual of the provisions on the form NAVMED 6320/9 now requiring presentation of a valid ID card within 30 calendar days. Deny treatment or admission in physician determined nonemergency situations of persons refusing to sign the certification on the NAVMED 6320/9. For persons rendered treatment, patient administration department personnel must determine their eligibility status within 30 calendar days and forward such determination to the fiscal department. If indicated,

billing action for treatment will then proceed following NAVMED P-5020.

(viii) *DEERS overrides.* Possession of an ID card alone does not constitute sufficient proof of eligibility when the DEERS check does not verify eligibility. What constitutes sufficient proof will be determined by the reason the patient failed the DEERS check. For example, groups most expected to fail DEERS eligibility checks are recent accession members and their dependents, Guard or Reserve members recently activated for training periods of greater than 30 days and their dependents, and parents and parents-in-law with expired ID cards. Upon presentation of a valid ID card, the following are reasons to "override" a DEERS check either showing the individual as ineligible or when an individual does not appear in the DEERS data base.

(A) *DD 1172.* Patient presents an original of a copy of a DD 1172, Application for Uniformed Services Identification and Privilege Card, which is also used to enroll beneficiaries in DEERS. If the original is used, the personnel support detachment (PSD) furnishing the original will list the telephone number of the verifying officer to aid in verification. Any copy presented must have an original signature in section III; printed name of verifying officer, his or her grade, title, and telephone number; and the date the copy was issued. For treatment purposes, this override expires 120 days from the date issued.

(B) *Recently issued identification cards—(1) DD 1173.* Patient presents a recently issued DD 1173, Uniformed Services Identification and Privilege Card. Examples are spouses recently married to sponsor, newly eligible stepchildren, family members of sponsors recently entering on active duty for a period greater than 30 days, parents or parents-in-law, and unremarried spouses recently determined eligible. For treatment purposes, this override expires 120 days from the date issued.

(2) *Other ID Cards.* Patient presents any of the following ID cards with a date of issue within the previous 120 days: DD 2, DD 2 (Ret), Form PHS 1866-1, or Form PHs 1866-3 (Ret). When these ID cards are used for the purpose of verifying eligibility for a child, collateral documentation is necessary to ensure the child is actually the alleged sponsor's dependent and in determining whether the child is within the age limiting criteria outlined in § 728.31(b)(4).

(C) *Active duty orders.* Patient or sponsor presents recently issued orders to active duty for a period greater than

30 days. Copies of such orders may be accepted up to 120 days of their issue date.

(D) *Newborn infants.* Newborn infants for a period of 1 year after birth provided the sponsor presents a valid ID card.

(E) *Recently expired ID cards.* If the DEERS data base shows an individual as ineligible due to an ID card that has expired within the previous 120 days (shown on the screen as "Elig with valid ID card"), care may be rendered when the patient has a new ID card issued within the previous 120 days.

(F) *Sponsor's duty station has an FPO or APO number or sponsor is stationed outside the 50 United States.* Do not deny care to bona fide dependents of sponsors assigned to a duty station outside the 50 United States or assigned to a duty station with an FPO or APO address as long as the sponsor appears on the DEERS data base. Before initiating nonemergency care, request collateral documentation showing relationship to sponsor when the relationship is or may be in doubt.

(G) *Survivors.* Dependents of deceased sponsors when the deceased sponsor failed to enroll in or have his or her dependents enrolled in DEERS. This situation will be evidenced when an eligibility check on the surviving widow or widower (or other dependent) finds that the sponsor does not appear (screen shows "Sponsor SSN Not Found") or the survivor's name appears as the sponsor but the survivor is not listed separately as a dependent. In any of these situations, if the survivor has a valid ID card, treat the individual on the first visit and refer him or her to the local personnel support detachment for correction of the DEERS data base. For second and subsequent visits prior to appearance on the DEERS data base, require survivors to present a DD 1172 issued per § 728.4(cc)(4)(viii)(A).

(H) *Patients Not Eligible for DEERS Enrollment.* (1) Secretarial designees are not eligible for enrollment in DEERS. Their eligibility determination is verified by the letter, on one of the service Secretaries' letterhead, of authorization issued.

(2) When it becomes necessary to make a determination of eligibility on other individuals not eligible for entry on the DEERS data base, patient administration department personnel will obtain a determination from the purported sponsoring agency, if appropriate. When necessary to treat or admit a person who cannot otherwise present proof of eligibility for care at the expense of the Government, do not deny care based only on the fact that the

individual is not on the DEERS data base. In such instances, follow the procedures in NAVMED P-5020 to minimize, to the fullest extent possible, the write-off of uncollectible accounts.

Subpart B—Members of the Uniformed Services on Active Duty

§ 728.11 Eligible beneficiaries.

(a) A member of a uniformed service, as defined in subpart A, who is on active duty is entitled to and will be provided medical and dental care and adjuncts thereto. For the purpose of this part, the following are also considered on active duty:

- (1) Members of the National Guard in active Federal service pursuant to a "call" under 10 U.S.C. 3500 or 8500.
- (2) Midshipmen of the United States Naval Academy.
- (3) Cadets of the United States Military Academy.
- (4) Cadets of the Air Force Academy.
- (5) Cadets of the Coast Guard Academy.

(b) The following categories of personnel who are on active duty are entitled to and will be provided medical and dental care and adjuncts thereto to the same extent as is provided for active duty members of the Regular service (except reservists when on active duty for training as delineated in § 728.21).

- (1) Members of the Reserve components.
- (2) Members of the Fleet Reserve.
- (3) Members of the Fleet Marine Corps Reserve.
- (4) Members of the Reserve Officers' Training Corps.
- (5) Members of all officer candidate programs.
- (6) Retired members of the uniformed services.

§ 728.12 Extent of care.

Members who are away from their duty stations or are on duty where there is no MTF of their own service may receive care at the nearest available Federal MTF (including designated USTFs) with the capability to provide required care. Care will be provided without regard to whether the condition for which treatment is required was incurred or contracted in line of duty.

(a) *All uniformed services active duty members.*

(1) All eligible beneficiaries covered in this subpart are entitled to and will be rendered the following treatment and services upon application to a naval MTF whose mission includes the rendering of the care required. This entitlement provides that when required care and services are beyond the capabilities of the facility to which the

member applies, the commanding officer of that facility will arrange for care from another USMTF, designated USTF, or other Federal source or will authorize and arrange for direct use of supplemental services and supplies from civilian non-Federal sources out of operation and maintenance funds.

(i) Necessary hospitalization and other medical care.

(ii) Occupational health services as defined in § 728.2(z).

(iii) Necessary prosthetic devices, prosthetic dental appliances, hearing aids, spectacles, orthopedic footwear, and other orthopedic appliances (see Subpart H). When these items need repair or replacement and the items were not damaged or lost through negligence, repair or replacement is authorized at Government expense.

(iv) Routine dental care.

(2) When a USMTF, with a mission of providing the care required, releases the medical management of an active duty member of the Navy, Marine Corps, Army, Air Force, or a commissioned corps member of USPHS or NOAA, the resulting civilian health care costs will be paid by the referring facility.

(3) The member's uniformed service will be billed for care provided by the civilian facility only when the referring MTF is not organized nor authorized to provide needed health care (see Part 732 of this chapter for naval members). Saturation of service or facilities does not fall within this exception. When a naval MTF retains medical management, the costs of supplemental care obtained from civilian sources is paid from funds available to operate the MTF which manages care of the patient. When it becomes necessary to refer a USPHS or NOAA commissioned corps member to a non-Federal source of care, place a call to the Department of Health and Human Services (DHHS), Chief, Patient Care Services on (301) 443-1943 or FTS 443-1943 if DHHS is to assume financial responsibility. Patient Care Services is the sole source for providing authorization for non-Federal care at DHHS expense.

(b) *Maternity episode for active duty female members.* A pregnant active duty member who lives outside the MHSS inpatient catchment area of all USMTFs is permitted to choose whether she wishes to deliver in a closer civilian hospital or travel to the USMTF for delivery. If such a member chooses to deliver in a naval MTF, makes application, and presents at that facility at the time for delivery, the provisions of § 728.12(a) apply with respect to the furnishing of needed care, including routine newborn care (i.e., nursery, newborn examination, PKU test, etc.);

arrangements for care beyond the facility's capabilities; or the expenditure of funds for supplemental care or services. Pay expenses incurred for the infant in USMTFs or civilian facilities (once the mother has been admitted to the USMTF) from funds available for care of active duty members, *unless* the infant becomes a patient in his or her own right either through an extension of the birthing hospital stay because of complications, subsequent transfer to another facility, or subsequent admission. If the Government is to assume financial responsibility for:

(1) Care of pregnant members residing within the MHSS inpatient catchment area of a uniformed services hospital or in the inpatient catchment area of a designated USTF, such members are required to:

(i) Make application to that facility for care, or

(ii) Obtain authorization, per Part 732 of this chapter, for delivery in a civilian facility.

(2) Non-Federal care of pregnant members residing outside inpatient catchment areas of USMTFs and USTFs, the member must request and receive authorization per Part 732 of this chapter. Part 732 of this chapter also provides for cases of precipitous labor necessitating emergency care. OPNAVINST 6000.1, Management of Pregnant Servicewomen, contains medical-administrative guidelines on management prior to admission and after discharge from admission for delivery.

(c) *Reserve and National Guard personnel.* In addition to those services covered in § 728.12 (a) and (b), Reserve and National Guard personnel are authorized the following under conditions set forth. (See § 728.25 for additional benefits for National Guard personnel.)

(1) Personnel whose units have an active Army mission of manning missile sites are authorized spectacle inserts for protective field masks.

(2) Personnel assigned to units designated for control of civil disturbances are authorized spectacle inserts for protective field masks M17.

§ 728.13 Application for care.

Possession of an ID card (a green colored DD 2 (with letter suffix denoting branch of service), Armed Forces Identification Card; a green colored PHS 1866-1, Identification Card; or a red colored DD 2 Res (Reservists on active duty for training)) alone does not constitute sufficient proof of eligibility. Accordingly, make a DEERS check, per § 728.4(cc), before other than emergency

care is rendered to the extent that may be authorized.

§ 728.14 Pay patients.

Care is provided on a reimbursable basis to: Coast Guard active duty officers, enlisted personnel, and academy cadets; Public Health Service Commissioned Corps active duty officers; and Commissioned Corps active duty officers of the National Oceanic and Atmospheric Administration. Accordingly, patient administration personnel will initiate the collection action process in Subpart J in each instance of inpatient or outpatient care provided to these categories of patients.

Subpart C—Members of Reserve Components, Reserve Officers' Training Corps, Navy and Marine Corps Officer Candidate Programs, and National Guard Personnel

§ 728.21 Navy and Marine Corps reservists.

(a) *Scope.* This § 728.21 applies to reservists, as those terms are defined in § 728.2, ordered to active duty for training or inactive duty training for 30 days or less. Reservists serving under orders specifying duty in excess of 30 days, such as Sea and Air Mariners (SAMS) while on initial active duty for training, will be provided care as members of the Regular service per subpart B.

(b) *Entitlement.* Per 10 U.S.C. 1074a(a), reservists who incur or aggravate an injury, illness, or disease in line of duty while on active duty for training or inactive duty training for a period of 30 days or less, including travel to and from that duty, are entitled to medical and dental care appropriate for the treatment of that injury, disease, or illness until the resulting disability cannot be materially improved by further hospitalization or treatment. Care is authorized for such an injury, illness, or disease beyond the period of training to the same extent as care is authorized for members of the Regular service (see subpart B) subject to the provisions of § 728.21(e).

(c) *Questionable circumstances.* If the circumstances are questionable, referral to the OMA or ODA is appropriate. If necessary, make referral to the Naval Medical Command (MEDCOM-33 for medical and MEDCOM-06 for dental) on determinations of entitlements.

(d) *Line of duty.* For the purpose of providing treatment under laws entitling reservists to care, an injury, illness, or disease which is incurred, aggravated, or becomes manifest while a reservist is employed in the performance of active

duty for training or inactive duty training (including authorized leave, liberty and travel to and from either duty) will be considered to have been incurred in line of duty (LOD) unless the condition was incurred as a result of the reservist's own misconduct or under other circumstances enumerated in JAG Manual, chapter VIII. While the LOD investigation is being conducted, such reservists remain entitled to care. If the investigation determines that the injury or illness was not incurred in line of duty, the civilian humanitarian nonindigent rate is applicable if further care is required in naval MTFs. (See DOD Military Pay and Allowances Entitlement Manual for allowable constructive travel times.)

(e) *Treatment and services authorized.* In addition to those services delineated above, the following may be rendered under circumstances outlined:

(1) Prosthetic devices, including dental appliances, hearing aids, spectacles, and orthopedic appliances that are lost or have become damaged during training duty, not through negligence of the individual, may be repaired or replaced at Government expense.

(2) Reservists covered by this subpart may be provided the following only if approved by the appropriate OMA or ODA, or by the Commander, Naval Medical Command (MEDCOM-33 for medical and MEDCOM-06 for dental) prior to initiation of services.

(i) Treatment for acute exacerbations of conditions that existed prior to a reservist's period of training duty. Limit care to that necessary for the prevention of pain or undue suffering until the patient can reasonably return to control of the member's private physician or dentist.

(A) Remediable physical defects and remediable treatment for other conditions.

(B) Elective surgery.

(ii) All dental care other than emergency treatment and that necessary to correct an injury incurred in the line of duty.

(f) *Authorization for care.* (1) Reservists covered by this subpart may be provided inpatient or outpatient care during a period of training duty without written authorization.

(2) Except in emergencies or when inpatient care initiated during a period of training duty extends beyond such period, reservists will be required to furnish written official authorization from their unit commanding officer, or higher authority, incident to receiving inpatient or outpatient care beyond the period of training duty. The letter of authorization will include name, grade or rate, social security number, and

organization of the reservist; type of training duty being performed or that was being performed when the condition manifested; diagnosis (if known); and a statement that the condition was incurred in line of duty and that the reservist is entitled to care. If the reservist has been issued a notice of eligibility (NOE) (Subpart I), the NOE may then be accepted in lieu of the letter of authorization. When authorization has not been obtained beforehand, care may be provided on a civilian humanitarian basis (see Subpart G) pending final determination of eligibility.

§ 728.22 Members of other reserve components of the uniformed services.

(a) Members of reserve components of the Coast Guard may be provided care the same as Navy and Marine Corps reservists.

(b) Members of reserve components of the Army and Air Force may be provided care in naval MTFs to the same extent that they are eligible for such care in MTFs of their respective services. Consult current Army Regulation 40-3, Medical, Dental, and Veterinary Care, or Air Force Regulation 168-6, Persons Authorized Medical Care, as appropriate, for particular eligibility requirements or contact the nearest appropriate service facility.

(c) When the service directive requires written authorization, obtain such authorization from the reservist's unit commanding officer or other appropriate higher authority.

(d) Naval MTFs in the United States are authorized to conduct physical examinations of and administer immunizations to inactive reserve Public Health Service commissioned officers upon presentation of a written request from the Commissioned Personnel Operations Division, OPM/OAM, 5600 Fishers Lane, Rockville, MD 20852.

§ 728.23 Reserve Officers' Training Corps (ROTC).

(a) *Eligible beneficiaries.* (1) Members of the Senior Reserve Officers' Training Corps of the Armed Forces including students enrolled in the 4-year Senior ROTC Program or the 2-year Advanced Training Senior ROTC Program.

(2) Designated applicants for membership in the Navy, Army, and Air Force Senior ROTC Programs during their initial 6-weeks training period (practice cruises or field training).

(3) Medical, dental, pharmacy, veterinary or science allied to medicine students who are commissioned officers of a reserve component of an Armed Force who have been admitted to and

training in a unit of a Senior Reserve Officers' Training Corps.

(b) *Extent of care.* (1) While attending or en route to or from field training or practice cruises:

(i) Medical care for a condition incurred without reference to line of duty.

(ii) Routine dental care.

(iii) Prosthetic devices, including dental appliances, hearing aids, spectacles, and orthopedic appliances that have become damaged or lost during training duty, not through negligence of the individual, may be repaired or replaced as necessary at government expense.

(iv) Care of remediable physical defects, elective surgery or other remediable treatment for conditions that existed prior to a period of training duty are not authorized without approval from the appropriate OMA or ODA, or from the Commander, Naval Medical Command (MEDCOM-33 for medical and MEDCOM-06 for dental).

(v) Medical examinations and immunizations.

(vi) ROTC members are authorized continued medical care, including hospitalization, upon expiration of their field training or practice cruise period, the same as reservists in § 728.21(b) and § 728.22.

(2) While attending a civilian educational institution:

(i) Medical care in naval MTFs, including hospitalization, for a condition incurred in line of duty while at or traveling to or from a military installation for the purpose of undergoing medical or other examinations or for purposes of making visits of observation, including participation in service-sponsored sports, recreational, and training activities.

(ii) Medical examinations, including hospitalization necessary for the proper conduct thereof.

(iii) Required immunizations, including hospitalization for severe reactions therefrom.

(c) *Authorization.* The individual's commanding officer will prepare a letter of authorization addressed to the commanding officer of the MTF concerned.

(d) *ROTC members as beneficiaries of the Office of Workers' Compensation Programs (OWCP).* Under circumstances described therein, render care as outlined in § 728.53 to members of the ROTC as beneficiaries of OWCP.

§ 728.24 Navy and Marine Corps Office Candidate Programs.

Members of the Reserve Officers Candidate Program and Platoon Leaders

Class are entitled to the same medical and dental benefits as are provided members of the Navy and Marine Corps Reserve Components. Accordingly, the provisions of § 728.21 are applicable for such members. Additionally, candidates for, or persons enrolled in such programs are authorized access to naval MTFs for the purpose of conducting special physical examination procedures which have been requested by the Commander, Naval Medical Command to determine their physical fitness for appointment to, or continuation in such a program. Upon a request from the individual's commanding officer, the officer in charge of cognizant Navy and Marine Corps recruiting stations, or officer selection officer, naval MTFs are authorized to admit such persons when, in the opinion of the cognizant officer, hospitalization is necessary for the proper conduct of the special physical examinations. Hospitalization should be kept to a minimum and treatment other than for humanitarian reasons, except as provided in this part, is not authorized.

§ 728.25 Army and Air Force National Guard personnel.

(a) *Medical and dental care.* Upon presentation of a letter of authorization, render care as set forth in AR 40-3 (Medical, Dental, and Veterinary Care) and AFR 168-6 (Persons Authorized Medical Care) to members of the Army and Air Force National Guard who contract a disease or become ill in line of duty while on full-time National Guard duty, (including leave and liberty therefrom) or while traveling to or from that duty. The authorizing letter will include name, social security number, grade, and organization of the member; type and period of duty in which engaged (or in which engaged when the injury or illness occurred); diagnosis (if known); and will indicate that the injury suffered or disease contracted was in line of duty and that the individual is entitled to medical or dental care. Limit care to that appropriate for the injury, disease, or illness until the resulting disability cannot be materially improved by further hospitalization or treatment.

(b) *Physical examinations.* AR 40-3 and AFR 168-6 also authorize physical examinations for National Guard personnel. Accordingly, when requested by an Army or Air Force National Guard unit's commanding officer, naval MTFs may perform the requested physical examination per the appropriate service directive, subject to the availability of space, facilities, and the capabilities of the staff.

Subpart D—Retired Members and Dependents of the Uniformed Services

§ 728.31 Eligible beneficiaries and health benefits authorized.

(a) *Retired members of the uniformed services.* Retired members, as defined in § 728.2(aa), are authorized the same medical and dental benefits as active duty members subject to the availability of space and facilities, capabilities of the professional staff, and the priorities in § 728.3, except that:

(1) Periodic medical examinations for members on the Temporary Disability Retired List, including hospitalization in connection with the conduct thereof, will be furnished on the same priority basis as care to active duty members.

(2) When vision correction is required, one pair of standard issue spectacles, or one pair of nonstandard spectacles, are authorized when required to satisfy patient needs. Two pairs of spectacles may be furnished only when professionally determined to be essential by the examining officer. Military ophthalmic laboratories will not furnish occupational type spectacles, such as aviation, industrial safety, double segment, and mask insert, to retired military personnel (NAVMECOMINST 6810.1 refers).

(b) *Dependents of members of former members.* Include:

- (1) The spouse.
- (2) The unremarried widow.
- (3) The unremarried widower.
- (4) An unmarried legitimate child, including an adopted child or a stepchild, who either—

(i) Has not passed his or her 21st birthday;

(ii) Is incapable of self-support because of a mental or physical incapacity that existed before the 21st birthday and is, or was at the time of the member's or former member's death, in fact dependent on the member for over one-half of his or her support; or

(iii) Has not passed the 23rd birthday, is enrolled in a full-time course of study in an institution of higher learning approved by the administering Secretary and is, or was at the time of the member's or former member's death, in fact dependent on the member for over one-half of his or her support. (If such a child suffers a disabling illness or injury and is unable to return to school, the child remains eligible for benefits until 6 months after the disability is removed, or until the 23rd birthday is reached, whichever comes first.)

(5) An unmarried illegitimate child or illegitimate step-child who is, or was at the time of sponsor's death, dependent on the sponsor for more than one-half of

his or her support; residing with or in a home provided by the sponsor or the sponsor's spouse, as applicable, and is—

(i) Under 21 years of age; or
 (ii) Twenty-one years of age or older but incapable of self-support because of a mental or physical incapacity that existed prior to the individual's 21st birthday; or

(iii) Twenty-one or 22 years of age and pursuing a full-time course of education that is approved per § 728.31(b)(4)(iii).

(6) A parent or parent-in-law, who is, or was at the time of the member's or former member's death, in fact dependent on the member for over one-half of such parent's support and residing in the sponsor's household.

(7) An unremarried former spouse of a member or former member who does not have medical coverage under an employer-sponsored health plan, and who:

(i) On the date of the final decree of divorce, dissolution, or annulment, had been married to the member or former member at least 20 years during which period the member of former member performed at least 20 years of service creditable in determining that member's or former member's eligibility for retired or retainer pay, or equivalent pay.

(ii) Had been married to the member of former member at least 20 years, at least 15 of which were during the period the member of former member performed service creditable in determining the member's eligibility for retired or retainer pay, or equivalent pay. The former spouse's sponsor must have performed at least 20 years of service creditable in determining the sponsor's eligibility for retired or retainer pay, or equivalent pay.

(A) Eligibility for such former spouses continue until remarriage if the final decree of divorce, dissolution, or annulment occurred before 1 April 1985.

(B) Eligibility terminates the later of: Either 2 years from the date of the final decree of divorce, dissolution, or annulment; or 1 April 1988 for such former spouses whose final decree occurred on or after 1 April 1985.

(iii) An unremarried former spouse of a deceased member of former member who meets the requirements of § 728.31(b)(7)(i) or (ii) may be provided medical and dental care as a dependent when the sponsor:

(A) Died before attaining age 60.

(B) At the time of death would have been eligible for retired pay under 10 U.S.C. 1331-1337 except that the sponsor was under 60 years of age; but the former spouse is not eligible for care until the date the sponsor would have attained age 60;

(C) Whether or not the sponsor elected participation in the Survivor Benefit Plan of 10 U.S.C. 1447-1455.

(c) *Eligibility factors.* Care that may be rendered to all dependents in this subpart D is subject to the availability of space and facilities, capabilities of the professional staff, and priorities in § 728.3. Additionally:

(1) Members of the uniformed services must be serving under orders specifying active duty for more than 30 days before their dependents are authorized benefits delineated in § 728.31(d).

(2) A dependent's eligibility begins on the date the member enters on active duty and ends as of midnight of the date the sponsor's period of active duty ends for any reason other than retirement or death. Dependents lose eligibility as of midnight of the date a member is officially placed in a deserter status. Eligibility is restored on the date a deserter is returned to military control.

(3) A dependent (other than a former spouse) of a member or former member who died before attaining age 60 and at the time of death—

(i) Would have been eligible for retired pay under chapter 67 of title 10 U.S.C. but for the fact that the member of former member was under 60 years of age, and

(ii) Had elected to participate in the Survivor Benefit Plan, may not be rendered medical or dental care under the sponsor's entitlement until the date on which such member of former member would have attained age 60.

(4) A spouse, not qualifying as a former spouse, who is divorced from a member loses eligibility for benefits as of midnight of the date the divorce becomes final. This includes loss of maternity care benefits for wives who are pregnant at the time a divorce becomes final. A spouse does not lose eligibility through issuance of an interlocutory decree of divorce even when a property settlement has been approved which releases the member from responsibility for the spouse's support. A spouse's eligibility depends upon the relationship of the spouse to the member; so long as the relationship of husband and wife is not terminated by a final divorce or annulment decree, eligibility continues.

(5) Eligibility of children is not affected by the divorce of parents except that a stepchild relationship ceases upon divorce or annulment of natural parent and step-parent. A child's eligibility for health benefits is not affected by the remarriage of the divorced spouse maintaining custody unless the marriage is to an eligible service member.

(6) A stepchild relationship does not cease upon death of the member step-parent but does cease if the natural parent subsequently remarries.

(7) A child of an active duty or retired member, adopted after that member's death, retains eligibility for health benefits. However, the adoption of a child of a living member (other than by a person whose dependents are eligible for health benefits at USMTFs) terminates the child's eligibility.

(8) If a member's child is married before reaching age 21 to a person whose dependents are not eligible for health benefits in USMTFs, eligibility ceases as of midnight on the date of marriage. Should the marriage be terminated, the child again becomes eligible for benefits as a dependent child if otherwise eligible.

(d) *Health benefits authorized.* (1) Inpatient care including services and supplies normally furnished by the MTF.

(2) Outpatient care and services.

(3) Drugs (see chapter 21, MANMED).

(i) Prescriptions written by officers of the Medical and Dental Corps, civilian physicians and dentists employed by the Navy, designated officers of the Medical Service Corps and Nurse Corps, independent duty hospital corpsmen, and others designated to write prescriptions will be filled subject to the availability of pharmaceuticals, and consistent with control procedures and applicable laws.

(ii) Prescriptions written by civilian physicians and dentists (non-Navy employed) for eligible beneficiaries may be filled if:

(A) The commanding officer or CO's designee determines that pharmacy personnel and funds are available.

(B) The items requested are routinely stocked.

(C) The prescribed quantity is within limitations established by the command.

(D) The prescriber is in the local area (limits designated by the commanding officer).

(E) The provisions of chapter 21, MANMED are followed when such services include the dispensing of controlled substances.

(4) Treatment on an inpatient or outpatient basis of:

(i) Medical and surgical conditions.

(ii) Contagious diseases.

(iii) Nervous, mental, and chronic conditions.

(5) Physical examinations, including eye examinations and hearing evaluations, and all other tests and procedures necessary for a complete physical examination.

(6) Immunizations.

(7) Maternity (obstetrical) and infant care, routine care and examination of the newborn infant, and well-baby care for mothers and infants meeting the eligibility requirements of § 728.31(b). If a newborn infant of an unmarried dependent minor daughter becomes a patient in his or her own right after discharge of the mother, classify the infant as civilian humanitarian nonindigent inasmuch as § 728.31(b) does not define the infant as a dependent of the active duty or retired service member. Therefore, the minor daughter's sponsor (parent) should be counseled concerning the possibility of Secretarial designee status for the infant (see § 728.77).

(8) Diagnostic tests and services, including laboratory and x-ray examinations. Physical therapy, laboratory, x-ray, and other ambulatory diagnostic or therapeutic measures requested by non-Navy employed physicians may be provided upon approval of the commanding officer or designated department heads. Rendering of such services is subordinate to and will not unduly interfere with providing inpatient and outpatient care to active duty personnel and others whose priority to receive care is equal to or greater than such dependents. Ensure that the release of any information to non-Navy employed physicians is in consonance with applicable provisions of SECNAVINST 5211.5C.

(9) Family planning services as delineated in SECNAVINST 6300.2A. Abortions, at the expense of the Government, may not be performed except where the life of the mother would be endangered if the fetus were carried to term.

(10) Dental care worldwide on a space available basis.

(11) Government ambulance services, surface or air, to transport dependents to, from, or between medical facilities when determined by the medical officer in charge to be medically necessary.

(12) Home calls when determined by the medical officer in charge to be medically necessary.

(13) Artificial limbs and artificial eyes, including initial issue, fitting, repair, replacement, and adjustment.

(14) Durable equipment such as wheelchairs, hospital beds, and resuscitators may be issued on a loan basis.

(15) Orthopedic aids, braces, crutches, elastic stockings, walking irons, and similar aids.

(16) Prosthetic devices (other than artificial limbs and eyes), hearing aids, orthopedic footwear, and spectacles or contact lenses for the correction of ordinary refractive error may not be

provided dependents. These items, however, may be sold to dependents at cost to the Government at facilities outside the United States and at specific installations within the United States where adequate civilian facilities are unavailable.

(17) Special lenses (including intraocular lenses) or contact lenses for those eye conditions which require these items for complete medical or surgical management of the condition.

(18) One wig if the individual has alopecia resulting from treatment of a malignant disease: *Provided* the individual has not previously received a wig at the expense of the United States.

(e) *Dependents of reserves.* (1) A dependent, as defined in § 728.31(b), of a deceased member of the Naval Reserve, the Fleet Reserve, the Marine Corps Reserve, or the Fleet Marine Corps Reserve, who—

(i) Was ordered to active duty or to perform inactive-duty training for any period of time.

(ii) Was disabled in the line of duty from an injury while so employed, and

(iii) Dies from such a specific injury, illness, or disease is entitled to the same care as provided for dependents in § 728.31(c).

(2) The provisions of this subpart D are not intended to authorize medical and dental care precluded for dependents of members of Reserve components who receive involuntary orders to active duty under 10 U.S.C. 270b.

(f) *Unauthorized care.* In addition to the devices listed in § 728.31(d)(16) as unauthorized, dependents are not authorized care for elective correction of minor dermatological blemishes and marks or minor anatomical anomalies.

§ 728.32 Application for care.

Possession of an ID card alone (DD 2 (Retired), PHS-1866-3 (Retired), or DD 1173 (Uniformed Services Identification and Privilege Card)) does not constitute sufficient proof of eligibility. Accordingly, a DEERS check will be instituted per § 728.4 (cc) before medical and dental care may be rendered except in emergencies. When required inpatient or outpatient care is beyond the capabilities of the naval MTF, the provisions of § 728.34 apply. When required inpatient care cannot be rendered and a decision is made to disengage a CHAMPUS-eligible beneficiary, the provisions of § 728.33 apply.

§ 728.33 Nonavailability statement (DD 1251).

(a) *General.* Per DODINST 6015.19 of 26 Nov. 1984, the following guidelines

are effective as of 1 Jan. 1985. All previously issued Nonavailability Statement guidelines and reporting requirements are superseded.

(b) *Applicability.* The following provisions are applicable to nonemergency inpatient care only. A DD 1251 is not required:

(1) For emergency care (see § 728.33(d)(1)).

(2) When the beneficiary has other insurance (including Medicare) that provides primary coverage for a covered service.

(3) For medical services that CHAMPUS clearly does not cover.

(c) *Reasons for issuance.* DD 1251's may be issued for only the following reasons:

(1) Proper facilities are not available.

(2) Professional capability is not available.

(3) It would be medically inappropriate (as defined in § 728.2(u)) to require the beneficiary to use the USMTF and the attending physician has specific prior approval from the facility's commanding officer or higher authority to make such determination.

(i) Issuance for this reason should be restricted to those instances when denial of the DD 1251 could result in a significant risk to the health of any patient requiring any clinical specialty.

(ii) Issuing authorities have discretionary authority to evaluate each situation and issue a DD 1251 under the "medically inappropriate" reason if:

(A) In consideration of individual medical needs, personal constraints on an individual's ability to get to the USMTF results in an unreasonable limitation on that individual's ability to get required medical care, and

(B) The issuing authority determines that obtaining care from a civilian source selected by the individual would result in significantly less limitations on that individual's ability to get required medical care than would result if the individual was required to obtain care from a USMTF.

(C) A beneficiary is in a travel status. The commanding officer of the first facility contacted, in either the beneficiary's home catchment area or the catchment area where hospital care was obtained, has this discretionary authority. Travel in this instance means the beneficiary is temporarily on a trip away from his or her permanent residence. The reason the patient is traveling, the distance involved in the travel, and the time away from the permanent residence is not critical to the principle inherent in the policy. The issuing officer to whom the request for a Nonavailability Statement is made

should reasonably determine that the trip was not made, and the civilian care is not (was not) obtained, with the primary intent of avoiding use of a USMTF or USTF serving the beneficiary's home area.

(d) *Guidelines for issuing—(1) Emergency care.* Emergency care claims do not require an NAS; however, the nature of the service or care must be certified as an emergency by the attending physician, either on the claim form or in a separate signed and dated statement. Otherwise, a DD 1251 is required by CHAMPUS-eligible beneficiaries who are subject to the provisions of § 728.33.

(2) *Emergency maternity care.* Unless substantiated by medical documentation and review, a maternity admission would not be deemed as an emergency since the fact of the pregnancy would have been established well in advance of the admission. In such an instance, the beneficiary would have had sufficient opportunity to obtain a DD 1251 if required in her residence catchment area.

(3) *Newborn infant(s) remaining in hospital after discharge of mother.* A newborn infant remaining in the hospital continuously after discharge of the mother does not require a separate DD 1251 for the first 15 days after the mother is discharged. Claims for care beyond this 15-day limitation must be accompanied by a valid DD 1251 issued in the infant's name. This is due to the fact that the infant becomes a patient in his or her own right (the episode of care for the infant after discharge of the mother is not considered part of the initial reason for admission of the mother (delivery), and is therefore considered a separate admission under a different diagnosis).

(4) *Cooperative care program.* When a DD 2161, Referral for Civilian Medical Care, is issued for inpatient care in connection with the Cooperative Care Program (§ 728.4(z)(5)(iv)) for care under CHAMPUS, a DD 1251 must also be issued.

(5) *Beneficiary responsibilities.* Beneficiaries are responsible for determining whether an NAS is necessary in the area of their residence and for obtaining one, if required, by first seeking nonemergency inpatient care in the USMTF or USTF serving the catchment area. Beneficiaries cannot avoid this requirement by arranging to be away from their residence when nonemergency inpatient care is obtained, e.g., staying with a relative or traveling. Individuals requiring an NAS because they reside in the inpatient catchment area of a USMTF or USTF also require an NAS for nonemergency

care received while away from their inpatient catchment area.

(e) *Issuing authority.* Under the direction of the Commander, Naval Medical Command, exercised through commanders of naval geographic medical commands, naval MTFs will issue Nonavailability Statements only when care required is not available from the naval MTF and the beneficiary's place of residence is within the catchment area (as defined in § 728.2(d)) of the issuing facility or as otherwise directed by the Secretary of Defense. When the facility's inpatient catchment area overlaps the inpatient catchment area of one or more other USMTFs or USTFs with inpatient capability and the residence of the beneficiary is within the same catchment area of one or more other USMTFs or USTFs with inpatient capability, the issuing authority will:

(1) Determine whether required care is available at any other USMTFs or USTFs whose inpatient catchment area overlaps the beneficiary's residence. If care is available, refer the beneficiary to that facility and do not issue a DD 1251.

(2) Implement measures ensuring that an audit trail related to each check and referral is maintained, including the check required before retroactive issuance of a DD 1251 as delineated in § 728.33(g). When other than written communication is made to ascertain capability, make a record in the log required in § 728.33(h) that "Telephonic (or other) determination was made on (date) that required care was not available at (name of other USMTF(s) or USTF(s) contacted)". The individual ascertaining this information will sign this notation.

(3) Once established that a DD 1251 is authorized and will be issued, the following will apply:

(i) Do not refer patients to a specific source of care.

(ii) Nonavailability Statements issued at commands outside the United States are not valid for care received in facilities located within the United States. Statements issued within the United States are not valid for care received outside the United States.

(iii) The issuing authority will:

(A) If capability permits, prepare a DD 1251 via the automated application of DEERS. Where this system is operational, it provides for transmitting quarterly reports to the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) by electronic means. System users should refer to their DEERS/NAS Users Manual for specific guidance on the use of the automated system. At activities where the DEER/NAS automated system is not operational, prepare each DD 1251 per

instructions on the reverse of the form. After completion, if authorized by the facility CO, the issuing authority will sign the DD 1251. Give a copy to the patient for presentation to a participating civilian provider, or for submission with the claim of a nonparticipating provider. Retain a copy for the issuing activity's records. Retain the original for subsequent transmittal to the Naval Medical Data Services Center per § 728.33(j).

(B) Explain to the patient or other responsible family member the validity period of the DD 1251 (see § 728.33(f)).

(C) Ensure that beneficiaries are clearly advised of the cost-sharing provisions of CHAMPUS and of the fact that the issuance of a Nonavailability Statement does not imply that CHAMPUS will allow any and all costs incurred through the use of the DD 1251. The issuance of a DD 1251 indicates only that care requested is not available at a USMTF or USTF serving the beneficiary's residence inpatient catchment area.

(D) Review, with the patient or responsible family member, instructions 1 through 6 on the face of the DD 1251 and have the patient or responsible family member sign acknowledgement that such review has been made and is understood.

(E) Advise recipients that CHAMPUS fiscal intermediaries may deny claims of individuals who are not enrolled in the Defense Enrollment Eligibility Reporting System (DEERS).

(f) *Validity period.* DD 1251's issued for:

(1) Other than maternity care are valid for a hospital admission occurring within 30 days of issuance and remain valid from the date of admission until 15 days after discharge from the facility rendering inpatient care. This allows for any follow-on treatment related directly to the original admission.

(2) Maternity episodes are valid if outpatient of inpatient treatment related to the pregnancy is initiated within 30 days of its issuance. They remain valid for care of the mother through termination of the pregnancy and for 42 days thereafter to allow for postnatal care to be included in the maternity episode. (See § 728.33(d)(3) for the validity period of DD 1251's for infants remaining after discharge of the mother.)

(g) *Retroactive issuance.* Issue Nonavailability Statements retroactively only if required care could not have been rendered in a USMTF or USTF as specified in § 728.33(e) at the time services were rendered in the civilian sector. At the time a retroactive issuance is requested, the facility

receiving the request will determine whether capability existed at the USMTF or USTF serving the inpatient catchment area wherein the beneficiary resides (resided) or at any of the facilities in the overlapping area described in § 728.33(e). While the date of service will be recorded on the DD 1251, send the retained original to the Naval Medical Data Services Center along with others issued during the week of issuance (§ 728.33(j) refers).

(h) *Annotating DD 1251's.* Before issuance, annotate each DD 1251 per the instructions for completion on the reverse of the form. DD 1251's issued under the CO's discretionary authority for the "medically inappropriate reason" (§ 728.33(c)(3)(ii)) will be annotated in the remarks section documenting the special circumstances necessitating issuance, the name and location of the source of care selected by the beneficiary, and approximate distance from the source selected to the nearest USMTF or USTF with capability (see instruction number 2 on the reverse of the DD 1251). Establish and maintain a consecutively numbered log to include for each individual to whom a DD 1251 is issued:

(1) Patient's name and identifying data.

(2) The facility unique NAS number (block number 1 on the DD 1251).

(i) *Appeal procedures.* Beneficiaries may appeal the denial of their request for a DD 1251. This procedure consists of four levels within Navy, any one of which may terminate action and order issuance of a Nonavailability Statement if deemed warranted:

(1) The first level is the chief of service, or director of clinical services if the chief of service is the cognizant authority denying the beneficiary's original request.

(2) The second level is the commanding officer of the naval MTF denying the issuance. Where the appeal is denied and denial is upheld at the commanding officer's level, inform beneficiaries that their appeal may be forwarded to the geographic commander having jurisdictional authority.

(3) The third level is the appropriate geographic commander, if the appeal is denied at this level, inform beneficiaries that their appeal may be forwarded to the Commander, Naval Medical Command, Washington, DC 20372-5120.

(4) The Commander, Naval Medical Command, the fourth level of appeal, will evaluate all documentation submitted and arrive at a decision. The beneficiary will be notified in writing of this decision and the reasons therefor.

(j) *Data collection and reporting.* Do not issue the original of each DD 1251

prepared at activities where the DEER/NAS automated system is not operational. Send the retained originals to the Commanding Officer, Naval Medical Data Services Center (Code-03), Bethesda, MD 20814-5066 for reporting under report control symbol DD-HA (Q) 1463(6320).

§ 728.34 Care beyond the capabilities of a naval MTF.

When either during initial evaluation or during the course of treatment of an individual authorized care in this subpart, a determination is made that required care or services are beyond the capability of the naval MTF, the provisions of § 728.4(z)(2) apply.

§ 728.35 Coordination of benefits—third party payers.

Title 10 U.S.C. 1095 directs the services to collect from third-party payers the reasonable costs of inpatient hospital care incurred by the United States on behalf of retirees and dependents. Naval hospital collection agents have been provided instructions relative to this issue and are responsible for initiating claims to third-party payers for the cost of such care. Admission office personnel must obtain insurance, medical service, or health plan (third-party payer) information from retirees and dependents upon admission and forward this information to the collection agent.

§ 728.36 Pay patients.

Care is provided on a reimbursable basis to retired Coast Guard officers and enlisted personnel, retired Public Health Service Commissioned Corps officers, retired Commissioned Corps officers of the National Oceanic and Atmospheric Administration, and to the dependents of such personnel. Accordingly, patient administration personnel will follow the provisions of subpart J to initiate the collection action process when inpatient or outpatient care is provided to these categories of beneficiaries.

Subpart E—Members of Foreign Military Services and Their Dependents

§ 728.41 General provisions.

(a) *Dependent.* As used in this subpart, the term "dependent" denotes a person who bears one of the following relationships to his or her sponsor:

(1) A wife.

(2) A husband if dependent on his sponsor for more than one-half of his support.

(3) An unmarried legitimate child, including an adopted or stepchild who is dependent on the sponsor for over one-

half of his or her support and who either:

(i) Has not passed the 21st birthday; or

(ii) Is incapable of self-support due to a physical or mental incapacity that existed prior to reaching the age of 21; or

(iii) Has not passed the 23rd birthday and is enrolled in a full-time course of study in an accredited institution of higher learning.

(b) *Transfer to naval MTFs in the United States.* Do not transfer personnel covered in this subpart to the United States solely for the purpose of obtaining medical care at naval MTFs. Consideration may be given however, in special circumstances following laws of humanity or principles of international courtesy. Transfer to naval MTFs in the United States of such persons located outside the United States requires approval of the Secretary of the Navy. Naval commands, therefore, should not commit the Navy by a promise of treatment in the United States. Approval generally will not be granted for treatment of those who suffer from incurable afflictions, who require excessive nursing or custodial care, or those who have adequate facilities in their own country. When a request is received concerning transfer for treatment at a naval MTF in the United States, the following procedures apply:

(1) Forward the request to the Chief of Naval Operations (OP-61), with a copy to the Commander, Naval Medical Command, Washington, DC 20372-5120 for administrative processing. Include:

(i) Patient's full name and grade or rate (if dependent, the sponsor's name and grade or rate also).

(ii) Country of which a citizen.

(iii) Results of coordination with the chief of the diplomatic mission of the country involved.

(iv) Medical report giving the history, diagnosis, clinical findings, results of diagnostic tests and procedures, and all other pertinent medical information.

(v) Availability or lack thereof of professional skills and adequacy of facilities for treatment in the member's own country.

(vi) Who will assume financial responsibility for costs of hospitalization and travel.

(2) The Chief of Naval Operations (OP-61) will, if appropriate, obtain State Department clearance and guidance and advise the Secretary of the Navy accordingly. The Commander, Naval Medical Command will furnish the Chief of Naval Operations information and recommendations relative to the medical aspects and the name of the naval MTF with the capability to

provide required care. If approved, the Chief of Naval Operations will furnish, through the chain of command, the commanding officer of the designated naval MTF authorization for admission of the beneficiary for treatment.

§ 728.42 NATO.

(a) *NATO SOFA nations.* Belgium, Canada, Denmark, Federal Republic of Germany, France, Greece, Iceland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Turkey, the United Kingdom, and the United States.

(b) *Beneficiaries.* The following personnel are beneficiaries under the conditions set forth.

(1) *Members of NATO military services and their dependents.* Military personnel of NATO nations, who, in connection with their official duties, are stationed in or passing through the United States, and their dependents residing in the United States with the sponsor may be provided care in naval MTFs to the same extent and under the same conditions as comparable U.S. uniformed services personnel and their dependents. Accordingly, the provisions of § 728.12 are applicable to military personnel and § 728.31(d) through § 728.34 to accompanying dependents.

(2) *Military ships and aircraft personnel.* Crew and passengers of visiting military aircraft and crews of ships of NATO nations which land or come into port at NATO or U.S. military airfields or ports within NATO countries.

(3) *NATO liaison officers.* In overseas areas, liaison officers from NATO Army Forces or members of a liaison detachment from such a Force.

(c) *Application for care.* Military personnel of NATO nations stationed in the United States and their dependents will present valid Uniformed Services Identification and Privilege Cards (DD 1173) when applying for care. For other eligible persons passing through the United States on official business and those enumerated in § 728.42(b) (2) and (3), orders or other official identification may be accepted in lieu of the DD 1173.

(d) *Disposition.* When it becomes necessary to return individuals to their home country for medical reasons, make immediate notification to the NATO unit sponsoring the member or dependent's sponsor. Include all pertinent information regarding the physical and mental condition of the individual concerned. Following are details of agreements among the Armed Forces of NATO, CENTO, and SEATO Nations on procedures for disposition of allied country patients by DOD medical installations.

(1) *Transfer of patients.* (i) The patient's medical welfare must be the paramount consideration. When deciding upon transfer of a patient, give due consideration to any increased medical hazard which the transfer might involve.

(ii) Arrangements for disposition of patients should be capable of being implemented by existing organizations. Consequently, no new establishment should be required specially for dealing with the transferring of allied casualties.

(iii) Transfer patients to their own national organization at the earliest practicable opportunity consistent with the observance of principles established in § 728.42(d)(1) (i) and (ii) and under any of the following conditions:

(A) When a medical facility of their own nation is within reasonable proximity of the facility of the holding nation.

(B) When the patient is determined to require hospitalization in excess of 30 days.

(C) Where there is any question as to the ability of the patient to perform duty upon release from the MTF.

(iv) The decision as to whether a patient, other than one requiring transfer under § 728.42(d)(1)(iii), is fit for release from the MTF is the responsibility of the facility's commanding officer.

(v) All clinical documents, to include x-rays, relating to the patient will accompany such patients on transfer to their own national organization.

(vi) The decision of suitability for transfer and the arrangements for transfer will be the responsibility of the holding nation.

(vii) Final transfer channels should be arranged by local liaison before actual movement.

(viii) Patients not suitable for transfer to their own national organization must be dealt with for treatment and disposition purposes as patients of the holding nation until they are transferred, i.e., they will be dealt with in military hospitals, military medical installations, or in civilian hospitals that are part of the military medical evacuation system of the holding nation.

(2) *Classification of patients.* Different channels for disposition will be required for the following two types of patients:

(i) *Patients not requiring admission.* Patients not requiring admission to an MTF will be returned to their nearest national unit under arrangements to be made locally.

(ii) *Patients admitted to medical installations.* All such patients will be dealt with per § 728.42(d)(1).

(e) *Care authorized outside the 48 contiguous United States.* Major overseas commanders may authorize

care in naval MTFs subject to the availability of space, facilities, and the capabilities of the professional staff in emergency situations only. *Provided*, the required care cannot reasonably be obtained in medical facilities of the host country or in facilities of the patient's own country, or if such facilities are inadequate. Provide hospitalization only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Administer dental treatment only as an adjunct to authorized inpatient care. Do not include dental prostheses or orthodontia.

§ 728.43 Members of other foreign military services and their dependents.

(a) *Foreign military service members.* For the purpose of § 728.43, members of foreign military services include only:

(1) Military personnel carried on the current Diplomatic List (Blue) or on the List of Employees of Diplomatic Missions (White) published by the Department of State.

(2) Military personnel assigned or attached to United States military units for duty; military personnel on foreign military supply missions accredited to and recognized by one of the military departments; and military personnel on duty in the United States at the invitation of the Secretary of Defense or one of the military departments. For the purpose of § 728.43, members of foreign Security Assistance Training Programs (SATP) and Foreign Military Sales (FMS) are not included (see § 728.44).

(3) Foreign military personnel accredited to joint United States defense boards or commissions when stationed in the United States.

(4) Foreign military personnel covered in agreements entered into by the Secretary of State, Secretary of Defense, or one of the military departments to include, but not limited to, United Nations forces personnel of foreign governments exclusive of NATO nations.

(b) *Care authorized in the United States.* Military personnel of foreign nations not covered in § 728.42 and their dependents residing in the United States with the sponsor may be routinely provided only outpatient medical care in naval MTFs on a reimbursable basis. *Provided*, the sponsor is in the United States in a status officially recognized by an agency of the Department of Defense. Dental care and hospitalization for such members and their dependents are limited to emergencies. All outpatient care and hospitalization in

emergencies are subject to reimbursement as outlined in § 728.46.

(c) *Application for care.* All personnel covered by § 728.43 will present orders or other official U.S. identification verifying their status when applying for care.

(d) *Disposition.* When it becomes necessary to return individuals covered by § 728.43 to their home country for medical reasons, make immediate notification to the sponsoring unit of the patient or patient's sponsor with a copy to the Chief of Naval Operations (OP-61). Include all pertinent information regarding the physical and mental condition of the individual concerned and full identification, diagnosis, prognosis, estimated period of hospitalization, and recommended disposition. Additionally, the provisions of § 728.42(d) (1) and (2) apply.

(e) *Care authorized outside the 48 contiguous United States.* Major overseas commanders may authorize care in naval MTFs subject to the availability of space, facilities, and the capabilities of the professional staff in emergency situations only. *Provided*, the required care cannot reasonably be obtained in medical facilities of the host country or in facilities of the patient's own country, or if such facilities are inadequate. Provide hospitalization only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Administer dental treatment only as an adjunct to authorized inpatient care. Do not include dental prostheses or orthodontia.

§ 728.44 Members of security assistance training programs, foreign military sales, and their ITO authorized dependents.

(a) *Policies.*—(1) *Invitational Travel Orders screening.* Prior to determining the levels of care authorized or the government or person responsible for payment for care rendered, carefully screen ITOs to detect variations applicable to certain foreign countries. For example, unless orders state differently, Kuwait has a civilian health plan to cover medical expenses of their trainees; trainees from the Federal Republic of Germany are personally responsible for reimbursing for inpatient care provided to their dependents; and all inpatient medical services for trainees from France and their dependents are to be borne by the individual trainee.

(2) *Elective and definitive surgery.* The overall policy with respect to elective and definitive surgery for Security Assistance Training Program (SATP), Foreign Military Sales (FMS)

personnel and their dependents is that conservatism will at all times prevail, except bona fide emergency situations which might threaten the life or health of an individual. Generally, elective care is not authorized nor should be started. However, when a commanding officer of a naval MTF considers such care necessary to the early resumption and completion of training, submit the complete facts to the Chief of Naval Operations (OP-63) for approval. Include the patient's name (sponsor's also if patient is an ITO authorized dependent), grade or rate, country of origin, diagnosis, type of elective care being sought, and prognosis.

(3) *Prior to entering training.* Upon arrival of an SATP or FMS trainee in the United States or at an overseas training site, it is discovered that the trainee cannot qualify for training by reason of a physical or mental condition which will require a significant amount of treatment before entering or completing training, return such trainees to their home country immediately or as soon thereafter as travel permits.

(4) *After entering training.* When trainees require hospitalization or are disabled after entering a course of training, return them to their home country as soon as practicable when, in the opinion of the commanding officer of the medical facility, hospitalization or disability will prevent training for a period in excess of 30 days. Forward a copy of the patient's clinical records with the patient. When a trainee is accepted for treatment that is not expected to exceed 30 days, notify the commanding officer of the training activity. Further, when a trainee is scheduled for consecutive training sessions convening prior to the expected data of release from a naval MTF, make the next scheduled training activity an information addressee. Upon release from the MTF, direct such trainees to resume training.

(b) *Care authorized.* Generally, all SATP and FMS personnel and their ITO authorized dependents are entitled to care to the same extent. However, certain agreements require that they be charged differently and that certain exclusions apply.

(1) *NATO members and their ITO authorized dependents—(i) Foreign military sales (FMS).* Subject to reimbursement per § 728.46, FMS personnel of NATO nations who are in the United States or at U.S. Armed Forces installations outside the United States and their accompanying ITO authorized dependents will be provided medical and dental care in naval MTFs to the same extent and under the same conditions as comparable United States

military personnel and their dependents except that:

(A) Dependent dental care is not authorized.

(B) Dependents are not authorized cooperative care under CHAMPUS.

(ii) *International military education and training (IMET).* Subject to reimbursement for inpatient care at the appropriate IMET rate for members or at the full reimbursement rate for dependents, IMET personnel of NATO nations who are in the United States or at U.S. Armed Forces installations outside the United States and accompanying dependents will be provided medical and dental care in naval MTFs to the same extent and under the same conditions as comparable United States military personnel and their dependents except that:

(A) Dependent dental care is not authorized.

(B) Dependents are not authorized cooperative care under CHAMPUS.

(2) *Other foreign members and ITO authorized dependents—(i) Foreign military sales.* Subject to reimbursement by the trainee or the trainee's government for both inpatient and outpatient care at the full reimbursement rate, FMS personnel of non-NATO nations and ITO authorized accompanying dependents may be provided medical and dental care on a space available basis when facilities and staffing permit except that:

(A) Prosthetic devices, hearing aids, orthopedic footwear, and similar adjuncts are not authorized.

(B) Spectacles may be furnished when required to enable trainees to perform their assigned duties. *Provided* the required spectacles are not available through civilian sources.

(C) Dental care is limited to emergency situations for the military member and is not authorized for dependents.

(D) Dependents are not authorized cooperative care under CHAMPUS.

(ii) *International military education and training.* Subject to reimbursement for both inpatient and outpatient care at the appropriate rates for members and dependents, IMET personnel of non-NATO nations may be provided medical and dental care on a space available basis when facilities and staffing permit except that:

(A) Prosthetic devices, hearing aids, orthopedic footwear, and similar adjuncts are not authorized.

(B) Spectacles may be furnished when required to enable trainees to perform their assigned duties. *Provided* the

required spectacles are not available through civilian sources.

(C) Dental care is limited to emergency situations for military members and is not authorized for dependents.

(D) Dependents are not authorized cooperative care under CHAMPUS.

(c) *Application for care.* Trainees and accompanying dependents will present official U.S. identification or orders verifying their status when applying for care. If any doubt exists as to the extent of care authorized, ITOs should be screened (see § 728.44(a)(1)).

(d) *Notification.* When trainees require hospitalization as a result of illness or injury prior to or after entering training, the training activity (the hospital if patient has been admitted) will make a message report through the normal chain of command to the Chief of Naval Operations (OP-63) with information copies to MAAG, COMNAV MEDCOM, Navy International Logistics Control Office (NAVIL CO), Unified Commander, the affected office, and the foreign naval attache concerned. Include details of the incident, estimated period of hospitalization, physical or mental condition of the patient, and diagnosis. For further amplification, see OPNAVINST 4950.1H and NAVCOMPTMAN 032103.

§ 728.45 Civilian components (employees of foreign military services) and their dependents.

(a) *Care authorized.* Beneficiaries covered in § 728.45 are only authorized care in naval MTFs in the United States and then only civilian humanitarian emergency care on a reimbursable basis (Subpart J) rendered at installations which have been designated as remote by the Secretary of the Navy. Make arrangements to transfer such beneficiaries to a civilian facility as soon as their condition permits.

(b) *Potential beneficiaries.*—(1) *NATO.* Civilian employee personnel (and their dependents residing with them) accompanying military personnel in § 728.42(b)(1), *Provided*, the beneficiaries are not stateless persons nor nationals of any state which is not a party to the North Atlantic Treaty, nor nationals of, nor ordinarily residents in the United States.

(2) *Others.* Civilian personnel not covered in § 728.45(b)(1) (and their dependents residing with them) accompanying personnel of foreign nations on duty in the United States at the invitation of the Department of Defense or one of the military departments.

(c) *Application for care.* Personnel covered by the provisions of § 728.45

will present orders or other official U.S. identification verifying their status when applying for care.

§ 728.46 Charges and collection.

(a) *Policy.* Pub. L. 99-591, section 9029, contains provisions prohibiting the expenditure of appropriated funds ". . . to provide medical care in the United States on an inpatient basis to foreign military and diplomatic personnel or their dependents unless the Department of Defense is reimbursed for the costs of providing such care: *Provided*, That reimbursements . . . shall be credited to the appropriations against which charges have been made for providing such care, except that inpatient medical care may be provided in the United States without cost to military personnel and their dependents from a foreign country if comparable care is made available to a comparable number of United States military personnel in that foreign country."

(b) *Canadian agreement.* On 3 November 1986, the Department of National Defence of Canada and DOD concluded a comparable care agreement that covers certain military personnel. The agreement stipulates that:

(1) DOD will, upon request, provide Canadian Forces members the same range of medical and dental services under the same conditions and to the same extent as such services are provided comparable United States military personnel. Inasmuch as the agreement covers only certain military personnel, the reimbursement provisions of Pub. L. 99-591 remain in effect for inpatient care provided to Canadian diplomatic personnel, Canadian dependents, and Canadian foreign military sales trainees who receive care in the United States. Further:

(2) Permanently stationed Canadian units with established strengths of more than 150 personnel are expected to have integral health care capability. Any health care services which members of such units receive from the host nation will be provided on a full reimbursement basis. Groups of larger than 150 personnel, which conduct collective training in the United States, are expected to deploy with an organic unit medical capability. Naval MTFs may be requested to provide services, beyond the capability of the organic unit, at full reimbursement rates.

(c) *Procedures.* (1) Until otherwise directed, naval MTFs in the 50 United States will collect the full reimbursement rate (FRR) for inpatient care provided to all foreign military personnel (except Canadians covered by the comparable care agreement in

§ 728.46(b), and military personnel connected with a Foreign Military Sales (FMS) case number), foreign diplomatic personnel, and to the dependents of both whether they are in the United States on official duty or for other reasons.

(2) Subpart J contains procedures for the initiation of collection action when inpatient care is rendered to beneficiaries from NATO nations and when either inpatient or outpatient care is rendered to all others enumerated in this part. Chapter II, part 4 of NAVMED P-5020 is applicable to the collection of and accounting for such charges.

Subpart F—Beneficiaries of Other Federal Agencies

§ 728.51 General provisions—the "Economy Act."

The Economy Act, 31 U.S.C. 1535, generally permits agency heads, or heads of major organizational units of agencies, to procure goods and services from other agencies or within their own agency so long as funds for procurement are available, the order is in the best interest of the Government, the source from which the goods or services are ordered can produce them or obtain them by contract, and the internal or inter-agency procurement is more convenient, or less expensive, than commercial procurement. Provisions of the Economy Act apply to requests from other Federal agencies for medical and dental care for beneficiaries for whom they are responsible. Consult specific provisions of the Act respecting financial and accounting limitations and requirements.

§ 728.52 Veterans Administration beneficiaries (VAB).

(a) *Eligible beneficiaries.*—Those who have served in the Armed Forces, have been separated under conditions other than dishonorable, and have been determined by the Veterans Administration (VA) to be eligible for care at VA expense. Prior to 7 September 1980, veterans status could be obtained by virtue of 1 day's honorable service. The following restrictions do not apply to individuals who are discharged from active duty because of a disability or who were discharged for reasons of "early out" or hardship program under 10 U.S.C. 1171 and 1173.

(1) For individuals with an original enlistment in the military service after 7 September 1980, the law generally denies benefits, including medical care.

(2) For individuals entering service after 16 October 1981, the law generally denies medical benefits when such

individuals do not complete the shorter of:

(i) Twenty-four months of continuous active duty, or

(ii) The full period for which that person was called or ordered to active duty.

(b) *Inpatient control*—Each VAB admitted will be required to conform to regulations governing the internal administration of the naval facility. Restrictive or punitive measures, including disciplinary action or denial of privileges, will conform as nearly as possible to VA instructions.

(c) *Resolution of problems*—All problems pertaining to VABs, including admission, medical or other records, and all correspondence will be matters of resolution between the commanding officer of the naval facility and the VA office of jurisdiction authorizing admission. Questions of policy and administration which cannot be so resolved will be forwarded, through the normal chain of command, to the Administrator of Veterans Affairs via COMNAVMECOM for resolution.

(d) *Care in the United States*—(1) *Inpatient care*. An eligible VAB may be admitted to a naval MTF on presentation of a written authorization for admission signed by an official of the VA office of jurisdiction. Neurological and certain neuropsychiatric patients without obvious evidence of psychosis and not requiring restraints, and instances of suspected tuberculosis, may be admitted for diagnosis. When diagnosed, promptly report instances of psychosis, psychoneurosis, and tuberculosis of present clinical significance to the VA office of jurisdiction with a request for transfer to a VA facility.

(i) *Extent of care*. Provide eligible VABs medical and surgical care, including prostheses such as eyes and limbs and appliances such as hearing aids, spectacles, or orthopedic appliances when required for the proper treatment of the condition upon which eligibility is based.

(ii) *Disposition of emergency admission*. Notify the appropriate VA office of jurisdiction by message or other expeditious means within 72 hours after the date and hour of an emergency admission of a potential VAB. Include a request for an authorization for admission and emergency treatment. If VA denies VAB status to such a person admitted in an emergency, the provisions of § 728.81(a) are applicable. Once admitted in an emergency situation, discharge a VAB promptly upon termination of the emergency unless arrangements have been made with the VA office of jurisdiction:

(A) For transfer to a VA treatment facility if further treatment is required.

(B) To retain the patient as a VAB in the naval MTF.

(2) *Outpatient care*. Outpatient care, including post hospitalization outpatient care, may be provided upon authorization by the VA office of jurisdiction. When outpatient followup care is requested, commanding officers are responsible for determining whether capabilities and workload permit providing such care. In an emergency, provide necessary care.

(3) *Physical examinations*. Upon a determination by a naval MTF commanding officer that space, facilities, and capabilities exist, naval MTFs may provide physical examinations when requested by the VA for the purpose of adjudicating claims for VA physical disability compensation. If authorized by the VA, patients may be admitted when the examination requires more than 1 day.

(4) *Dental care*. Limit dental treatment to inpatients who require services adjunctive to medical or surgical conditions for which hospitalized.

(e) *Care outside the United States*—

(1) *Eligible beneficiaries*. Beneficiaries described in § 728.52(a) who are citizens of the United States and residing or sojourning abroad may, within the capabilities of the facility as determined by the commanding officer, be provided inpatient and outpatient care upon presentation of an authorization from the appropriate VA office of jurisdiction listed in § 728.52(e)(3).

(2) *Emergency care*. Overseas naval MTFs furnishing emergency care to potential VABs will promptly notify the appropriate VA office of jurisdiction and request authorization for treatment and instructions for disposition of the patient.

(3) *Offices of jurisdiction*. The following activities are vested with responsibility for issuing authorizations for care and furnishing disposition instructions for VABs in overseas naval MTFs:

(i) In the Trust Territory of the Pacific (Micronesia), VA Office, Honolulu, Hawaii.

(ii) In the Philippines, VA Regional Office, Manila, Philippines.

(iii) In Canada, Canadian Department of Veterans Affairs, Ottawa, Canada.

(iv) In all other foreign countries, consular offices of U.S. embassies.

(f) *Forms required*. (1) Complete a VA 10-10 (Application for Medical Benefits) when potential VABs are admitted for emergency care without prior authorization.

(2) Prepare a VA 10-10m (Medical Certificate and History) when care is

rendered. All information required in the medical certificate thereon will be furnished whether the admission is subsequently approved or disapproved by the VA office of jurisdiction.

(3) Since the completion of VA 10-10m requires an examination of patients, admissions which are disapproved will be reported as medical examinations on DD 7A, Report of Treatment Furnished Pay Patients, Outpatient Treatment Furnished (Part B) (See Subpart J).

(4) Prepare and submit a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished (Part A)) on all VABs and potential VABs admitted (see Subpart J).

(5) Complete an SF 502 (Narrative Summary) or SF 539 (Abbreviated Clinical Record), as appropriate, when a VAB or potential VAB is discharged or otherwise released. When an interim report of hospitalization is requested by the VA office of jurisdiction, it may be prepared on an SF 502.

§ 728.53 Department of Labor, Office of Workers' Compensation Programs (OWCP) beneficiaries.

(a) *Potential beneficiaries*. The following may be beneficiaries of one of the programs sponsored by the Office of Workers' Compensation Programs (OWC) under the conditions set forth. They are not beneficiaries of OWCP until authorized as such by the appropriate district officer of OWCP. However, they may be carried as potential beneficiaries pending OWCP determination of eligibility. DOD civilian employees provided medical services under a Defense or service health program are not included under this authority (see subpart G).

(1) Members and applicants for membership in the Reserve Officers' Training Corps of the Navy, Army, and Air Force, provided the condition necessitating treatment was incurred in line of duty during an off-campus training regimen. Such care is authorized for injury (a disease or illness which is the proximate result of performance of training is considered an injury) incurred while engaged in:

(i) Training.

(ii) Flight instructions.

(iii) Travel to or from training or flight instructions.

(2) The following employees of the Government of the United States, regardless of nationality or place of work, are entitled to receive care as outlined in § 728.53(e) for work incurred traumatic injuries at the expense of OWCP. (In addition to injury by accident, a disease or illness which is the proximate result of performance of

employment duties is considered an injury.) This category includes but is not limited to:

(i) Civilian student employees in training at Navy and Marine Corps facilities.

(ii) Civilian seamen in the service of vessels operated by the Department of the Army (see § 728.53(a)(7) and § 728.80(c)(2) for civilian Military Sealift Command (MSC) personnel).

(iii) All civilian employees of the Government except nonappropriated-fund-activity employees.

Nonappropriate fund employees may be covered under the Longshore and Harbor Workers' Compensation Act (contact cognizant district office of OWCP).

(3) Civilian members of the Civil Air Patrol (except Civil Air Patrol Cadets) for injury or disease which is the proximate result of active service or travel to and from such service, rendered in performance or support of operational missions of the Civil Air Patrol under the direction and written authority of the Air Force.

(4) Former Peace Corps enrollees for injury or disease which is the proximate result of their former employment with the Peace Corps or which was sustained or contracted while located with the Peace Corps outside the United States and its territories.

(5) Former Job Corps enrollees for injury or disease which is the proximate result of employment with the Job Corps.

(6) Former VISTA (Volunteers in Service to America) enrollees for injury or disease which is the proximate result of employment with VISTA.

(7) Military Sealift Command (MSC) civilian marine personnel (CIVMARBERS or CIVMARS) (including temporary employees, intermittent employees, and employees with less than 1 year's service) are entitled to occupationally related care at the expense of OWCP. CIVMARS are in a crew status only after reporting to their assigned ship. They are in a travel status from crewing point to ship and return. While in a travel status, they are entitled to the same health care benefits as other Federal civil service employees in a travel status (5 U.S.C. 8101).

CIVMARS presenting for treatment with a properly completed CA-16, Request for Examination and/or Treatment, will:

(i) Enter the naval MTF's system through the occupational medicine service.

(ii) Be treated for any injury or disease proximately caused by their employment. Although the actual determination of whether an illness or injury is occupationally related is a

function of OWCP, determinations are based on the required injury report along with the treatment record from the attending physician. Therefore, when doubt exists as to the relationship of the condition to the potential patient's employment, the physician should report an unbiased medical conclusion and the medical rationale therefor, indicating the conditions which are responsible for the claimant's disability. As a general rule, the following may be initially considered as occupationally related, however, it should be emphasized that OWCP is the final approval authority:

(A) Any injury or illness occurring as a direct result of employment. May occur on a ship, at a Government installation ashore, or in an aircraft while performing a requirement of employment.

(B) Any injury or illness which becomes manifest while away from work (on leave or liberty) while in a crew status or travel status as long as the condition may be directly related to job activities or to exposures incident to travel to ship assignment.

(C) Required immunizations.

(D) Required physical examinations.

(E) Periodic medical surveillance screening examinations for DOD occupational and industrial health programs, i.e., asbestos medical surveillance, hearing conservation, etc.

(iii) Be referred to a non-Federal source of care where back-to-work care may be provided at the CIVMAR's expense after, if necessary, the immediate emergency is alleviated when a reasonable determination can be made that the injury or illness is not occupationally related.

(A) Per 5 U.S.C. 7901(c)(3), the health service program for Federal civilian employees is limited to referral of employees, upon their request, to private sources of care.

(B) Long term extended care of chronic illnesses such as hypertension, diabetes, etc., is not authorized in naval MTFs at the expense of OWCP nor at the CIVMAR's personal expense.

(C) Patients who cannot be referred, because of medical reasons or because non-Federal sources are not available or available but inadequate, may be retained in naval MTFs at the expense of the CIVMAR or of his or her private insurance until transfer becomes possible. Although the means of access to the naval MTF may have been through the occupational medicine service, retention in the naval MTF is on a civilian humanitarian basis. This is also applicable when OWCP disallows a CIVMAR's claim (see § 728.53(c)).

(b) *Authorization required.* Personnel in § 728.53(a) (1) through (6) may be

rendered inpatient and outpatient care as outlined in § 728.53(e), unless otherwise stipulated in § 728.53, upon presentation of a properly prepared and signed authorization from CA-16 (Request for Examination and/or Treatment). District offices of OWCP will honor these authorizations for 60 days unless written notice of termination of authorization is given earlier. Whereas the CA-16 is used primarily for traumatic injuries, it may also be used to authorize examination and treatment for disease or illness provided the affected agency has obtained prior permission from the cognizant district office of OWCP. If the condition for which treatment is requested appears related to employment, treatment of beneficiaries in § 728.53(a) (1) through (7) may be initiated without presentation of a CA-16. Patients provided treatment without a CA-16 may be carried as OWCP beneficiaries from the time of initial treatment, provided the appropriate district office of OWCP is notified and requested to submit a CA-16 within 48 hours giving authorization as of the date of actual treatment. OWCP will not be liable for payment of bills for unauthorized treatment. Post hospitalization care following authorized inpatient care does not require an additional authorization. First aid treatment rendered civilian employees does not require an authorization form.

(c) *Disallowance by OWCP.* When OWCP determines that any claim should be disallowed, OWCP will advise the naval facility rendering care that no further treatment should be rendered at OWCP expense. The patient ceases to be an OWCP beneficiary as of the date of receipt of the notice of disallowance by the naval MTF and the patient will be so notified. Any treatment subsequent to the date of receipt of the notice of disallowance will be at the personal expense of the patient (see § 728.81(a)).

(d) *Authorization for transfer.* Prior approval of OWCP is required before a transfer can be effected, except in an emergency or when immediate treatment is deemed more appropriate in another Federal facility. When transfer is effected without approval, the transferring facility will immediately request such authorization from the appropriate district office of OWCP. When authorized by OWCP, evacuation to the United States can be effected per OPNAVINST 4630.25B. Medical records and a CA-16 will accompany such patients.

(e) *Care authorized*—(1) *Inpatient care*. Medical and surgical care necessary for the proper treatment of the condition upon which eligibility is based. Specific OWCP authorization is required before major surgical procedures can be performed unless the urgency of the situation is such that time does not permit obtaining said authorization. All necessary prostheses, hearing aids, spectacles, and orthopedic appliances will be furnished when required for proper treatment of the condition upon which eligibility is based. Upon specific authorization, damaged or destroyed medical braces, artificial limbs, and other orthopedic and prosthetic devices will be replaced or repaired, except that eyeglasses and hearing aids will not be replaced or repaired unless their damage or destruction is incidental to a personal injury requiring medical services.

(2) *Outpatient care*. Complete medical and surgical care not requiring hospitalization, and posthospitalization services following authorized inpatient care in a naval MTF for the proper treatment of the condition upon which eligibility is based.

(3) *Dental care*. Limit dental treatment to emergencies and that care necessary as an adjunct to inpatient hospital care authorized in advance. Such care will not include dental prostheses, unless specifically authorized, nor orthodontic treatment.

(f) *Reports and records*. (1) Copies of medical records will accompany OWCP patients being transferred from one medical treatment facility to another. Records accompanying OWCP patients to a debarkation hospital will be the same as for military personnel and will clearly identify the patient as an OWCP beneficiary.

(2) Forward a CA-20 (Attending Physician's Report) to the appropriate district office of OWCP on discharge of the patient unless hospitalization exceeds 1 month. In such instances, a report will be submitted every 30 days. When extensive hospitalization is required, use an SF 502 or a narrative format in lieu of CA-20. When submitted to OWCP, the physician's report will include:

- (i) History.
- (ii) Physical findings.
- (iii) Laboratory findings.
- (iv) Abstract of hospital records.
- (v) Diagnosis for conditions due to injury and not due to injury.
- (vi) Rationalized medical opinion for the physician's belief that the illness or disease treated was causally related to a specific condition or set of conditions to which the claimant was subjected.

(vii) Condition on discharge with opinion as to degree of impairment due to injury, if any.

(3) Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered to any OWCP beneficiary.

§ 728.54 U.S. Public Health Service (USPHS), other than members of the uniformed services.

(a) *Potential beneficiaries*. The following may be beneficiaries of the USPHS for care in naval MTFs upon submission of the necessary form from appropriate officials as outlined in § 728.54(b).

(1) *Within and Outside the United States*. Any individuals the USPHS may determine to be eligible for care on an interagency reimbursable basis.

(2) *Within the 48 Contiguous United States and the District of Columbia*. American Indians, Alaska Natives, Eskimos, and Aleuts.

(3) *In Alaska*. American Indians, Eskimos, and Aleuts.

(b) *Authorization required*—(1) *Normal circumstances*. An American Indian or Alaska Native may be rendered inpatient care upon presentation of form HRSA 43 (Contract Health Service Purchase Order for Hospital Services Rendered) or HRSA form 84 (Purchase/Delivery Order for Contract Health Services Other Than Hospital Inpatient or Dental). Either form must be signed by an appropriate Indian Health Service or Alaska Native Health Service area/program official.

(2) *Emergencies*. In an emergency, care may be rendered upon written request of patient's commanding officer or superior officer, or the patient if neither of the above is available. When emergency care is rendered without prior authorization, the facility rendering care must notify the service unit director of the patient's home reservation within 72 hours from the time such care is rendered unless extenuating circumstances preclude prompt notification.

(c) *Care authorized*. Unless limited by the provisions stipulated in § 728.54(a) and subject to the provisions of § 728.3, the following care may be rendered, when requested, to all beneficiaries enumerated in § 728.54(a).

(1) *Inpatient care*. Necessary medical and surgical care.

(2) *Outpatient care*. Necessary medical and surgical care.

(3) *Dental care*. (i) Limit dental care in the United States, its territories,

possessions, and the Commonwealth of Puerto Rico to emergencies for the relief of pain or acute conditions and that necessary as an adjunct to inpatient hospital care. Prosthetic dental appliances and permanent restorations are not authorized.

(ii) In overseas areas, dental care is authorized to the extent necessary pending the patient's return to the United States, its territories, possessions, or the Commonwealth of Puerto Rico.

(d) *Report*. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or a DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.55 Department of Justice beneficiaries.

Upon presentation of a letter of authorization that includes disposition of SF 88 (Report of Medical Examination), SF 93 (Report of Medical History), and address for submission of claim, the following personnel may be furnished requested care as beneficiaries of the Department of Justice. See subpart J on completing and submitting forms for central collection of the cost of care provided.

(a) *Federal Bureau of Investigation*. Investigative employees of the Federal Bureau of Investigation (FBI) and applicants for employment as special agents with the FBI may be provided:

- (1) Immunizations.
- (2) Physical examinations and hospitalization when required to determine physical fitness. Use this period of hospitalization for diagnostic purposes only. Do not correct disqualifying defects.

(b) *U.S. Marshals*. U.S. Marshals may receive physical examinations and hospitalizations when required to determine physical fitness. Use this period of hospitalization for diagnostic purposes only. Do not correct disqualifying defects.

(c) *Claimants against the United States*. Claimants whose suits or claims against the United States are being defended by the Department of Justice may be furnished physical examinations to determine the extent and nature of the injuries or disabilities being claimed. Hospitalization is authorized for proper conduct of the examination. Upon completion, forward the report of the examination promptly to the U.S. Attorney involved.

§ 728.56 Treasury Department beneficiaries.

(a) *Potential beneficiaries.* The following may be beneficiaries of the Treasury Department and may be rendered care as set forth below.

(1) Secret Service Special Agents and support personnel.

(2) Secret Service Agents providing protection to certain individuals.

(3) Persons being provided protection by the Secret Service.

(4) Agents of the U.S. Customs Service.

(5) Prisoners (detainees) of the U.S. Customs Service.

(b) *Care authorized.* (1) Secret Service Special Agents may be provided routine annual physical examinations upon request and presentation of a letter of authorization. Conduct and record examinations in the same manner as routine examinations rendered naval officers except that they may be conducted only on an outpatient basis. If hospitalization is considered desirable in connection with an examination, patient administration department personnel will contact the United States Secret Service at (202) 535-5641 at the address in § 728.56(c). Enter a statement, attesting to the fact that hospitalization is desirable, in item 73 or 75 of the SF 88, as appropriate, before forwarding to the United States Secret Service as directed by the letter of authorization.

(2) Secret Service Agents providing protection to certain individuals and those persons being provided such protection may be rendered all required medical services including hospitalization subject to the provisions of § 728.3.

(3) Agents of the U.S. Customs Service and their prisoners (detainees) may be provided emergency medical treatment and evacuation services to the nearest medical facility (military or civilian) in those remote areas of the United States where no other such services are available. Limit evacuation to the continental United States and do not cross borders. The Navy's responsibility for medical care of such prisoners terminates once the medical emergency has been resolved. Guarding of prisoners, while they or their captors are receiving treatment at naval MTFs, remains the responsibility of the U.S. Customs Service or other appropriate Federal (nonmilitary) law enforcement agencies.

(c) *Reports and records.* (1) When examinations are rendered to Secret Service Special Agents and support personnel, forward one copy of the SF 88, one copy of the SF 93, and one copy of any forms provided with the letter of authorization to United States Secret

Service, Administrative Operations Division, Safety and Health Branch, 1800 G Street, NW., Room 845, Washington, DC 20223 or as otherwise directed by the letter of authorization. Provide an information copy to the Deputy Comptroller of the Navy.

(2) Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.57 Department of State and associated agencies.

Eligibility for care under the provisions of § 728.57 will be determined by the Department of State, Office of Medical Services.

(a) *Beneficiaries.* Officers and employees of the following agencies, their dependents, and applicants for appointment to such agencies are authorized inpatient and outpatient medical care as set forth below in addition to that care that may be authorized elsewhere within this part (i.e., § 728.53, § 728.55, § 728.56, and § 728.58). Limit dental care to that delineated in § 728.57(b)(6).

(1) Department of State—U.S. Arms Control and Disarmament Agency and the Office of International Conferences.

(2) U.S. Agency for International Development.

(3) International Communications Agency.

(4) ACTION—Peace Corps Staff.

(5) Department of Agriculture—Foreign Agriculture Service.

(6) Department of Commerce—Bureau of Public Roads.

(7) Department of Interior—Bureau of Reclamation and the U.S. Geological Survey.

(8) Department of Transportation—Federal Aviation Administration and the Federal Highway Administration.

(9) Department of Justice—Drug Enforcement Agency.

(10) Department of Treasury—U.S. Customs, U.S. Secret Service, Office of International Affairs (OIA), U.S.—Saudi Arabian Joint Commission for Economic Cooperation (JECOR), and the Internal Revenue Service.

(11) National Aeronautics and Space Administration.

(12) Library of Congress.

(13) Beneficiaries of such other agencies as may be included in the Department of State Medical Program.

(b) *Care authorized.*—(1) *General.* The Foreign Service Act of 1946, as amended, authorizes care delineated in § 728.57. Subject to the restrictions and priorities of § 728.3 and the restrictions

of § 728.57, care may be rendered at the expense of the Department of State or one of the agencies listed in § 728.57(a). The law allows for payment when care is furnished for an illness or injury which results in hospitalization or equal treatment. Outpatient care is only authorized as an adjunct to hospitalization.

(2) *Overseas.* (i) When, in the opinion of the principal or administrative officer of an overseas post of the Department of State, an individual meets the conditions of eligibility, the post will furnish authorization to the naval MTF for care at the expense of the Department of State or one of the agencies listed in § 728.57(a).

(ii) Should the Department of State official determine that the illness or injury does not meet the conditions of eligibility for care at the expense of one of the agencies, all care provided will be at the expense of the patient or patient's sponsor and charged at the full reimbursement rate.

(3) *In the United States.* (i) Care is not authorized for an injury or illness incurred in the United States.

Authorizations and other arrangements for care in the United States for individuals incurring injury or illness outside the United States will be provided by the Deputy Assistant Secretary for Medical Services, Department of State, using appropriate authorization form(s). When personnel are admitted in an emergency without prior authorization, the commanding officer of the admitting naval MTF will immediately request authorization from the Deputy Assistant Secretary for Medical Services.

(ii) The extent of care furnished in the United States, to individuals in § 728.57(a) who are evacuated to the United States for medical reasons, will be comparable in all respects to that which is authorized or prescribed for these individuals outside the United States. When determined appropriate by the Deputy Assistant Secretary for Medical Services, officers and employees and their accompanying dependents who have returned to the United States for nonmedical reasons may be furnished medical care at the expense of one of the above agencies for treatment of an illness or injury incurred while outside the United States.

(4) *Physical examinations.* The Secretary of State is authorized to provide for comprehensive physical examinations, including dental examinations and other specific testing, of applicants for employment and for officers and employees of the Foreign Service who are U.S. citizens and for

their dependents, including examinations necessary to establish disability or incapacity for retirement purposes. An authorization will be executed by an appropriate Department of State official and furnished in duplicate to the naval MTF, listing the type of examination required and stating that the individual is entitled to services at the expense of the Department of State. Furnish reports per the letter of authorization.

(5) *Immunizations.* Inoculations and vaccinations are authorized for officers, employees, and their dependents upon written authorization from an appropriate Department of State official. This authorization, in duplicate, will include the type of inoculation or vaccination required and will state that the individual is entitled to services at the expense of the Department of State. Furnish reports per the letter of authorization.

(6) *Dental care.* Limit dental care to emergencies for the relief of pain or acute conditions, or dental conditions as an adjunct to inpatient care. Do not provide prosthetic dental appliances.

(c) *Evacuation to the United States.* Should a beneficiary in an overseas naval MTF require prolonged hospitalization, the commanding officer of the overseas facility will report the requirement to the nearest Department of State principal or administrative officer and request authority to return the patient to the United States. Release dependents who decline evacuation to the custody of their sponsor. Aeromedical evacuation may be used per OPNAVINST 4630.25B. Travel of an attendant or attendants is authorized at Department of State expense when the patient is too ill or too young to travel unattended.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.58 Federal Aviation Agency (FAA) beneficiaries.

(a) *Beneficiaries.* Air Traffic Control Specialists (ATCS) of the FAA when appropriate authorization has been furnished by the FAA regional representative.

(b) *Authorization.* Written authorization from an FAA Regional Flight Surgeon is required and will include instructions for forwarding the results of services rendered.

(c) *Care authorized.* Subject to the provisions of § 728.3, authorized personnel may be rendered chest x-rays,

electrocardiograms, basic blood chemistries, and audiograms, without interpretation in support of the medical surveillance program for ATCS personnel established by the FAA.

(d) *Report.* Complete and submit, per Subpart J, a DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) outpatient care is rendered.

§ 728.59 Peace Corps beneficiaries.

(a) *Potential beneficiaries.* (1) Applicants for the Peace Corps.

(2) Peace Corps Volunteers.

(3) Minor children of a Peace Corps volunteer living with the volunteer.

(b) *Care authorized in the United States.* Upon written request of a Peace Corps official, stating care to be provided and disposition of reports, the following may be provided subject to the provisions of § 728.3.

(1) *Physical examinations.* Physical examinations are authorized on an outpatient basis only. Except for interpretation of x-rays, make no assessment of the physical qualifications of examinees.

(i) Preselection physical examination may be provided applicants (volunteers) for the Peace Corps.

(ii) Separation or other special physical examinations may be provided volunteers and their dependents as listed in § 728.59(a)(3). Unless otherwise prescribed in written requests, report such examinations of Peace Corps volunteers on SF-88 and SF-93. Include:

(A) Medical history and systemic review.

(B) Chest x-ray with interpretation.

(C) Complete urinalysis, serology, and blood type.

(D) Pelvic examination and Pap smear for all female volunteers.

(E) Hematocrit or hemoglobin for all females and for all males over 40 years of age.

(F) Electrocardiogram for all volunteers over 40 years of age.

(2) *Immunizations.* Immunizations, as requested, may be provided all beneficiaries listed in § 728.59(a).

(3) *Medical care.* Both inpatient and outpatient care may be provided volunteers for illnesses or injuries occurring during their period of service which includes all periods of training. Dependents of volunteers specified in § 728.59(a)(3) are authorized care to the same extent as their sponsor.

(4) *Dental care.* Limit dental care to emergencies. Render only that care essential to relieve pain or prevent imminent loss of teeth. All beneficiaries seeking dental care will be requested, whenever possible, to furnish advanced authorization.

(c) *Care authorized outside the United States—(1) Physical examinations.*

Termination physical examinations may be provided volunteers and eligible dependents of volunteers. In most instances, Peace Corps staff physicians will provide these examinations; however, help may be required of naval MTFs for ancillary services.

(2) *Immunizations.* When requested, immunizations may be provided all beneficiaries listed in § 728.59(a).

(3) *Medical care.* When requested in writing by a representative or physician of a Peace Corps foreign service post, volunteers, eligible dependents of volunteers, and trainees of the Peace Corps may be provided necessary medical care at Peace Corps expense. When emergency treatment is rendered without prior approval, forward a request to the Peace Corps foreign service post as soon as possible.

(4) *Dental care.* Limit dental care to emergencies. Render only that care essential to relieve pain or prevent imminent loss of teeth. All beneficiaries seeking dental care will be requested, whenever possible, to furnish advanced authorization.

(5) *Evacuation to the United States.* When a beneficiary in an overseas naval MTF requires prolonged hospitalization, the commanding officer of the overseas facility will report the requirement to the nearest Peace Corps foreign service post and request authorization to return the patient to the United States. Releases custody of dependents to their sponsor when evacuation is declined. Aeromedical evacuation may be used per OPNAVINST 4630.25B. Travel of attendant(s) is authorized when the patient is too ill or too young to travel unattended.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment Part B) when outpatient or inpatient care is rendered.

§ 728.60 Job Corps and Volunteers in Service to America (VISTA) beneficiaries.

(a) *Beneficiaries.* Job Corps and VISTA enrollees and Job Corps applicants may be provided services as set forth. For former members, see § 728.53.

(b) *Authorization required.* (1) *Job Corps enrollees.* Presentation of a Job Corps Identification Card after appointment has been made by the corpsmember's Job Corps center.

(2) *Job Corps applicants.* Presentation of a letter from a screening agency (e.g.,

State Employment Service) after an appointment has been made by that agency.

(3) *VISTA Volunteers and VISTA Trainees.* A "Blue-Cross and Blue Shield Identification Card" is issued to such personnel as identification. Each card has a VISTA identification number which will be used on all records and correspondence.

(c) *Care authorized.* Normally, medical services are provided only when civilian of VA facilities are not available, or if available, are incapable of providing needed services. However, upon presentation of an appropriate authorization, the following services may be rendered subject to the provisions of § 728.3.

(1) Job Corps enrollees are authorized emergency medical care upon presentation of their Job Corps Identification Card; however, the corpsmember's Job Corps center should be notified immediately.

(2) Job Corps applicants may be provided pre-enrollment physical examinations and immunizations on an outpatient basis only.

(3) Job Corps enrollees, VISTA trainees, and VISTA volunteers are authorized:

(i) Outpatient medical examinations, outpatient treatment, and immunizations.

(ii) Inpatient care for medical and surgical conditions which, in the opinion of the attending physician, will benefit from definitive care within a reasonable period of time. When found probable that a patient will require hospitalization in excess of 45 days, notify the Commander, Naval Medical Command (MEDCOM-33) by the most expeditious means.

(iii) Limit dental care to emergencies. Render only that care essential to relieve pain or prevent imminent loss of teeth. Beneficiaries seeking dental care will be requested to furnish, whenever possible, advanced authorization.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.61 Medicare beneficiaries.

(a) *Care authorized.* Emergency hospitalization and other emergency services are authorized for beneficiaries of the Social Security Health Insurance Program for the Aged and Disabled (Medicare) who reside in the 50 United States and the District of Columbia, Guam, Puerto Rico, the Virgin Islands, American Samoa, and the Northern

Mariana Islands. Such care in naval MTFs may be rendered when emergency services, as defined in § 728.61(b), are necessary.

(b) *Emergency services.* Services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(1) Placing the patient's health in serious jeopardy.

(2) Serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(c) *General provisions—(1) Limitations.* Benefit payments for emergency services under Medicare can be made for only that period of time during which the emergency exists. Therefore, when the emergency is terminated and it is permissible from a medical standpoint, discharge or transfer the patient to a facility that participates in Medicare.

(2) *Notification.* Notify the nearest office of the Social Security Administration as soon as possible when a Medicare beneficiary is rendered treatment.

(d) *Report.* Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

Subpart G—Other Persons

§ 728.71 Ex-service maternity care.

(a) *Eligible beneficiaries.* After separation from the service under honorable conditions because of pregnancy, or separated from the service under honorable conditions and found to have been pregnant at the time of separation, the following former members and their newborn infant(s) may be provided care as set forth below. The rendering of this care is subject to the provisions of § 728.3. When certified by medical authorities that the pregnancy existed prior to entry into service (EPTE), maternity benefits are not authorized.

(1) Former women members of the Army, Air Force, Navy, and Marine Corps.

(2) On or after 12 August 1985, former women members of the Commissioned Corps of the United States Public Health Service (USPHS) and the National Oceanic and Atmospheric Administration (NOAA).

(b) *Care authorized.* (1) Former women members may be rendered medical and surgical care in naval MTFs incident to that pregnancy, prenatal care, hospitalization, postnatal care, and, when requirements of SECNAVINST 6300.2A are met, abortions. Limit postnatal care to 6 weeks following delivery. Do not promise civilian sources under any circumstances for either the mother or the infant as such care is not authorized.

(2) Treatment of the newborn infant in USMTFs includes care, both inpatient and outpatient, only during the first 6 weeks (42 days) following delivery. If the newborn infant requires care beyond the 6-weeks postnatal period, the mother or other responsible family member must make arrangements for disposition to private, State, welfare, or another Federal facility.

(c) *Application for care.* In making application for care authorized by § 728.71, former women members should apply either in person or in writing to the Armed Forces inpatient MTF nearest their home and present either their DD 214 (Armed Forces of the United States Report of Transfer or Discharge) or DD 256A (Honorable Discharge Certificate) as proof of eligibility for requested care. In areas with more than one Armed Forces MTF available and capable of providing required care, application should be made to the MTF of the service from which separated, as applicable. Disengagement in such areas to MTFs of other services may be made only when space is not available or capability does not exist in the MTF of the services from which the individual was separated.

(d) *Charges and collection.* Charges and reimbursement procedures for care rendered to beneficiaries in § 728.71(a)(2) are the same as prescribed by current regulations for active Coast Guard, USPHS, and NOAA members.

§ 728.72 Applicants for enrollment in the Senior Reserve Officers' Training Program.

When properly authorized, designated applicants (including applicants for enrollment in the 2-year program and Military Science II enrollees applying for Military Science III) may be furnished medical examinations at naval MTFs including hospitalization necessary for the proper conduct thereof. Medical care, including hospitalization, is authorized for diseases contracted or injuries incurred in line of duty while at or traveling to or from a military installation for the purpose of undergoing medical or other examinations or for visits of observation.

§ 728.73 Applicants for enlistment or reenlistment in the Armed Forces, and applicants for enlistment in the reserve components.

(a) Upon referral by a commander of a Military Enlistment Processing Station (MEPS), applicants will be furnished necessary medical examinations, including hospitalization when qualifications for service cannot otherwise be determined. Use the hospitalization period only for diagnostic purposes. Do not correct disqualifying defects.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.74 Applicants for appointment in the regular Navy or Marine Corps and reserve components, including members of the reserve components who apply for active duty.

(a) Necessary medical examinations may be furnished, including hospitalization when qualifications for service cannot otherwise be determined. Use such a period of hospitalization only for diagnostic purposes. Do not correct disqualifying defects.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or MEPS may be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.75 Applicants for cadetship at service academies and applicants for the Uniformed Services University of Health Sciences (USUHS).

(a) Upon presentation of a letter of authorization from the Department of Defense Medical Examination Review Board (DODMERB), applicants for cadetship at Service Academies (Navy, Army, Air Force, Coast Guard, and Merchant Marine) and applicants for the Uniformed Services University of Health Sciences (USUHS) will be furnished medical examinations at facilities designated by the DODMERB. Hospitalization is authorized when qualifications for service cannot otherwise be determined. Use the hospitalization period for diagnostic purposes only, and not to correct disqualifying or other defects. Perform examinations and make disposition of completed forms per BUMEDINST 6120.3M.

(b) Applicants who suffer injury or acute illness while awaiting or undergoing processing at Navy and Marine Corps facilities or at MEPS may

be furnished emergency medical and dental care, including emergency hospitalization, for that injury or illness.

§ 728.76 Naval Home residents.

Provide necessary medical and dental care, both inpatient and outpatient, to residents of the Naval Home when requested by the Governor of the Home. In an emergency, care may be rendered without prior approval of the Governor; however, the Governor of the Home should be contacted immediately and requested to furnish authorization.

§ 728.77 Secretarial designees.

Subject to the capabilities of the professional staff and the availability of space and facilities, naval MTFs and DTFs will provide treatment to individuals that have been granted Secretarial designee status by any of the three service Secretaries (Navy, Army, or Air Force), the Secretary of Commerce for NOAA personnel, the Secretary of Health and Human Services for USPHS personnel, or the Secretary of Transportation for Coast Guard personnel.

(a) *Potential designees.* Upon a showing of sufficient cause, the Secretary of the Navy may authorize individuals, not otherwise authorized by law, to receive such care as is available in naval MTFs in the United States. Designation may be extended on a worldwide basis for preadoptive children and wards of active duty members, and for abused dependents delineated in § 728.77(a)(6). Temporary in loco parents or foster parent status of the member with regard to a minor is insufficient for approval. Also, civilian health care under the CHAMPUS program cannot be authorized for other than abused dependents. The Secretary's discretionary authority is exercised most conservatively, however, favorable action is usually taken on requests involving the following situations:

(1) Preadoption proceedings wherein an active duty member or a retired member has taken affirmative legal action to adopt a child.

(2) Custodianships and guardianships authorized by a court order wherein the member is designated by the court as the custodian or guardian and the child is fully dependent upon the active duty or retired member sponsor.

(3) Evaluation and selection of nonbeneficiaries who are donor candidates for an organ or tissue transplant procedure in behalf of a military service beneficiary.

(4) Nonbeneficiary participants in officially approved clinical research studies.

(5) Unremarried former spouses who: Require care for a condition incurred during or caused/aggravated by conditions associated with the member's or former member's creditable service; do not qualify under the former spouses act; and do not have medical coverage under an employer-sponsored health plan which will provide for the care required.

(6) Abused dependents of discharged or dismissed former uniformed services members in need of medical or dental care resulting from knowledge of the abuse or for an injury or illness resulting from abuse by the former member. Eligibility will terminate the earliest of 1 year after the date on which the member is discharged or dismissed from a uniformed service, or when care is no longer needed.

(7) In other instances wherein the circumstances clearly merit the providing of treatment in naval MTFs, and in which the best interest of the patient, the Navy, and the Government will be served, favorable Secretarial action may result. The mere need of medical care by a former beneficiary or other person, alone, will not support approval of such a request.

(b) *Requests for consideration.* Requests for consideration will be submitted to the Commander, Naval Medical Command (MEDCOM-33) by applicants via their command, when applicable, or by the Medical Department command concerned. Requests should include any pertinent information which will support resolution and a return address. Requests involving:

(1) Preadoption must include a legible reproducible copy of an interim court order or adoption agency placement agreement which names the sponsor and identifies the other participating parties. A petition for a court order is insufficient to support a recommendation for approval.

(2) Custodianships and guardianships must include a legible reproducible copy of the court order, identification of the parties, and also identify any amounts of income to which the ward is entitled.

(3) Participants in clinical research studies must include:

(i) Sufficient clinical information concerning the nature of the study.

(ii) Benefits which may accrue to the individual.

(iii) The extent, if any, to which access by other authorized beneficiaries will be impaired.

(iv) Benefits which will accrue to the command, e.g., enhancement of training, maximum use of specialized facilities, etc.

(v) Recommended duration of designation.

(vi) Whether the consenting individual has been informed concerning the nature of the study, its personal implications, and freely consents.

(4) Unremarried former spouses must include:

(i) A notarized copy of the marriage license.

(ii) A statement attesting to the fact that the sponsoring former spouse achieved 20 or more years of creditable military service.

(iii) Copy of divorce decree with official date.

(5) Abused dependents must include:

(i) Full name, social security number, grade or rate, branch or service, and date and type of discharge or dismissal of the former member. Such a member must have received a dishonorable or bad-conduct discharge or dismissal from a uniformed service as a result of court-martial conviction for an offense involving abuse of a dependent of the member.

(ii) Full names, social security numbers (if assigned), and relationship to the former member of any dependent in need of medical or dental care to treat adverse health conditions resulting from such dependent's knowledge of the abuse or any injury or illness suffered by the abused person as a result of such abuse.

(c) *Blanket designation.* (1) The Secretary of Defense has granted Secretarial designee status to full-time Schedule "A" faculty members of the Uniformed Services University of Health Sciences (USUHS). They have been provided documentation substantiating their eligibility and, where necessary, an eligibility termination date. These personnel are authorized routine care at the Naval Hospital, Bethesda, MD. At other naval MTFs, only emergency treatment is authorized while they are traveling on official university business. The letter of authorization excludes routine dental care, prosthetic appliances, and spectacles.

(2) The following officials within the Government, the Department of Defense, and military departments have been granted blanket Secretarial designation for medical and emergency dental care in naval MTFs in the United States:

- (i) The President.
- (ii) The Vice President.
- (iii) Members of the Cabinet.
- (iv) Article III Federal Judges.
- (v) U.S. Court of Military Appeals Judges.
- (vi) Members of Congress.

(vii) The Secretary, Deputy Secretary, and the Assistant Secretaries of Defense.

(viii) The Under Secretary of Defense for Policy.

(ix) The Under Secretary of Defense for Research and Engineering.

(x) The Secretaries, Under Secretaries, and the Assistant Secretaries of the Military Departments.

(d) *Authorization.* Designees will present a signed letter bearing the letterhead of the designating service. Secretarial designees are not included in the DEERS data base and may not possess Government identification cards. Therefore, the only proof of their eligibility for treatment may be the letter of authorization. When a Secretarial designee presents for treatment:

(1) Ask for identification of the individual presenting the letter of authorization to assure that the person seeking care is the individual to whom the letter was issued.

(2) Check the expiration date on the letter of authorization. Many authorizations are issued for only a specified period of time, e.g., abused dependents—no longer than 1 year.

(3) Check to assure that the individual is applying for care authorized by the letter of authorization. Designation is often granted for a specific diagnosis or specific mode of treatment.

(4) Check to assure that the individual has not been designated for care only as specific facility. Many authorizations are granted for conditions or for care that can be rendered only by a specified physician or under a specific program.

(5) Place a copy of the letter of authorization in the individual's Health Record or outpatient treatment record on the left side at the first visit or admission.

(e) *Charges and collection.* (1) Interagency rates are applicable for inpatient and outpatient care provided outside the National Capital Region to all individuals listed in § 728.77(c)(2) with the exception of Members of Congress. Charges are at full reimbursement rates for Members of Congress provided inpatient or outpatient care outside the National Capital Region.

(2) In the National Capital Region:

(i) Charges are waived for outpatient care provided to all categories listed in § 728.77(c)(2).

(ii) Charge interagency rates for inpatient care of all individual in § 728.77(c)(2) except Members of Congress. Charge Members of Congress at full reimbursement rates.

(3) Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished,

Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered to Secretarial designees whose charges for care have not been waived.

§ 728.78 American Red Cross representatives and their dependents.

(a) *Potential beneficiaries.*

(1) Volunteer workers.

(2) Full-time, paid employees.

(3) Dependents of personnel enumerated in § 728.78(a) (1) and (2) when accompanying their sponsor outside the continental United States, including Alaska, Hawaii, and Puerto Rico.

(b) *Care authorized.* (1) When services of the American Red Cross (ARC) have been accepted in behalf of the Federal Government under applicable DOD regulations, beneficiaries in § 728.78(a)(1) are considered "employees" of the Government for the purpose of this part and are authorized health care in USMTFs, both in and outside the United States for work-related conditions. See § 728.53(a)(2) regarding the specific application of this authorization.

(2) Beneficiaries enumerated in § 728.78(a) (1) and (2) are authorized health care in USMTFs located outside the United States for both work and nonwork-related conditions. See § 728.53(a)(2) for treatment of work-related conditions of those in § 728.78(a)(1).

(3) Beneficiaries identified in § 728.78(a) (1), (2), and (3) are authorized emergency care in USMTFs outside the continental United States, including Alaska, Hawaii, and Puerto Rico where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals. Provide hospitalization only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Routine dental care, other than dental prosthesis and orthodontia, is authorized on a space available basis provided facilities are not otherwise available in reasonably accessible non-Federal facilities.

(c) *Records disposal.* Upon completion of treatment of accredited representatives of the American Red Cross or their dependents, forward medical records, including all clinical records and x-ray films, to the Medical Director, National Headquarters, American Red Cross, 20th and D Street NW., Washington, DC 20006.

(d) *Charges and collection.* Charge beneficiaries in § 728.78(a) (1) and (2)

the rate applicable to officer personnel and dependents in § 728.78(a)(3) the dependent rate. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered to ARC personnel or to their dependents.

§ 728.79 Employees of Federal contractors and subcontractors.

(a) *Beneficiaries.* (1) U.S. citizen contractor, engineering, and technical service personnel designated as U.S. Navy Technicians.

(2) Civilian employees of contractors and subcontractors operating under U.S. Government contracts.

(3) Dependents of personnel enumerated in § 728.79(a) (1) and (2) when accompanying their sponsor outside the continental United States or in Alaska.

(b) *Care authorized.* (1) Beneficiaries identified in § 728.79(a) (1) and (2) may be provided emergency care in naval MTFs for illnesses and injuries occurring at work in or outside the United States.

(2) While serving outside the continental United States or in Alaska, where facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities, beneficiaries identified in § 728.79(a) (1), (2), and (3) may receive hospitalization and necessary outpatient services in naval MTFs on a reimbursable basis. Except for beneficiaries in § 728.79(a)(1) who are serving aboard naval vessels, all others enumerated may only be hospitalized for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Routine dental care, other than dental prosthesis and orthodontia, is authorized on a space available basis provided facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(c) *Charges and collection.* Care is authorized on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.80 U.S. Government employees.

(a) Civil service employees of all Federal agencies, including teachers employed by Department of Defense Dependent's Schools (DODDS) and their dependents, may be provided

hospitalization and necessary outpatient services, (other than occupational health services), on a reimbursable basis, outside the continental limits of the United States and in Alaska, where facilities are not otherwise available in reasonably accessible and appropriate non-Federal hospitals. Except for employees who are serving aboard naval vessels, hospitalization may be furnished only for acute medical and surgical conditions, exclusive of nervous, mental, or contagious diseases or those requiring domiciliary care. Routine dental care, other than dental prosthesis and orthodontia, is authorized on a space available basis provided facilities are not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(b) Such civilian employees and their dependents may be provided medical, surgical, dental treatment, hospitalization, and optometric care at installations in the United States which have been designated remote by the Secretary of the Navy for the purpose of providing medical care.

(c) The major objective of the following programs for civil service employees, regardless of location, is emergency treatment for relief of minor ailments or injuries to keep the employee on the job:

(1) The Department of Labor, Office of Workers' Compensation Programs (OWCP), governs the overall medical care program for employees of the Government who sustain injuries while in the performance of duty, including diseases proximately caused by conditions of employment (see § 728.53).

(2) Federal civil service employees and applicants for such employment are authorized services as outlined in chapter 22, section XIII, of the Manual of the Medical Department (MANMED). When appropriated fund and nonappropriated fund employees, including unpaid volunteer employees, require emergency and nonemergency occupational health services due to an illness or an injury on the job, provide this limited care through your occupational health service, emergency room, or evening primary care clinic, as appropriate. This care is rendered free of charge to the employee, the employee's command, or insurance carrier. Included with this group are Military Sealift Command (MSC) civilian marine personnel (authorized additional care and services as outlined in BUMINST 6320.52 and care under § 728.53(a)(7)) and members of the National Oceanic and Atmospheric Administration (NOAA) serving with the Navy.

(3) Under the technical control of the Surgeon General of the Army, the DOD Civilian Employees' Health Service is responsible for administering the health program for all Federal civil service employees in the District of Columbia area.

(d) Care, other than occupational health services, is provided on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.81 Other civilians.

(a) *General.* In an emergency, any person may be rendered care in naval MTFs to prevent undue suffering or loss of life or limb. Limit care to that necessary only during the period of the emergency, and if further treatment is indicated, initiate action to transfer the patient to a private physician or civilian facility as soon as possible. Further, subject to the provisions of § 728.3, the following personnel are authorized care as set forth.

(b) *Beneficiaries and extent of care.*

(1) Provide all occupational health services to civilian employees paid from nonappropriated funds, including Navy exchange employees and service club employees, free of charge (see § 728.80(c)(2)). Provide treatment of occupational illnesses and injuries other than in emergencies per rules and regulations of the Office of Workers' Compensation Programs (see § 728.53).

(2) Civilians attending the Federal Bureau of Investigation (FBI) Academy, Marine Corps Development and Education Command, Quantico, VA, may be rendered care at the Naval Medical Clinic, Quantico, VA, for emergencies. Such persons who are in need of hospitalization for injuries or disease may be hospitalized and classed as civilian humanitarian nonindigents with the approval of the cognizant hospital's commanding officer.

EXCEPTION: Certain individuals, such as employees of the Federal Bureau of Investigation who are injured in the line of duty, may be entitled to care at the expense of the Office of Workers' Compensation Programs (OWCP) (see § 728.53).

(3) The following civilians who are injured or become ill while participating in Navy or Marine Corps sponsored sports, recreational or training activities may be rendered care on a temporary (emergency) basis until such time as

disposition can be effected to another source of care.

(i) Members of the Naval Sea Cadet Corps.

(ii) Junior ROTC/NDCC (National Defense Cadet Corps) cadets.

(iii) Civilian athletes training or competing as part of the U.S. Olympic effort.

(iv) Civilians competing in Navy or Marine Corps sponsored competitive meets.

(v) Members of Little League teams and Youth Conservation groups.

(vi) Boy Scouts and Girl Scouts of America.

(4) Other civilian personnel included below are not normally eligible for care in naval MTFs; however, under the conditions set forth, care may be rendered.

(i) *Potential beneficiaries.*

(A) Civilian representatives of religious groups.

(B) Educational institutions representatives.

(C) Athletic clinic instructors.

(D) USO representatives.

(E) Celebrities and entertainers.

(F) Social agencies representatives.

(G) Others in a similar status to those in § 728.81(b)(4)(i) (A) through (F).

(H) News correspondents.

(1) Commercial airline pilots and employees.

(i) Volunteer workers. This category includes officially recognized welfare workers, other than Red Cross.

(ii) *Care authorized.*

(A) Persons enumerated in § 728.81(b)(4)(i) (A) through (G), who are contracted to provide direct services to the Armed Forces and who are acting under orders issued by the Department of Defense or one of the military departments to visit military commands overseas, and their accompanying dependents, may be provided medical care in naval MTFs outside the 48 contiguous United States and the District of Columbia provided local civilian facilities are not reasonably available or are inadequate. Limit inpatient care to acute medical and surgical conditions exclusive of nervous, mental, or contagious diseases, or those requiring domiciliary care. Routine dental care, other than dental prostheses and orthodontia, is authorized on a space available basis outside the United States, provided such care is not otherwise available in reasonably accessible and appropriate non-Federal facilities.

(B) Persons enumerated in § 728.81(b)(4)(i) (H) and (I) are authorized emergency medical and dental care in naval MTFs outside the 48 contiguous United States and the

District of Columbia provided local civilian facilities are not reasonably available or are inadequate.

(C) Persons enumerated in § 728.81(b)(4)(i)(J), both within and outside the 48 contiguous United States and the District of Columbia, may receive care in naval MTFs for injuries or diseases incurred in the performance of duty as beneficiaries of OWCP (see § 728.53). Additionally, if such volunteers are sponsored by an international organization (e.g., the United Nations) or by a voluntary nonprofit-relief agency registered with and approved by the Advisory Committee on Voluntary Aid (e.g., CARE), they may receive other necessary nonemergency medical care and occupational health services while serving outside the 48 contiguous United States and the District of Columbia.

(c) *Charges and collection.* Care is provided on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

§ 728.82 Individuals whose military records are being considered for correction.

Individuals who require medical evaluation in connection with consideration of their individual circumstances by the Navy, Army, and Air Force Board for Correction of Military Records are authorized evaluation, including hospitalization when necessary for the proper conduct thereof.

§ 728.83 Persons in military custody and nonmilitary Federal prisoners.

(a) *Potential beneficiaries.*

(1) Military prisoners.

(2) Nonmilitary Federal prisoners.

(3) Enemy prisoners of war and other detained personnel.

(b) *Care authorized—(1) Military prisoners.*

(i) Whose punitive discharges have been executed but whose sentences have not expired are authorized all necessary medical and dental care.

(ii) Whose punitive discharges have been executed and who require hospitalization beyond expiration of sentences are not eligible for care but may be hospitalized as civilian humanitarian nonindigents until final disposition can be made to some other appropriate facility.

(iii) On parole pending completion of appellate review or whose parole changes to an excess leave status

following completion of sentence to confinement while on parole are not members of the military service and as such are authorized care as outlined in subpart B.

(iv) On parole whose punitive discharge has been executed are not members of the military service and are therefore not entitled to care at Government expense. If the circumstances are exceptional, individuals herein who are not authorized care may request Secretarial designee status under the provisions of § 728.77.

(2) *Nonmilitary Federal prisoners.* Under the provisions of § 728.83, nonmilitary Federal prisoners are authorized only emergency medical care. When such care is being rendered, the institution to which prisoners are sentenced must furnish necessary guards to effectively maintain custody of prisoners and assure the safety of other patients, staff members, and residents of the local area. Under no circumstances will military personnel be voluntarily used to guard or control such prisoners. Upon completion of emergency care, make arrangements for immediate transfer of the prisoners to a nonmilitary MTF or for return to the facility to which sentenced.

(3) *Enemy prisoners of war and other detained personnel.* Subject to the provisions of § 728.3, enemy prisoners of war and other detained personnel are entitled to and may be rendered all necessary medical and dental care.

(c) *Charges and collection.* Care provided individuals enumerated in § 728.83(b)(1) (ii), (iv), and § 728.83(b)(2) is on a reimbursable basis. Complete and submit, per Subpart J, a DD 7 (Report of Treatment Furnished Pay Patients, Hospitalization Furnished, Part A) or DD 7A (Report of Treatment Furnished Pay Patients, Outpatient Treatment, Part B) when outpatient or inpatient care is rendered.

Subpart H—Adjuncts to Medical Care

§ 728.91 General 28.

Adjuncts to medical care include but are not limited to prosthetic devices such as artificial limbs, artificial eyes, hearing aids, orthopedic footwear, spectacles, wheel chairs, hospital beds, and similar medical support items or aids which are required for the proper care and management of the condition being treated. Generally, expenses incurred for procurement of such items, either from civilian sources as supplemental care or from stocks maintained by the facility, are payable from operation and maintenance funds

available for support of naval MTFs. However, certain adjuncts may be cost-shared under CHAMPUS for CHAMPUS-eligible individuals under circumstances enumerated in the cooperative care or services criteria of § 728.4(z).

§ 728.92 Policy.

(a) Provide adjuncts to medical care to eligible beneficiaries receiving inpatient or outpatient care when, in the opinion of the attending physician, such adjuncts will offer substantial assistance in overcoming the handicap or condition and thereby contribute to the well-being of the beneficiary.

(b) Unless necessary for humanitarian reasons, do not furnish orthopedic and prosthetic appliances on an elective basis to members of the naval service with short periods of service remaining

when the defect requiring the appliance existed prior to entry into service and when such members will be separated from the service because of these defects.

(c) For active duty members, make the initial allowance of orthopedic footwear and orthopedic alterations to standard footwear the same quantity as provided in the initial clothing allowance.

(d) Base the number of orthopedic and prosthetic appliances issued or replaced for other authorized recipients upon the individual's requirements as determined by the attending physician to be consistent with the highest standards of modern medicine.

(e) Former members of the uniformed service should be advised that they may obtain durable medical equipment,

medical care, and adjuncts from Veterans Administration facilities.

(f) Dependents are authorized certain adjuncts per §§ 728.31 (c) and (d) and in instances where items are not normally authorized at the expense of the Government, they may be provided at cost to the United States if available from Government stocks under the following conditions:

(1) Outside the United States.

(2) At specific stations within the United States which have been authorized by the Secretary of the Navy to sell these items.

§ 728.93 Chart of adjuncts.

The following chart and footnotes provide information relative to adjuncts which may be furnished the several categories of beneficiaries eligible for medical care at naval MTFs.

Adjuncts	Active duty and retired members	Others authorized the same benefits as active duty or retired members ⁽⁶⁾	Dependents authorized the same benefits	Other beneficiaries ⁽⁸⁾
Ambulance service.....	Yes.....	Yes.....	Yes ⁽¹⁾	No
Artificial eyes.....	Yes.....	Yes.....	Yes.....	Maybe ⁽³⁾
Artificial limbs.....	Yes.....	Yes.....	Yes.....	Maybe ⁽³⁾
Contact or special lenses ⁽¹¹⁾	Yes ⁽⁴⁾	Yes ⁽⁴⁾	Maybe ⁽²⁾ ⁽⁴⁾ ⁽⁶⁾	No
Crutches ⁽⁷⁾	Yes.....	Yes.....	Yes.....	Yes
Dental prostheses.....	Yes.....	Yes.....	Maybe ⁽⁹⁾	Maybe ⁽⁹⁾
Elastic stockings.....	Yes.....	Yes.....	Yes.....	Yes
Hearing aids ⁽¹⁰⁾	Yes ⁽⁵⁾	Yes ⁽⁵⁾	Maybe ⁽²⁾	Maybe ⁽³⁾
Hearing aid parts and batteries.....	Yes ⁽¹⁰⁾	Yes ⁽¹⁰⁾	Maybe ⁽²⁾ ⁽¹⁰⁾	No
Hospital beds ⁽⁷⁾	Yes.....	Yes.....	Yes.....	Yes
Joint braces.....	Yes.....	Yes.....	Yes.....	Yes
Orthopedic footwear.....	Yes.....	Yes.....	Maybe ⁽²⁾	Maybe ⁽³⁾
Prosthetic devices, other ⁽⁷⁾	Yes.....	Yes.....	Maybe ⁽²⁾	No
Respirators and inhalators ⁽⁷⁾	Yes.....	Yes.....	Yes.....	Yes ⁽¹⁾
Resuscitators ⁽⁷⁾	Yes.....	Yes.....	Yes.....	Yes ⁽¹⁾
Spectacles.....	Yes.....	Yes.....	Maybe ⁽²⁾ ⁽⁶⁾	No
Walking irons ⁽⁷⁾	Yes.....	Yes.....	Yes.....	Yes
Wheel chairs ⁽⁷⁾	Yes.....	Yes.....	Yes.....	Yes

⁽¹⁾ When considered medically appropriate by the attending physician.

⁽²⁾ See § 728.92(f).

⁽³⁾ Outside the United States and at designated remote stations when considered medically appropriate by the attending physician.

⁽⁴⁾ Contact or special lenses are not to be issued solely for cosmetic reasons. Further guidelines are contained in NAVMEDCOMINST 6810.1.

⁽⁵⁾ In addition to the hearing aid, include in initial issue one spare receiver cord, approximately 1 month's supply of batteries, and a statement indicating make, model, type of receiver, serial number, code, part numbers, "B" battery voltage, and type of "A" and "B" batteries, as appropriate. Provide replacement of hearing aids upon the same basis as initial issue and, except in unusual circumstances, will not be replaced within 2 years of the initial furnishing or the last replacement of the appliance.

⁽⁶⁾ Spectacles, contact lenses, or intraocular lenses may be provided dependents with eye conditions which require these items for complete medical or surgical management of a condition other than ordinary refractive error. For further information, consult NAVMEDCOMINST 6810.1.

⁽⁷⁾ May be loaned on a custody basis at the discretion of the attending physician.

⁽⁸⁾ See subpart of this part relating to specific beneficiary.

⁽⁹⁾ When considered by the attending physician and dentist to be an adjunct to a medical or surgical condition other than dental and when in consonance with existing legislation and directives.

⁽¹⁰⁾ For further guidelines, consult BUMEDINST 6320.41B.

⁽¹¹⁾ Includes intraocular lenses required for implantation upon removal of cataracts:

Subpart I—Reservists—Continued Treatment, Return to Limited Duty, Separation, or Retirement for Physical Disability

§ 728.101 General.

(a) *Notice of eligibility (NOE)*. While the NOE is basically a document that substantiates entitlement to a disability benefit equal to pay and allowances, it may be accepted when required to substantiate eligibility for benefits other than pay and allowances, i.e., treatment in USMTFs under the provisions of title 10, United States Code.

(b) *Physical disability benefits*. The following, excerpted and paraphrased from SECNAVINST 1770.3, paragraph 10, is applicable when a reservist may be entitled to physical disability benefits.

(1) When a notice of eligibility (NOE) has been issued to a member hospitalized in a naval MTF and the attending physician is of the opinion that recovery is not anticipated or that the reservist is not expected to be fit for return to full duty within a reasonable period, a medical board will be convened and the case managed the same as that of a Regular member. Assure that a copy of the NOE accompanies the medical board report forwarded to the Central Physical Evaluation Board. Disability benefits, equal to pay and allowances, will continue in such instances until final disposition.

(2) There is no limited duty status, per se, for inactive reservists. However, if the attending physician determines that a reservist is temporarily unfit for full duty, but will be fit for full duty following a period of convalescence or following duty with physical limitations, not to exceed 6 months, the physician may return the reservist to duty with a summary of the hospitalization or treatment. The summary will set forth the limitations posed by the member's disability and the period of such limitations. Followup hospitalization, treatment, and evaluation for the same condition may be provided at USMTFs during the period of restricted duty, if required. If, during the period of the restricted duty, it appears that the reservist will be *permanently* unfit for full duty, promptly authorize the reservist to report for evaluation, treatment if required, and appearance before a medical board at the nearest naval MTF capable of accomplishing same. Admission to the sicklist is

authorized, when required. Should the medical board recommend appearance before a physical evaluation board, disability benefits equal to pay and allowances should continue until final disposition is effected.

§ 728.102 Care from other than Federal sources.

The provisions of this subpart do not authorize care for reservists at other than Federal facilities nor out of funds available for operation of USMTFs (supplemental care) after a period of active duty or a period of training duty ends, including travel to and from such training. Such care may be rendered under the provisions of Part 732 of this chapter.

Subpart J—Initiating Collection Action on Pay Patients

§ 728.111 General.

The Comptroller of the Navy has approved a system of transactions that generates reports to COMNAV MEDCOM on unfunded reimbursable transactions. The purpose of the final report is to provide data on services furnished by naval health care facilities for which central collection from other Government agencies and private parties is required.

§ 728.112 Responsibilities.

(a) *Patient administration departments*. The initiation of the collection process begins with patient administration departments. Collection action cannot be accomplished unless patient administration departments take the initial step to complete:

(1) *DD 7, Report of Treatment Furnished Pay Patients, Hospitalization Furnished (Part A)*. Prepare a separate substantiating DD 7, in triplicate, for each category of pay patient receiving inpatient care. At the end of each day that any pay patient is admitted, submit DD 7's to the collection agent.

(2) *DD 7A, Report of Treatment Furnished Pay Patients, Outpatient Treatment Furnished (Part B)*. Prepare a separate substantiating DD 7A, in triplicate, for each category of pay patient receiving outpatient care. At the end of each day that any pay patient is treated on an outpatient basis, submit DD 7A's to the collection agent.

(b) *Collection agents*. Upon receipt of a completed DD 7 or DD 7A, collection agents will take the action indicated in paragraph 24304 of the Resource

Management Handbook, NAVMED P-5020, to effect central collection action.

§ 728.113 Categories of pay patients.

The categories of patients for whom collection action must be initiated are:

(a) *Coast Guard*. (1) Active Officers. (2) Retired Officers. (3) Active Enlisted. (4) Retired Enlisted. (5) Dependents. (6) Cadets.

(b) *Public Health Service*. (1) Active Officers. (2) Retired Officers. (3) Dependents of Officers.

(c) *National Oceanic and Atmospheric Administration (NOAA)*. (1) Active Officers. (2) Retired Officers. (3) Dependents of Officers.

(d) *Foreign*. (1) NATO Officers (Except Canadians provided care under the comparable care agreement.). (2) NATO Enlisted (Except Canadians provided care under the comparable care agreement.). (3) NATO Dependents. (4) Civilians Accompanying NATO Members. (5) Foreign Military Sales (FMS) Officers. (6) FMS Enlisted. (7) FMS Dependents. (8) FMS Civilians. (9) Military Grant Aid Officers. (10) Military Grant Aid Enlisted. (11) Military Grant Aid Dependents. (12) Military Grant Aid Civilians. (13) Military Officers From Other Than NATO Nations. (14) Military Enlisted From Other Than NATO Nations. (15) Dependents of Officers and Enlisted From Other Than NATO Nations. (16) Civilians Accompanying Military Members of Other Than NATO Nations. (17) Nationals and Their Dependents.

(e) *Secretarial Designees Not Exempted From Paying*.

(f) *Others*. (1) Merchant Marines. (2) Military Sealift Command (MSC) Personnel. (3) Public Health Service Beneficiaries (Other than Commissioned Corps). (4) Veterans Administration Beneficiaries. (5) Peace Corps Beneficiaries. (6) Job Corps Beneficiaries. (7) Volunteers In Service to America (VISTA) Beneficiaries. (8) Office of Workers Compensation Program (OWCP) Beneficiaries. (9) Bureau of Employees Compensation (BEC) Beneficiaries. (10) Department of State and Other Federal Agencies Beneficiaries (prepare a separate form for each Federal agency). (11) Civilian Humanitarian Nonindigents (CHNI). (12) Trust Territory Beneficiaries. (13) Others Not Specified Above Who Are Not Entitled to Health Benefits at the Expense of the Government.

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Friday
September 4, 1987

Part V

Department of Energy

Federal Energy Regulatory Commission

18 CFR Parts 2 and 284

**Regulation of Natural Gas Pipelines After
Partial Wellhead Decontrol; Data Request**

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

18 CFR Parts 2 and 284

[Docket No. RM87-34-000]

Regulation of Natural Gas Pipelines
After Partial Wellhead Decontrol

Issued: August 28, 1987.

AGENCY: Federal Energy Regulatory
Commission, DOE.

ACTION: Notice of data request.

SUMMARY: The Federal Energy Regulatory Commission has sent to forty-five interstate natural gas pipelines the attached data request concerning the nature and extent of their take-or-pay problems. While only pipelines are required to respond to this data request, the Commission also invites any producers desiring to do so to file responses to the request.

DATE: All responses must be filed within thirty days of the effective date of Order No. 500.¹

ADDRESS: The cover letter, paper copy, and magnetic tape, if any, must be submitted to: Office of the Secretary, Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426.

Hand delivery may be made to: Office of the Secretary, Federal Energy Regulatory Commission, Room 3110, 825 N. Capitol Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Marilyn L. Rand, (202) 357-8674

John E. Moriarty, (202) 357-8824

Office of Pipeline and Producer

Regulation, Federal Energy Regulatory
Commission, 825 North Capitol Street,
NE., Washington, DC 20426.**SUPPLEMENTARY INFORMATION:**

Take notice that on August 26, 1987, the Federal Energy Regulatory Commission sent to forty-five interstate natural gas pipelines a data request concerning the nature and extent of their take-or-pay problems. In Order No. 500,² the Commission stated that it would issue this data request in order to obtain information necessary to respond to the decision of the United States Court of Appeals for the District of Columbia in *Associated Gas Distributors v. FERC*.³ In particular, the

information sought in this data request is necessary to enable the Commission to respond to the Court's direction that the Commission reassess its decision in Order No. 436 not to invoke its power under NGA section 5 to modify or set aside jurisdictional contracts with troublesome take-or-pay provisions.

While only pipelines are required to respond to this take-or-pay data request, the Commission also invites any producers desiring to do so to file responses to the attached data request. Those producers filing responses need not submit responses to all questions in all schedules. However producers should file their responses, to the maximum extent possible, in the format described in the instructions to the data request. At a minimum, producers must identify the schedule and the particular questions within each schedule, to which responses are made. Producers are also encouraged, to the maximum extent possible, to submit their responses on magnetic computer tape as prescribed in the instructions to the data request. Producers filing responses must comply with all other instructions set forth on pages 1 and 2 of the data request under "General Information for Take-or-Pay Data Request." The Commission strongly encourages those producers filing responses to conform their responses to the procedures and format required for pipelines so that the Commission can process all responses promptly. Producer responses, like pipeline responses, must be filed within thirty days of the effective date of Order No. 500.

Kenneth F. Plumb,

Secretary.

TAKE-OR-PAY DATA REQUEST

[FERC-593; OMB No. 19020149; Expires 11/7/87]

August 28, 1987.

**General Information for Take-or-Pay
Data Request****A. How To Submit**

All data is to be submitted on 9-track magnetic computer tape(s) conforming in all respects to the requirements of the Federal Information Processing Standard Publication, FIPS Pub. 79, "Magnetic Tape Tables and File Structure for Information Interchange." Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, Virginia 22161. Level three labeling standards described in the federal standard should be utilized for file formats, tape labels and record formats. All tapes will be returned to the respondent within 30 days of their

receipt at the Commission. The respondent should include file names, file attributes and recording density in a cover letter accompanying each tape.

Each tape must be accompanied by one paper copy tape listing of the data submitted on magnetic tape. The specifications for the magnetic tape layout are included in Exhibit A. The specifications for the paper copy are included in Exhibit B.

B. Where to Submit

(1) Submit the tape, the cover letter, and the paper copy to: Office of the Secretary, Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426.

(2) Hand delivery can be made to: Office of the Secretary, Federal Energy Regulatory Commission, Room 3110, 825 N. Capitol Street, NE., Washington, DC 20426.

Retain a copy of the tape for your files.

C. Attestation

All filings with the Commission require the subscription and attestation prescribed in § 385.2005 of the Commission's regulations. Accordingly, the cover letter, mentioned above, should also attest that the information on the paper copy tape listing is the same as the information on the magnetic tape and that the contents of the paper copy and magnetic tape are true to the best knowledge and belief of the signer.

D. Records Retention To Support Tape

The respondent is required to maintain records which support the tape for a period of at least one (1) year.

E. Waivers

Waivers from the magnetic tape provision and other requirements, including the time by which the data must be filed, may be granted on a case-by-case basis for good cause shown.

F. Requests For Confidential Treatment

Respondents may request confidential treatment of their responses. See, 18 CFR 388.110 (1987).

G. Whom To Contact

For general questions contact: Marilyn L. Rand, (202) 357-8674.

For technical reporting questions contact: John E. Moriarty, (202) 357-8824.

**General Instructions for Take-or-Pay
Data Request****A. Introduction**

This data request consists of six contract-summary schedules. Three of these same schedules (i.e., Schedules

¹The Federal Energy Regulatory Commission will publish a notice of the effective date of Order No. 500. See 52 FR 30334, August 14, 1987.

²52 FR 30334 (Aug. 14, 1987).

³No. 85-1811, et. al.

No. 4, 5, and 6, see below) are to be used to report on an aggregated basis data for company-totals only. A narrative-text schedule may also be provided at the option of the respondent to *supplement* (not substitute for) data reported on Schedules 1 through 6.

1. The contract-summary schedules are:

- Schedule 1. Contract Summary Information
- Schedule 2. Contract Take-or-Pay Provisions (As of July 1, 1987)
- Schedule 3. Contract Pricing Provisions (As of July 1, 1987)
- Schedule 4. Take-or-Pay History (One for each calendar year 1983-1986 and for the first six months of 1987)
- Schedule 5. Take-or-Pay Obligations, Prepayments, and Settlements (One for each calendar year 1983-1986 and for the first six months of 1987)
- Schedule 6. Contract Reformations and Terminations (One for each calendar year 1983-1986 and for the first six months of 1987)

2. The summary schedules are:

- Schedule 4. A summary of Schedule 4 for all contracts (One for each calendar year 1983-1986 and for the first six months of 1987)
- Schedule 5. A summary of Schedule 5 for all contracts (One for each calendar year 1983-1986 and for the first six months of 1987)
- Schedule 6. A summary of Schedule 6 for all contracts (One for each calendar year 1983-1986 and for the first six months of 1987)

3. The narrative-text schedule is:

- Schedule 7. Narrative Text Schedule (This schedule provides the respondent the opportunity to clarify the data reported on Schedules 1 through 6. Note, however, that Schedule 7 cannot be used as a substitute for Schedules 1 through 6.)

B. Reports for Individual Contracts

1. Which Contracts to Report Individually

A contract should be reported individually if:

- (a) It is an active contract (i.e., not an expired or terminated contract), and had an annual deliverability of more than one billion cubic feet between January 1, 1983 and June 30, 1987.
- (b) It is an expired or terminated contract and had a deliverability of more than one billion cubic feet between January 1, 1983 and June 30, 1987, and is associated with any of the following five conditions:
 - (i) A remaining unresolved take-or-pay exposure;
 - (ii) An outstanding prepayment for gas not taken;

(iii) A settlement payment to extinguish or mitigate take-or-pay exposure;

(iv) A payment to terminate or reform the contract in consideration of take-or-pay related to this or any other contract; or

(v) Non-cash consideration to terminate or reform the contract in consideration of take-or-pay related to this or any other contract.

(c) It does not meet the criteria identified in (a) or (b) but would be necessary to be added to those contracts reported under (a) and (b) so that the sum effect of contracts reported on an individual basis would account for 90 percent of the "Pipeline Estimate of Cumulative Take-or-Pay Obligation at End of Year," as would be reported at Schedule 5 column (1), for the period ending December 31, 1986.

2. Schedules to Report for Individual Contracts

Schedules for individual contracts should be reported as follows:

(a) Schedule 1 should be reported for all contracts which are subject to individual reporting. (See item B.1. above.) Note, however, that if a contract does not now nor did at any time since 1982 include a take-or-pay provision, only Items 1 through 6 and 11(e) should be reported on Schedule 1 for that contract.

(b) Schedules 2 and 3 should be reported only for those contracts which now, or did since 1982, include a take-or-pay provision. That is, if the answer to Question 6 on Schedule 1 is "Yes," then Schedules 2 and 3 should be reported.

(c) Schedules 4 and 5 should be reported only for those contracts for which:

- (i) There is or has been a past or present take-or-pay exposure, a gas prepayment, or take-or-pay settlement associated with the contract, or
- (ii) Gas covered by the contract was temporarily or permanently released with take-or-pay credit, or

(iii) The contract was reformed or terminated as either partial or complete consideration for take-or-pay related to this or any other contract, or

(iv) The contract does now or did since 1982 include a take-or-pay clause. That is, if the answer to either Question 6, or to any portion of Question 11 (a) through (d) is "Yes," then Schedules 4 and 5 should be reported.

(d) Schedule 6 should be reported only if there has been a contract reformation or termination for the purpose of resolving take-or-pay related to this contract or any other contract since 1982. That is, if the answer to Question

11(e) on Schedule 1 is "Yes," then Schedule 6 should be reported.

C. Company-Summary Schedules

The company summary schedules are company total data. The company-summary schedules should be submitted for each year 1983 through 1986 and for the first six months of 1987. Only the "Totals" line need be completed in reporting company-total data. That is, the company-total data does not have to be reported by "NGPA Section" category. Moreover, only the following columns need be completed in reporting company-total data:

- Schedule 4: Column (g)
- Schedule 5: Columns (a) through (n)
- Schedule 6: Column (i)

D. Miscellaneous Instructions

1. All data on Schedule No. 1 should be reported on a contract-summary basis (i.e., not segregated by NGPA category or subcategory). All data on Schedule Nos. 2 through 6 should be reported separately for each NGPA category or subcategory of gas covered by the contract. However, in regard to Schedule Nos. 2 and 3, the data should be reported on the "Whole Contract" line, if all of the provisions and terms of the contract apply consistently and equally to all gas covered by the contract, regardless of the NGPA category or subcategory of gas.

2. Report all gas volumes in MMBtu's (i.e., Billion Btu's).

3. Report all dollars in thousands of dollars.

4. Report all percentages to the nearest whole percentage (e.g., 75).

5. The various terms used here are intended to have the same meanings as in the documents recently issued by the Commission. See, for example:

"Statement of Policy;" Take-or-Pay Provisions in Gas Purchase Contracts; Docket No. PL81-1-000 (Issued December 16, 1982).

"Statement of Policy and Interpretive Rule;" Regulatory Treatment of Payments Made in Lieu of Take-or Pay Obligations; Docket No. PL85-1-000 (Issued April 10, 1985).

"Proposed Statement of Commission Policy;" Recovery of Take-or-Pay Buy-Out and Buy-Down Costs by Interstate Natural Gas Pipelines; Docket No. PL87-3-000 (Issued March 5, 1987).

6. Where an answer is requested on a yes or no basis, enter a "Y" for yes or "N" for no.

7. Schedule-specific instructions are given to clarify data items and to make reference to source publications. Unless otherwise instructed, all items are self-explanatory.

8. Note: Previous experience has shown that respondents occasionally report dollars and volumes in the wrong units (e.g., MMBtu or dollars). This can lead to very serious problems in processing and analyzing data. Respondents are therefore requested to be particularly careful in reporting the correct units.

9. Use the following codes for the

NGPA categories in the computer tape submission:

- Code = 1 Whole Contract
- Code = 2 102(d)
- Code = 3 Other 102
- Code = 4 103 (Price Controlled)
- Code = 5 Other 103
- Code = 6 104 Pre 1973
- Code = 7 104 1973-74 Biennium
- Code = 8 104 Post 1974
- Code = 9 104 Other

- Code = 10 106(a)
- Code = 11 107(c)(5)
- Code = 12 Other 107
- Code = 13 108 Jurisdictional
- Code = 14 108 Non-jurisdictional
- Code = 15 105/106(b)
- Code = 16 109
- Code = 17 Totals

10. "Casinghead gas," as used here, is gas which is produced concurrently with the production of crude oil.

Specific Instruction for Take-or-Pay Data Request

SCHEDULE NO. 1—CONTRACT SUMMARY INFORMATION

Schedule reference	Instructions
1(a), 1(b), 3(a), 3(b).....	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176.
2.....	Enter the respondent's own designation for the contract or agreement as it would appear in the purchaser's Form No. 542-PGA filings.
3.....	Complete items 3(a) through 3(d) and 3(f) for each seller who is a signatory to the contract being reported and has a working interest of at least 10 percent. These items must be reported for the operator, even if it has no working interest in the leases covered by the contract.
3(e).....	Enter the FERC Gas Rate Schedule Number assigned to the contract. If not applicable, enter "NA" (Not Applicable).
4(a) through 4(h).....	Enter as defined in "Instructions For Filing FERC Form No. 542-PGA Purchased Gas Adjustment (PGA) Filing." Note: If the contract covers gas produced in more than one field, area, or state, the largest or principal location data (field, area, etc.) should be entered. The respondent may provide supplemental data or notations on Schedule 7.
6.....	Enter "Y" or "N" as to whether the contract does now or did at any time since 1982, include a take-or-pay provision.
Complete 7 through 11.....	(d) only if the answer in 6 is "Y." Complete 11 (e) regardless of answer to 6.
8.....	Enter the date of the most recent rollover or significant renegotiation of this contract. "Significant" means a permanent change of 10 percent or more in the price and/or take-or-pay quantity provisions of this contract.
9(a).....	Enter month, day, and year, if the contract contains a fixed expiration date; otherwise enter "NA" in each data field (i.e., enter "NA" for "mm," "dd," and "yy.")
10.....	A "market-out clause" means a clause giving the purchaser the right to terminate the contract at the purchaser's discretion.

SCHEDULE NO. 2—CONTRACT TAKE-OR-PAY PROVISIONS

Schedule reference	Instructions
Contract No.	Enter the respondent's own designation for the contract (Same as Schedule 1, Item 2).
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a).....	Enter "Y" if take-or-pay is based on reserves; if not, enter "N."
(b).....	Enter "Y" if take-or-pay is based on deliverability; if not, enter "N."
(c).....	Enter "Y" if take-or-pay is based on a method other than reserves or deliverability; if not, enter "N."
(d).....	If take-or-pay is based on deliverability, enter the annual percentage which applies to casinghead gas (gas which is produced concurrently with the production of crude oil).
(e).....	If take-or-pay is based on deliverability, enter the annual percentage which applies to all gas other than casinghead gas.
(f).....	If take-or-pay for casinghead gas is based on reserves, enter the number which completes the ratio 1:..... For example, if the reserve ratio is 1:7300, enter 7300.
(g).....	If take-or-pay for all gas other than casinghead gas is based on reserves, enter the number which completes the ratio 1:..... For example, if the reserve ratio is 1:7300; enter 7300.
(h).....	Enter the number of years during which the contract permits the purchaser to make up any gas. If no make-up right exists, enter "0" (Zero).
(i).....	Enter "Y" if there are make-up rights after the contract expires or is terminated; if not, enter "N."
(j).....	Enter "Y" if the contract provides that the seller will refund payment upon expiration or termination of the contract for gas paid for but not taken; if not, enter "N."

SCHEDULE NO. 3—CONTRACT PRICING PROVISIONS

Schedule reference	Instructions
Contract No.	Enter the respondent's own designation for the contract (Same as Schedule 1, Item 2).
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a).....	Enter "Y" if the contract contains a price provision which allows the contract price to escalate to the NGPA Maximum Lawful Price; otherwise, enter "N."
(b).....	Enter "Y" if the contract price is referenced to NGPA prices; otherwise, enter "N."
(c).....	Enter "Y" if the contract states a fixed price or states a fixed rate of price escalation; otherwise, enter "N."
(d) through (h).....	If the contract does not contain a price redetermination clause, enter "N" in columns (d) through (h). If the contract does contain a redetermination clause, columns (d) through (h) should be completed as follows:
(d).....	Enter the code indicating the frequency with which the contract allows the price to be redetermined: A—1 year or less B—Greater than 1, up to 3 years C—Greater than 3 years D—Upon request E—Not specified F—Other G—Required by contract deregulation
(e).....	Enter "Y" if the contract contains a market sensitive pricing clause which allows the price to adjust to reflect current market conditions. This includes provisions with language such as the price will be based on the "fair market value" or the price will reflect an "economic analysis of all factors affecting value."
(f).....	If the contract has a redetermination clause which ties the price to an alternate fuel price or index, enter one of the following codes: A—Price tied to No. 2 fuel oil with an adjustment for transportation and distribution charges. B—Price tied to No. 2 fuel oil with no adjustment for transportation and distribution charges. C—Price tied to No. 6 fuel oil with an adjustment for transportation and distribution charges. D—Price tied to No. 6 fuel oil with no adjustment for transportation and distribution charges. E—Price tied to other fuel prices such as crude oil or an average of prices for more than one type of fuel oil; e.g., a mix of No. 2 and No. 6 fuel oil.

SCHEDULE NO. 3—CONTRACT PRICING PROVISIONS—Continued

Schedule reference	Instructions
(g)	Enter "Y" if the redetermination clause has a most-favored-nation provision, i.e., the contract calls for the redetermination to be based on any of the clauses detailed below. This may mean it is either the single determination factor or it shall be considered along with other factors in the negotiation. Most-favored-nation clauses require the contract prices to be tied to the: —Highest contract price paid by buyer for same area —Highest contract price from same area paid by any purchaser —Average of several of the highest contract prices from the same area
(h)	Enter "Y" if the contract redetermination process includes any other factors not included in columns (e) through (g).
(i)	Enter "Y" if the contract has a "buyer protection" clause currently operable under which the price of gas can be adjusted below the price called for under redetermination or other price adjustment terms. Enter "N" if the contract does not have such a clause, or if the contract has a "buyer protection" clause which becomes effective only when a given category of gas is deregulated, and that gas is still price controlled.
(j)	Enter "Y" if the contract does not allow the price to fall below a specified level; otherwise, enter "N."
(k)	Enter "Y" if the actual price paid is based on a unilateral action by the purchaser; otherwise, enter "N."
(l)	Enter "Y" if the actual price paid is set under a market-out clause; otherwise, enter "N."
(m)	Enter "Y" if the actual price paid is a renegotiated price; otherwise, enter "N."
(n)	Enter "Y" if the actual price paid is equal to the NGPA Maximum Lawful Price; otherwise, enter "N."
(o)	Enter "Y" if the actual price paid is determined under some mechanism other than those in (k) through (n); otherwise, enter "N."

SCHEDULE NO. 4—TAKE-OR-PAY HISTORY

Schedule reference	Instructions
Contract No	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a)	Enter the physical annual deliverability of the gas covered by the contract.
(b)	Enter the annual take-or-pay quantity obligation. For example, if take-or-pay were 90%, the quantity in column (b) would equal 90% times column (a).
(c)	Enter the quantity actually taken under the contract during the year.
(d)	Enter the take-or-pay quantity not taken but released, and for which a take-or-pay credit was received.
(e)	Enter the take-or-pay quantity obligation which was not taken nor released. This quantity should equal columns (b), less (c), less (d). This quantity should also equal the quantity reported at Schedule 5, column (c).
(f)	Enter the portion of (e) which the purchaser expects to ultimately recover or recoup.
(g)	Enter the portion of (e) which the purchaser does not expect to ultimately recover or recoup; because, for example, there are no make-up rights in the contract, the contract has expired, the make-up period specified in the contract has expired, the reserves are not sufficient to permit recovery of the prepayments, prepayments have been made or requested to be made repeatedly on the same gas reserves, etc. This quantity should equal columns (e), less (f).

SCHEDULE NO. 5—TAKE-OR-PAY OBLIGATIONS, PRE-PAYMENTS, AND SETTLEMENTS

Schedule reference	Instructions
Contract No	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
(a)	Enter the cumulative quantity for which the purchaser has an outstanding take-or-pay obligation. Column (a) for 1983 should be the cumulative quantity on January 1, 1983. For all years after 1983, the amount in column (a) will be the amount from column (k) of the preceding year.
(b)	Enter the cumulative dollar amount associated with the quantity in (a).
(c)	Enter the quantity of additional take-or-pay obligation during the year. This quantity should equal the quantity reported at Schedule 4, column (e).
(d)	Enter the dollar amount associated with the quantity in (c).
(e)	Enter the quantity of conventional, recoupable gas prepayments.
(f)	Enter the dollar amount associated with the quantity in (e).
(g)	Enter the quantity resolved by a settlement payment or non-cash consideration in lieu of a conventional prepayment.
(h)	Enter the dollar amount associated with the quantity in (g).
(i)	Enter the dollar amount or value paid to settle the quantity and dollar amount in (g) and (h).
(j)	When the schedule reports on an individual-contract basis, enter "Y" if the settlement included a non-cost consideration; if not, enter "N." When the schedule reports on an aggregated contract basis, enter "A."
(k)	Enter the cumulative quantity of gas for which the purchaser has an outstanding take-or-pay obligation on December 31. This amount is equal to the sum of (a) plus (c) less the sum of (e) and (g).
(l)	Enter the dollar amount associated with the quantity (k). This amount is equal to the sum of (b) plus (d) less the sum of (f) and (h).
(m)	Enter the cumulative quantity of gas for which a take-or-pay claim has actually been billed by the producer.
(n)	Enter the dollar amount associated with the quantity in (m).

SCHEDULE NO. 6—CONTRACT REFORMATIONS AND TERMINATIONS

Schedule reference	Instructions
Contract No	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
When reporting contracts on an individual basis, the following instructions apply:	
(a), (b)	Enter "Y" or "N."
(c) through (f)	Enter the take-or-pay obligation that existed before and after the contract reformation/termination. If the take-or-pay obligation is based on deliverability enter the obligation as a percent. If the take-or-pay obligation is based on reserves enter the number which completes the ratio 1:_____. For example, if the reserve ratio is 1:7300, enter 7300. Where termination applies, enter "T" in (e) and (f).
(g), (h)	Enter "Y" or "N" if there was a market out clause in the contract either before or after reformation/termination. A "market out clause" means a clause giving the purchaser the right to determine the contract at the purchaser's discretion. Where termination applies, enter "T" in (h).
(i)	Enter the amount of any cash paid by the purchaser to reform or terminate this contract in consideration of take-or-pay related to this or any other contract.
(j)	Enter "Y" or "N" as to whether any non-cash consideration was given by the purchaser to reform or terminate this contract in consideration of take-or-pay related to this or any other contract.
When reporting contracts on an aggregate basis, the following instructions apply:	
(a) through (h), (j)	Enter "A."
(i)	Enter the amount of any cash paid by the purchaser to reform or terminate contracts in consideration of take-or-pay.

SCHEDULE NO. 7—NARRATIVE-TEXT SCHEDULE

Schedule reference	Instructions
Contract No.	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
All	This Schedule provides the respondent the opportunity to clarify the data reported on Schedules 1 through 6. Note, however, that Schedule 7 cannot be used as a substitute for Schedules 1 through 6. Schedule 7 may be used by the respondent to, for example, clarify the data reported at Schedule 4, column (g), "Quantity Not Recoupable." The instructions for this item specify that any unrecoverable or unrecoupable take-or-pay quantity (MMMBtu's) should be reported on an aggregate basis. The respondent is encouraged to segregate and quantify the reason(s) why the gas is not recoverable or recoupable. The respondent is also encouraged to assign dollar values to any segregated quantities. Schedule 7 may also be used to clarify and quantify the respondent's future take-or-pay obligations, costs, etc. These and other types of clarification and quantification may be very useful in evaluating possible future actions by the Commission.

Schedule 1—Contract Summary Information (as of July 1, 1987, Except as Otherwise Specified)

1. Purchaser:
 - (a) Name _____
 - (b) Pipeline Code Number _____
2. PGA Identification: Contract Number _____
3. Seller(s) with gross working interest of at least 10 percent.
 - (a) Name _____
 - (b) Seller Code Number _____
 - (c) Gross Working Interest Percent _____
 - (d) Operator, yes/no _____
 - (e) Rate Schedule Number _____
 - (f) Seller and Purchaser Affiliated? yes/no _____
4. Production Area
 - (a) Field Name _____
 - (b) Field Code _____
 - (c) Area Name _____
 - (d) Area Code _____
 - (e) State Name _____
 - (f) State Code _____
5. Is any of the gas covered by this contract now or has it ever been since 1982:
 - (a) Purchaser-owned production? yes/no _____
 - (b) Affiliated company production? yes/no _____
 - (c) Other? yes/no _____
6. Does this contract now or did it at any time since 1982 include a take-or-pay provision? yes/no _____
7. What is the date of the initial contract? mm__dd__yy__
8. What is the date of the most recent renegotiation or rollover of this contract? mm__dd__yy__
9. What determines the expiration of this contract? (complete all that apply)
 - (a) Fixed expiration date? mm__dd__yy__
 - (b) Life of lease/life of reserves covered by this contract? yes/no _____
 - (c) Short-term agreement? (such as purchases on a year-to-year or more frequent basis; currently in force until one party gives notice; spot purchase contract; etc.) yes/no _____
10. Does this contract now or did it at any time since 1982 include a market-out clause? yes/no _____
11. In regard to this contract, is there now or has there been at any time since 1982:
 - (a) Take-or pay exposure? yes/no _____
 - (b) Prepayment for gas? yes/no _____
 - (c) Settlement of take-or-pay? yes/no _____
 - (i) Partial? yes/no _____
 - (ii) Complete? yes/no _____
 - (d) Release, with take-or-pay credit, of any of the gas covered by this contract? yes/no _____
 - (e) Reformation or termination of contract as consideration for settlement of take-or-pay related to this contract or any other contract? yes/no _____

Contract No. _____
 Purchaser Name _____
 Pipeline Code No. _____

SCHEDULE 2.—CONTRACT TAKE-OR-PAY PROVISIONS

[As of July 1, 1987]

NGPA section	Based on			If deliverability basis, percent of del. required		If reserve basis, take/res. ratio		Make up rights		Refund provision Y/N
	Res. Y/N	Del. Y/N	Other Y/N	Csgnhd.	Other	Csgnhd.	Other	Yrs.	After cont. term. Y/N	
"Whole Contract"										
102(d)										
Other 102										
103 (Price Controlled)										
Other 103										
104 Pre 1973										
104 1973-74 Biennium										
104 Post 1974										
104 Other										
106(a)										
107(c)(5)										
Other 107										
108 Jurisdictional										
108 Non-jurisdictional										
105/106(b)										
109										

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

SCHEDULE NO. 7—NARRATIVE-TEXT SCHEDULE

Schedule reference	Instructions
Contract No.....	Enter the respondent's own designation for the contract (same as Schedule 1, Item 2) when the schedule reports an individual contract. Enter "AGR" when the schedule reports the company totals aggregated together.
Purchaser Name, Pipeline Code No.	Enter the name and code as contained in the Buyer/Seller Code List, U.S. Department of Energy publication DOE/EIA-0176 (Same as Schedule 1, Item 1).
All.....	This Schedule provides the respondent the opportunity to clarify the data reported on Schedules 1 through 6. Note, however, that Schedule 7 cannot be used as a substitute for Schedules 1 through 6. Schedule 7 may be used by the respondent to, for example, clarify the data reported at Schedule 4, column (g), "Quantity Not Recoupable." The instructions for this item specify that any unrecoverable or unrecoupable take-or-pay quantity (MMMBtu's) should be reported on an aggregate basis. The respondent is encouraged to segregate and quantify the reason(s) why the gas is not recoverable or recoupable. The respondent is also encouraged to assign dollar values to any segregated quantities. Schedule 7 may also be used to clarify and quantify the respondent's future take-or-pay obligations, costs, etc. These and other types of clarification and quantification may be very useful in evaluating possible future actions by the Commission.

Schedule 1—Contract Summary Information (as of July 1, 1987, Except as Otherwise Specified)

1. Purchaser:
 - (a) Name _____
 - (b) Pipeline Code Number _____
2. PGA Identification: Contract Number _____
3. Seller(s) with gross working interest of at least 10 percent.
 - (a) Name _____
 - (b) Seller Code Number _____
 - (c) Gross Working Interest Percent _____
 - (d) Operator, yes/no _____
 - (e) Rate Schedule Number _____
 - (f) Seller and Purchaser Affiliated? yes/no _____
4. Production Area
 - (a) Field Name _____
 - (b) Field Code _____
 - (c) Area Name _____
 - (d) Area Code _____
 - (e) State Name _____
 - (f) State Code _____
5. Is any of the gas covered by this contract now or has it ever been since 1982: _____

- (a) Purchaser-owned production? yes/no _____
 - (b) Affiliated company production? yes/no _____
 - 6. Does this contract now or did it at any time since 1982 include a take-or-pay provision? yes/no _____
 - 7. What is the date of the initial contract? mm__ dd__ yy__
 - 8. What is the date of the most recent renegotiation or rollover of this contract? mm__ dd__ yy__
 - 9. What determines the expiration of this contract? (complete all that apply)
 - (a) Fixed expiration date? mm__ dd__ yy__
 - (b) Life of lease/life of reserves covered by this contract? yes/no _____
 - (c) Short-term agreement? (such as purchases on a year-to-year or more frequent basis; currently in force until one party gives notice: spot purchase contract; etc.) yes/no _____
 - (d) Other? yes/no _____
 - 10. Does this contract now or did it at any time since 1982 include a market-out clause? yes/no _____
 - 11. In regard to this contract, is there now or has there been at any time since 1982:
 - (a) Take-or pay exposure? yes/no _____
 - (b) Prepayment for gas? yes/no _____
 - (c) Settlement of take-or-pay? yes/no _____
 - (i) Partial? yes/no _____
 - (ii) Complete? yes/no _____
 - (d) Release, with take-or-pay credit, of any of the gas covered by this contract? yes/no _____
 - (e) Reformation or termination of contract as consideration for settlement of take-or-pay related to this contract or any other contract? yes/no _____
- Contract No. _____
 Purchaser Name _____
 Pipeline Code No. _____

SCHEDULE 2.—CONTRACT TAKE-OR-PAY PROVISIONS

[As of July 1, 1987]

NGPA section	Based on			If deliverability basis, percent of del. required		If reserve basis, take/res. ratio		Make up rights		Refund provision Y/N	
	Res. Y/N	Del. Y/N	Other Y/N	Csgnhd.	Other	Csgnhd.	Other	Yrs.	After cont. term. Y/N		
											(a)
"Whole Contract".....											
102(d).....											
Other 102.....											
103 (Price Controlled).....											
Other 103.....											
104 Pre 1973.....											
104 1973-74 Biennium.....											
104 Post 1974.....											
104 Other.....											
106(a).....											
107(c)(5).....											
Other 107.....											
108 Jurisdictional.....											
108 Non-jurisdictional.....											
105/106(b).....											
109.....											

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

Contract No. _____ Purchaser Name _____ Pipeline Code No. _____

SCHEDULE 6.—CONTRACT REFORMATIONS AND TERMINATIONS

[Year ____]

NGPA section	Contract status at end of year		Contract changes in effect at end of year						Considerations given by pipeline	
	Reformed Y/N	Terminated Y/N	Take-or-pay obligation				Market out provision		Cash (\$1,000s)	Non-cash Y/N
			Before		After		Before	After		
			Percent	T/R	Percent	T/R	Y/N	Y/N		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	
102(d)										
Other 102										
103 (Price Controlled)										
Other 103										
104 Pre 1973										
104 1973-74 Biennium										
104 Post 1974										
104 Other										
106(a)										
107(c)(5)										
Other 107										
108 Jurisdictional										
108 Non-jurisdictional										
105/106(b)										
109										
Totals										

Schedule 7

Schedule 7 is not printed in the Federal Register. It consists of the heading "NARRATIVE TEXT" with blank space provided below it for the text.

Exhibit A—Tape Layout for Take-or-Pay Data Request

The specific instructions provide the necessary directions for filling out the various schedules. The tape layout

merely provides a means for submitting that data on computer tape.

SCHEDULE 1

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch = 1
Purchaser Name.....	3-23	Character	
Purchaser Code.....	24-29	Character	
Contract No.....	30-35	Character	
Seller Name.....	36-56	Character	See Note 1 Below
Code Number.....	57-62	Character	
Gross Working Interest.....	63-64	Numeric	
Operator.....	65	Character	
Rate Schedule No.....	66-71	Character	
Affiliated.....	72	Character	
Field Name.....	73-93	Character	
Field Code.....	94-99	Character	
Area Name.....	100-120	Character	
Area Code.....	121-126	Character	
State Name.....	127-147	Character	
State Code.....	148-149	Numeric	
Purchaser Owned Coverage.....	150	Character	
Affiliated Coverage.....	152	Character	
Take-or-Pay Provision.....	153	Character	
Date of Initial Contract.....	154-159	Numeric	
Renegotiation/Rollover.....	160-165	Numeric	
Fixed Expiration Date.....	166-171	Numeric	
Life of Lease/Life.....	172	Character	
Short-term Agreement.....	173	Character	
Other.....	174	Character	
Market-Out.....	175	Character	
Take-or-Pay Expense.....	176	Character	
Prepayment.....	177	Character	
Partial Settlement.....	178	Character	
Complete Settlement.....	179	Character	
Release.....	180	Character	

SCHEDULE 1—Continued

Item	Character position	Data type	Comments
Reformation/Termination	181	Character	

Note 1: Since there can be up to 10 sellers reported per contract, repeat positions 1-72 for each seller.

SCHEDULE 2

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch=2
Purchaser Name.....	3-23	Character	
Purchaser Code.....	24-29	Character	See General Instructions. See also Note 2 below
Contract No.....	30-35	Character	
NGPA Code.....	36-37	Numeric	
Reserve	38	Character	
Delivery	39	Character	
Other.....	40	Character	
Casinghead Delivery	41-42	Numeric	
Other Delivery.....	43-44	Numeric	
Casinghead Reserve.....	45-49	Numeric	
Other Reserve.....	50-54	Numeric	
Rights Years.....	55-56	Numeric	
Terminations.....	57	Character	
Refund	58	Character	

Note 2: Repeat entire Schedule, positions 1-58, for each NGPA code used.

SCHEDULE 3

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch=3.
Purchaser Name.....	3-23	Character	
Purchaser Code.....	24-29	Character	See General Instructions.
Contract No.....	30-35	Character	
NGPA Code.....	36-37	Character	
Ceiling Price	38	Character	
NGPA Price	39	Character	
Fixed	40	Character	
Frequency.....	41	Character	
Market Sensitive	42	Character	
Fuel Parity.....	43	Character	
Most Favored Nation	44	Character	
Other	45	Character	
Buyer Protection	46	Character	
Price Floor	47	Character	
Unilateral Action	48	Character	
Market Out.....	49	Character	
Renegotiation.....	50	Character	
NGPA Ceiling Price	51	Character	
Other.....	52	Character	

Note 3: Repeat entire Schedule, positions 1-52, for each NGPA code used.

SCHEDULE 4

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch=4.
Purchaser Name.....	3-23	Character	
Purchaser Code.....	24-29	Character	

SCHEDULE 4—Continued

Item	Character position	Data type	Comments
Contract No.....	30-35	Character	See Note 3 below. See General Instructions.
NGPA Code.....	36-37	Numeric	
Deliverability.....	38-46	Numeric	
Take-or-Pay.....	47-55	Numeric	
Quantity Taken.....	56-64	Numeric	
Quantity Released.....	65-73	Numeric	
Quantity Not Taken.....	74-82	Numeric	
Quantity Recoupable.....	83-91	Numeric	
Quantity Not Recoupable.....	91-100	Numeric	

Note 4: If Schedule 4 is being used to report a Take-or-Pay history for an individual contract, use the contract number in positions 30-35. If Schedule 4 is being used to report total company data use the code "AGR" in positions 30-35 and report data in only positions 91-100.

Note 5: Repeat entire Schedule, positions 1-100, for each NGPA code used. This note does not apply to the company total report.

SCHEDULE 5

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch=5.
Purchaser Name.....	3-23	Character	
Purchaser Code.....	24-29	Character	See Note 4 below. See General Instructions.
Contract No.....	30-35	Character	
NGPA Code.....	36-37	Numeric	
Cumulative Volume.....	38-46	Numeric	
Beginning Obligations.....	47-55	Numeric	
Volume During Year.....	56-64	Numeric	
Obligation.....	65-73	Numeric	
Pre-Pay Volume.....	74-82	Numeric	
Pre-Pay Dollars.....	83-91	Numeric	
Settlement Volume.....	92-100	Numeric	
Settlement Dollars.....	101-109	Numeric	
Basis Dollars.....	110-118	Numeric	
Non-Cost.....	119	Character	
Ending Volume.....	120-128	Numeric	
Ending Dollars.....	129-137	Numeric	
Ending Billed Volume.....	138-146	Numeric	
Ending Billed Dollars.....	147-155	Numeric	

Note 6: If Schedule 5 is being used to report for an individual contract, use the contract number in positions 30-35. If Schedule 5 is being used to report total company data use the code "AGR" in positions 30-35 and report only total data in positions 38-155.

Note 7: Repeat entire Schedule, positions 1-155, for each NGPA code used. This note does not apply to the company total report.

SCHEDULE 6

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch=6.
Purchaser Name.....	3-23	Character	
Purchaser Code.....	24-29	Character	See Note 5 below. See General Instructions.
Contract No.....	30-35	Character	
NGPA Code.....	36-37	Numeric	
Reformed.....	38	Character	
Terminated.....	39	Character	
TOP Before Percent.....	40-41	Numeric	
TOP Before T/R.....	42-47	Numeric	
TOP After Percent.....	48-49	Character	Numeric for %. Numeric for T/R.
TOP After T/R.....	50-55	Character	
Market Before.....	56	Character	
Market After.....	57	Character	
Cash.....	58-66	Numeric	
Non-Cash.....	67	Character	

Note 8: If Schedule 6 is being used to report for an individual contract, use the contract number in positions 30-35. If Schedule 6 is being used to report total company data use the code "AGR" in positions 30-35, and report data in only positions 58-66.

Note 9: Repeat entire Schedule, positions 1-67, for each NGPA code used. This note does not apply to the company total report.

SCHEDULE 7

Item	Character position	Data type	Comments
Schedule No.....	1-2	Numeric	Sch=7.
Schedule Reference.....	3-4	Numeric	Schedule to which text applies.
Line Counter.....	5-6	Numeric	Enter consecutively as additional lines of text are added.
Text.....	7-78	Character	

Exhibit B—Paper Copy Specifications

The Commission requires all respondents to submit a paper copy that is attested to as valid. This paper copy also reflects the data submitted on tape and is considered a paper copy duplicate of the electronically stored data. This section specifies the rules for creating paper copies.

The following conventions will apply to paper copies from a mainframe:

1. A CHARACTER item for the print image is defined as not more than 120 alphanumeric characters and punctuation.
2. A TEXT item for the print image may exceed 120 alphanumeric characters including punctuation.
3. A line of printout will be 132 or fewer columns.
4. Each NUMERIC item in a record, except the last item, will be printed with a trailing comma. (ASCII-44 decimal)
5. Each CHARACTER item in a record, except the last item, will be printed with a trailing bar. (ASCII-124 decimal)
6. If the sum of the lengths of the items to be printed that are not text, and including commas and bars, exceed 132 columns, then the record continuation can be printed on a second and subsequent lines but do not split a field when continuing. The second and any subsequent lines must be indented 6 spaces from the left hand margin (except for TEXT items as described below). The last whole item on a given line, other than the last item of the record, must be printed with the appropriate trailing comma or bar. The end of the record should be marked by the end of a line in the printout.
7. If the last item available for the line is TEXT, then alternately print the non-TEXT items on the first line, the line of

TEXT on the second line without indenting, the non-TEXT items on the third line and the line of TEXT on the fourth and so on until the entire record is printed.

8. Use commas to denote blank fields.

9. Between the last record of one record type and the first record of another type, there should be three blank lines.

10. The first record of each schedule should be printed on a new page.

11. The data collection layout, definitions, instructions and footnotes define the terms and printing order.

[FR Doc. 87-20313 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

18 CFR Parts 2 and 284

[Docket No. RM87-34-000; Order No. 500]

Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol; Information Collection Requirements Approved by OMB

August 20, 1987.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of data request; OMB Control Number.

SUMMARY: On August 7, 1987, the Federal Energy Regulatory Commission issued an interim rule (Order No. 500) in Docket No. RM87-34-000, 52 FR 30334 (August 14, 1987), readopting the open access transportation regulations, originally promulgated in Order No. 436, with modifications intended to respond to the concerns of the United States Court of Appeals for the District of Columbia Circuit in *Associated Gas Distributors v. FERC* (No. 85-1811, *et al.*). As a result of the interim rule the Commission is sending interstate

natural gas pipeline companies a data request (FERC-593) (published elsewhere in this issue of the **Federal Register**) to determine the extent and nature of pipelines' take-or-pay obligations with respect to various NGPA pricing categories for natural gas. This data request was submitted to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act. OMB has provided an OMB control number.

EFFECTIVE DATE: The OMB approval of the information requirements is effective from August 20, 1987 until November 7, 1987.

FOR FURTHER INFORMATION CONTACT: Richard O. Howe, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capital Street, NE., Washington, DC 20426, Phone: (202) 357-8308.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act, 44 U.S.C. 3501-3520 (1982), and the Office of Management and Budget's (OMB) regulations, 5 CFR Part 1320 (1987) require that OMB approve information collection requirements imposed by agency rule. OMB has temporarily approved the information collection requirements of the Commission's data request contained in FERC-593 for 90 days and issued Control Number 1902-0149. The information requirements are discussed in the preamble to the interim rule but are not codified in the regulatory text. The information collected will be used in preparation of a final rule. This OMB Control Number is effective until November 7, 1987.

Kenneth F. Plumb,
Secretary.

[FR Doc. 87-19634 Filed 9-3-87; 8:45 am]

BILLING CODE 6717-01-M

federal register

Friday
September 4, 1987

Part VI

Department of Health and Human Services

Food and Drug Administration

**21 CFR Part 58
Good Laboratory Practice Regulations;
Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 58

[Docket No. 83N-0142]

Good Laboratory Practice Regulations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends the regulations that specify good laboratory practice (GLP) for nonclinical laboratory studies. The amendments clarify, delete, or amend several provisions of the GLP regulations to reduce the regulatory burden on testing facilities. The changes will also achieve a substantial reduction in the paperwork burden imposed upon the regulated industries by the current regulations. Significant changes are made in the provisions respecting quality assurance, protocol preparation, test and control article characterization, and retention of specimens and samples based on FDA's experience in implementing the regulations. The agency has determined that the changes will not compromise the objective of the GLP regulations, which is to assure the quality and integrity of the safety data submitted in support of the approval of regulated products.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Paul D. Lepore, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2390.

SUPPLEMENTARY INFORMATION:

Background

In the *Federal Register* of October 29, 1984 (49 FR 43530), FDA published a proposal to amend the agency's regulations in 21 CFR Part 58, which prescribe good laboratory practice for conducting nonclinical laboratory studies (the GLP regulations). The proposal was the result of an evaluation of the GLP regulations and of the data obtained by the agency's inspection program to assess laboratory compliance with the regulations. The evaluation led the agency to conclude that some of the provisions of the regulations could be revised to permit nonclinical testing laboratories greater flexibility in conducting nonclinical laboratory studies without compromising public protection. FDA invited comments on all aspects of the proposal and provided 60 days for interested persons to submit comments,

views, data, and information on the need to revise any other provisions of Part 58.

Comments

FDA received 33 comments: 19 from manufacturers of articles regulated by FDA, 4 from associations, 8 from foreign or domestic testing or consulting laboratories, and 2 from individuals within FDA. The majority of these comments endorsed the proposed changes. Many of the comments suggested additional revisions to the GLP regulations or modifications to the proposed changes. A summary of the comments received by FDA during the comment period and the agency's response to them follows.

General

1. One comment urged FDA to initiate training procedures for its field personnel so that the regulated community would obtain maximum benefit from the revisions to the GLP regulations.

FDA agrees that agency field personnel who conduct inspections of nonclinical testing laboratories need to understand the specific requirements of the GLP regulations to follow appropriate inspectional practices and procedures. FDA has, to date, conducted 17 training courses at its National Center for Toxicological Research in Jefferson, AR, to provide training in good laboratory practice and the associated laboratory inspection techniques. FDA intends to continue to provide such training for its personnel.

2. Eight comments urged FDA to encourage the Environmental Protection Agency (EPA) to adopt similar revisions to its good laboratory practice standards. The comments noted that unless EPA amends its good laboratory practice standards to conform them to FDA's GLP regulations, nonclinical laboratories will still be required to comply with EPA's more stringent requirements. Therefore, regardless of any changes that FDA makes in its regulations, laboratories will not benefit from the revisions unless the EPA regulations are similarly revised.

FDA recognizes that certain nonclinical laboratories that are subject to FDA's regulations are also subject to the good laboratory practice standards established by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2600 et seq.). When this final rule becomes effective, some of the provisions of the GLP regulations will differ from the good laboratory practice standards established by EPA. FDA has consulted

with EPA officials respecting the changes to FDA's regulations effected by this final rule and will cooperate fully with EPA when that agency propose to revise its regulations.

Scope

3. Except for editorial changes to § 58.1, FDA did not propose to change the scope of Part 58. One comment, however, urged the agency to revise § 58.1 further to make clear that batch release safety tests performed on specific batches of biological products intended for use in clinical trials after tests to establish the basic safety profile have been conducted are subject to the GLP regulations.

FDA declines to change final § 58.1 on the ground that the studies described by the comment are within the current scope of Part 58. The animal tests performed with an investigational biological product prior to licensing, including the batch release safety tests, are intended to establish the safety of the product. Accordingly, any such test would constitute a nonclinical laboratory study as defined in § 58.3(d). Because such test would also be intended to support a marketing application for a product regulated by FDA, it would be subject to the GLP regulations.

Definitions

4. Four comments endorsed FDA's proposal to change the definition of "control article" in § 58.3(c) to exclude from the definition feed and water administered to control groups of a test system. One comment, however, expressed concern that, by relaxing essential standards, the proposed change would compromise the quality of the animal test.

FDA does not agree that excluding feed and water from the definition of "control article" will compromise test quality. The regulations will continue to contain provisions adequate to control the use of feed and water in a nonclinical laboratory study. For example, § 58.31(e) requires management to assure that materials are available as scheduled, § 58.45 provides for proper feed storage, § 58.81(b)(2) requires the preparation of standard operating procedures for animal care (e.g., nutrition), § 58.90(g) requires periodic analysis of feed and water for interfering contaminants, and final § 58.120(a)(7) (formerly § 58.120(a)(9)) requires the protocol to contain a description or an identification of the diet, including specifications for acceptable levels of contaminants. Other sections of the regulations also

apply to feed or water that is used as a carrier for the test or control article. For example, § 58.31(d) requires management to assure that test and control article mixtures have been appropriately tested, § 58.47 requires that a testing facility include storage areas that are adequate to preserve the identity, strength, purity, and stability of such mixtures, and § 58.113 requires the laboratory to conduct appropriate analyses for uniformity of the mixture, as well as concentration and stability of the test article in the mixture. As discussed at length in the preamble to the proposal (49 FR 43531), the amendment to § 58.3(c) will mean that the feed and water provided to the control groups of a test system will not be subject to certain provisions of the regulations, e.g., those requiring control articles to be characterized and tested for stability (§ 58.105), retained as reserve samples (§ 58.195), or accountable with respect to use (§ 58.107). As discussed above, however, the regulations will continue to require the provision of adequate supplies of feed and water, a description of the feed, proper storage, and use accountability procedures as directed by the protocol, and standard operating procedures. Further, only feed and water shown to be free from unacceptable contamination may be used in a study.

For the reasons above, FDA concludes that the change to § 58.3(c) will not compromise the quality of the animal test and that the term "control article" should be reserved for the discrete substances/articles and vehicles other than feed and water administered to groups of the test system to provide a basis of comparison with the test article.

5. Four comments on proposed § 58.3(d) endorsed FDA's proposal to allow laboratories to conduct several experiments using the same test article under a single, comprehensive protocol. One comment, however, expressed concern that by amending the definition of "nonclinical laboratory study," FDA may inadvertently encourage laboratories to establish protocols that (1) are too brief to assure the quality and integrity of safety data developed through a study conducted under the protocol, or (2) do not describe study procedures in sufficient detail for such assurance, because lengthy "umbrella protocols" may be difficult to administer and track during the amendment process.

Under the revised definition in § 58.3(d), a single "umbrella" protocol may be used for concurrent testing of more than one test article using a single common procedure, e.g., mutagenicity

testing, or for a battery of studies of one test article conducted in several test systems. Section 58.120 requires that each study have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study, and § 58.33 requires the study director to assure that the protocol is approved and followed.

FDA notes that the changed definition of "nonclinical laboratory study" does not require any laboratory to establish "umbrella" protocols—it only allows it as an option. The agency recognizes that a longer, more complex protocol might be more difficult to manage than a simpler one; however, using an "umbrella" protocol should be more efficient than using several closely related protocols. The quality or accuracy of test data and procedures should not be compromised, while the paperwork burden should be reduced. In any event, the laboratory remains responsible for assuring that the validity of any study that it conducts is not adversely affected due to an inadequate protocol.

6. One comment urged FDA to revise further the definition of nonclinical laboratory study to define the terms "study initiation" and "study termination."

FDA recognizes that differing words and phrases are used within the GLP regulations to denote dates respecting significant events that occur during a laboratory study. For this reason, the agency agrees that it may be useful to add to the regulations definitions of the terms "study initiation" and "study completion."

FDA advises that the study initiation date represents the date on which the study director has completed plans in preparation for the technical conduct of a study (see § 58.33) and on which, under § 58.31(e), management is required to make certain that personnel, resources, facilities, equipment, materials, and methodologies for the study are available as scheduled. On the study initiation date, the study is entered on the master schedule sheet (see § 58.35(b)(1)). After this date, any protocol changes are to be made only in accordance with the procedure described in § 58.120(b). Accordingly, FDA is adding new § 58.3(o) to define "study initiation" to mean the date the protocol is signed by the study director.

The study completion date is the date on which the study director signs the final report (see final § 58.185(b)). On the study completion date, the study director is required to make certain that raw data, documentation, protocols, specimens, and final reports are

transferred to the archives (see § 58.33(f)), and under § 58.35, the quality assurance unit may retire the study from the master schedule sheet. This date also specifies the beginning of the record retention period under § 58.195(b). After the study completion date, final reports may be amended only in accordance with the procedure described in § 58.185(c). Accordingly, FDA is adding new § 58.3(p) to define "study completion" to mean the date the final report is signed by the study director. As a necessary conforming amendment, FDA is also amending § 58.185(b) to provide that the final report shall contain the dated signature of the study director.

FDA advises that the phrase "close of the study" as used in § 58.33(f) refers to the study completion date. Also, the terms "terminate" and "discontinue" as used in § 58.195(b)(3) are used in their ordinary senses to mean stop, cease, break off, or give up, denoting that a study has been ended before the planned study completion date. For these reasons, FDA believes that these terms do not need any further definition to make clear their meanings.

7a. Three comments urged FDA to expand the definition of "raw data" under § 58.3(k) to provide that the computer record of "hand-recorded data entered into the computer verbatim and verified" could be substituted for the original source as raw data.

FDA does not agree that the computer record of hand-recorded data may be considered as raw data. Individuals who enter data from a laboratory study into the computer commonly do not have any knowledge of the conditions under which the data were collected and may not understand the data originator's notations that regularly are included on the hand-recorded data sheets. The probability of error in data entry is greatly increased under these circumstances.

7b. One comment urged the agency to revise § 58.3(k) to make clear that the term "raw data" as it pertains to the findings of the histopathological examinations refers only to the signed and dated final report of the pathologist.

FDA does not agree that it needs to amend the definition of raw data relative to the findings of histopathological examinations. In pertinent part, § 58.3(k) defines raw data as laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities and are necessary for the reconstruction and evaluation of the final report. Although the notes taken by a pathologist during

histopathological examination of slides are indeed the result of original observations, these notes are not necessary for the reconstruction and evaluation of the final report. The final report is evaluated by an analysis of the pathology syndrome as described in the pathologist's report, which is required under § 58.185(a)(12). Further, because § 58.190(a) requires histopathological blocks, tissues, and slides to be retained as specimens, the final report can be reconstructed by verification of the pathology findings by, e.g., a second pathologist or by a team of pathologists.

The pathologist's interim notes, therefore, which are subject to frequent changes as the pathologist refines the diagnosis, are not raw data because they do not contribute to study reconstruction. Accordingly, only the signed and dated final report of the pathologist comprises raw data respecting the histopathological evaluation of tissue specimens.

Testing Facility Management

8. One comment objected to FDA's proposal to delete the provision in § 58.31(b) that requires testing facility management to document as "raw data" the replacement of a study director. The comment argued that it could be difficult to retrieve such documentation if data were transferred to another location after completion of a study.

FDA proposed to delete the requirement in § 58.31(b) to document study director replacement as "raw data" in the agency's belief that other provisions of the GLP regulations adequately require documentation of this event. The agency continues to believe that the requirement in § 58.31(b) is redundant to such other provisions and is not necessary to assure the quality and integrity of the safety data developed through a study conducted by a laboratory. For example, § 58.35(b)(1) provides that the master schedule sheet shall contain the name of the study director. Thus, replacement of the study director would necessitate an updating of the master schedule sheet. The master schedule sheet itself is "raw data" because it is a record that is the result of laboratory activities and is necessary for the reconstruction of the study. Also, § 58.120(b) requires that any change in an approved protocol and the reason or reasons for the change are to be documented. Because § 58.120(a)(11) of the final rule (previously § 58.120(a)(15)) requires that the protocol contain the dated signature of the study director, replacement of the study director would constitute such a change. Other provisions of the regulations require the quality assurance

unit to retain the master schedule sheet and copies of protocols as an easily accessible system of records for a specified period after completion of the study (§ 58.195(d)). Therefore, it should not be difficult to identify the term of each study director even if records are transferred elsewhere after study completion.

Study Director

9. Several comments objected to § 58.33 in its entirety on the grounds that (1) the regulation does not clearly define the responsibility of the study director and (2) the wording of the regulation implies that the study director must be technically competent in all areas of a study. One comment argued that the study director should be responsible only for "coordinating" the technical conduct, interpretation, analysis, documentation, and reporting of results.

FDA discussed at length in the preamble to the GLP final rule the intent of § 58.33 and the requirements applicable to the individual who is designated the study director for any study (43 FR 59986, 59995; December 22, 1978). As discussed in that preamble, the study director represents the single, fixed point of responsibility for overall conduct of each study. Although "coordination" of the pieces of a study logically is part of the study director's responsibilities, to limit his or her responsibilities to mere "coordination" would compromise public protection if another person were not such designated fixed point and would add an unnecessary burden if FDA were to require a laboratory to employ an additional person to provide such a point. The study director is charged with the technical conduct of a study, including interpretation, analysis, documentation, and reporting of results. FDA does not intend, however, that the individual is to be technically competent in all areas of a study. FDA's inspectional experiences have demonstrated that if responsibility for proper study conduct is not assigned to one person, a potential exists for the issuance of conflicting instructions and improper protocol implementation.

FDA concludes that the comments did not provide any new data or information to negate the agency's original determinations and that it should retain § 58.33 as it was established in the December 22, 1978, final rule.

10. One comment objected to FDA's proposal to delete the phrase "and verified" from § 58.33(b), which currently requires that the study director assure that all experimental data are "verified" as well as accurately recorded. The comment argued that

removing the study director's obligation to assure that the data have been verified would dilute the responsibility of the study director for proper conduct of the study.

FDA has carefully reevaluated its proposal to remove the phrase "and verified" from § 58.33(b). FDA proposed to delete the phrase from the regulation in response to arguments from management of testing facilities that they misinterpreted the provision, apparently believing that it required the study director personally to witness each data observation. FDA did not intend the provision to so require. Rather, the agency regards the study director as responsible for assuring that all experimental data are verified.

Ordinarily the verification required by § 58.33(b) is obtained by the individual collecting the data, using data verification procedures described in the protocol or in the specific standard operating procedure, and by the individual's supervisor as part of the supervisory quality control procedures. "Verified" is used to describe the study director's responsibility to assure the accurate recording of data. Verification in this sense does not require the study director to observe every data collection event but does require the study director to make certain that the study conduct procedures designated in the protocol for a study and the standard operating procedures established for a study are followed. For all these reasons, FDA has decided to retain the phrase "and verified" to confirm the need for data verification in nonclinical laboratory studies.

11. Two comments urged that the study director's responsibility for assuring placement in the archives of the study records specified under § 58.33(f) be transferred to testing facility management under § 58.31. The comments argued that raw data and documentation are under the immediate control of facility management rather than the study director.

The change suggested by the comments would conflict with the study director's responsibility identified in § 58.33 of representing the single point of study control (see paragraph 9 of this preamble). The archived materials of each study, including raw data and documentation, constitute lasting proof of study validity. The transfer of such materials to the archives is a critical step in study control that assures that the archived materials are complete and adequate for study reconstruction. Indeed, these revised regulations further emphasize the study director's control function by defining the study

completion date as the date the final report is signed and dated by the study director; after this date, the study director assures that all required materials are transferred to the archives. Consequently, FDA declines to accept the change proposed by the comments.

Quality Assurance Unit

12. FDA received eight comments regarding § 58.35(a), which sets forth the composition and function of the Quality Assurance Unit (QAU). One comment endorsed FDA's proposal to substitute "which" for the current phrase, "composed of one or more individuals who," to make clear the personnel who can perform quality assurance duties. The comment suggested, however, that the agency use the term "function" or "activity" in § 58.35(a) in place of the current term "unit" to make it clear that quality assurance monitoring need not be performed by individuals of a permanently staffed unit. Four comments disagreed strongly with the proposed change to § 58.35(a), arguing that the change inappropriately implies that assurance of a well-conducted study does not require special training or experience. The comments also asserted that verifiable data are produced as a result of the current requirement for an independent, fixed and permanently staffed quality assurance unit. Other comments argued that individuals should not monitor studies similar to their own work. Some comments requested further clarification of the required composition of the QAU.

FDA does not believe that identification of the quality assurance unit as a "function" or "activity" would serve to clarify the composition or function of the QAU. FDA never has intended that the QAU necessarily has to be a separate entity or a permanently staffed "unit" (see 43 FR 59996). "Quality assurance unit" has become an accepted term to describe those individuals responsible for quality assurance as described in § 58.35. FDA also does not agree that the proposed revision to § 58.35(a) implies that assurance of a well-conducted study does not require special training or experience on the part of individuals monitoring the conduct and reporting of a nonclinical laboratory study. FDA continues to believe that well-qualified and trained personnel are essential to quality assurance under the GLP regulations and that one of management's most important responsibilities in maintaining effective quality assurance is to provide an adequate number of such personnel (§ 58.31 (c) and (e)).

FDA concludes from the comments that the requirements set forth in § 58.35(a) have been misinterpreted in some instances to mean that the regulations require that the QAU be composed of individuals whose sole duties are in quality assurance. In fact, the agency intends only that quality assurance activities be separated from study direction and conduct activities; that is, a trained and qualified person who works on one study can perform quality assurance duties on any study in which he or she is not involved. FDA's reason for requiring separation of quality assurance functions from study conduct functions is fundamental—to assure that quality assurance personnel can act candidly, without bias or a real or perceived conflict of interest. In effecting the separation required by the GLP regulations, FDA was aware that many small laboratories could not afford the operation of a permanently staffed QAU. For this reason, the agency concluded that the separation of functions on a study-by-study basis as permitted in the existing and revised regulations would provide effective quality assurance. The agency's intent in defining the composition and function of the QAU was discussed at length in the preamble to the current GLP regulations (see 43 FR 59996). FDA believes that the change now being made more clearly reflects the agency's original intent.

13. One comment recommended that FDA delete the word "sheet" from the term "master schedule sheet" in § 58.35(b)(1) on the ground that there are methods for maintaining a master schedule other than use of an actual "sheet."

FDA acknowledges that current technology allows for various methods for maintaining a master schedule, ranging from sophisticated computerized procedures to procedures whereby such information is contained in written records. Regardless of the method utilized, however, the master schedule information is "raw data" within the meaning of the GLP regulations and copies of the master schedule are required to be retained in the study archives in accordance with § 58.195(b). The agency is, therefore, retaining the term "master schedule sheet" to emphasize that the master schedule constitutes raw data subject to agency inspection and that the records must be retained.

14. One comment suggested that FDA delete the current provision in § 58.35(b)(1), which requires a laboratory to include the name of the sponsor of each study on the master schedule sheet for all studies conducted

at the facility. The comment urged the agency to allow sponsor identification by code.

FDA agrees that including the sponsors' name on the master schedule sheet is not essential either for the conduct of management's functions listed in § 58.31 or for the conduct of proper quality assurance under § 58.35. Sponsor identification by code is an adequate procedure, provided that the name of any sponsor is made available to FDA upon request. Accordingly, FDA is amending § 58.35(b)(1) to read " * * * identity of the sponsor * * *."

15. One comment suggested that FDA further revise § 58.35(b)(1) to allow the master schedule sheet to be indexed by study number rather than test article on the ground that multiple studies may be performed on each test article.

FDA recognizes that a nonclinical laboratory may have in progress several studies on each test article that is listed on the master schedule sheet. The agency concludes, however, that indexing by study number alone and not by test article would be inappropriate. The master schedule sheet is the mechanism through which the QAU can assure management that the facilities are adequate and that there are sufficient numbers of qualified personnel available to accomplish the scheduled work (see 43 FR 59997). In addition, § 58.31(e) requires management to assure that study materials (e.g., test articles) are available as scheduled. The use of study numbers rather than test articles as index terms would, therefore, frustrate a major purpose of the master schedule sheet and impede the conduct of an important management function.

16. Three comments endorsed FDA's proposal to delete the current requirement under § 58.35(b)(1) that the status of the final report be a distinct entry on the master schedule sheet. One comment, however, objected to the proposal on the basis that frequently there are delays in completing the final report, and the study status often is different from the expected date of completion of the report.

FDA believes that the comment that objected to the proposal misconstrued the purpose of revising § 58.35(b)(1). Section 58.35(b)(1) currently requires that the master schedule sheet contain separate headings for the "current status" of the study and for the "status of the final report" of the study. FDA considers the preparation of the final report to be a study event, current status of which should be reflected on the master schedule sheet. Preparation of the final report is similar to other study

events (e.g., test article-mixture preparation, test system dosing, in life observations) that are listed under "current status." Under this revision to § 58.35(b)(1), the master schedule sheet would contain the same information respecting the final report as is required under the current GLP regulations, but the information would be included only under the "current status" heading. The agency advises that "expected date of completion of a final report" is not a "status" entry. Such information has not been required in the past nor is this information being required now.

17. FDA proposed to revise § 58.35(b)(3) to provide specifically that the QAU need only inspect "each nonclinical laboratory study" on a schedule adequate to assure the integrity of the study. Four comments recommended that the agency further revise the regulation to substitute the word "studies" for the phrase "each nonclinical laboratory study" alleging that inspection of multiple short duration studies can result in expenditure of significant time and effort with little derived benefit. Two comments argued that inspection of short duration studies conducted repeatedly at the same facility by the same personnel is not necessary and suggested that, in lieu of requiring inspection of each study, standard operating procedures be developed to determine the inspection frequency of various types of studies. These comments also recommended that such inspections be used to demonstrate compliance of other similar studies conducted in the same time frame.

FDA does not agree with the comments. The quality of each nonclinical laboratory study submitted to the agency in support of an application for a research or marketing permit for a product regulated by FDA is critical to a determination of the safety of the product. The principle of quality assurance advanced in the GLP regulations is to inspect studies to identify and correct problems in a timely fashion. FDA is convinced that such problems can be detected only through a program of vigorous inspection of each study. This does not mean, however, that every phase of every study needs to be inspected by the QAU (see paragraph 18 of this preamble).

18. Two comments disagreed with FDA's proposal to modify the current requirement in § 58.35(b)(3) that the QAU inspect each phase of a study at specified intervals. The comments argued that elimination of specified quality assurance inspection intervals may result in decreased compliance by

cost-cutting laboratories. Another comment urged FDA to identify the critical phases of a nonclinical laboratory study to be inspected by the QAU.

Section 58.35(b)(3) currently provides that the QAU is to inspect at periodic intervals each phase of a nonclinical laboratory study. For studies lasting more than 6 months, the inspections are to be conducted every 3 months. For studies lasting less than 6 months, the inspections are to be conducted at intervals adequate to assure the integrity of the study (including each phase at least once). The term "each phase" was intended to emphasize the need for repeated surveillance so that the QAU observes at least once during the course of the study each critical operation. The term "periodic" was included in the regulation to indicate the need for more than one inspection of certain repetitive, continuing operations. In light of current information, however, FDA does not believe that such a rigid schedule is essential to assure study quality. The agency has learned through its inspection program that the quality of toxicology testing is much higher than that envisioned in 1976 when FDA proposed to establish the GLP regulations (see 41 FR 51206, 51207-51208; November 19, 1976).

Contemporary concepts of quality assurance emphasize the effectiveness of thorough, in-depth inspections of study processes (i.e., all operations required to accomplish a study phase) in place of quick, spot checks of individual operations with a study. Thorough examination of personnel, facilities, equipment, standard operating procedures, data collection procedures, raw data books, and other features associated with a study phase can achieve more effective quality assurance than does a more superficial observation of the conduct of the same study phase in a series of studies.

The agency has concluded that the QAU's inspection schedule should take into account the need for inspection of each study on a schedule adequate to assure the integrity of the study being monitored. The change in § 58.35(b)(3) permits the QAU to exercise reasonable flexibility and judgment so that inspections can be scheduled to best achieve the goal of assuring that studies are properly conducted. The agency advises, however, that each study, no matter how short, needs to be inspected in-process at least once. Further, across a series of studies all phases should be inspected in order to assure the integrity of the studies. For these reasons, FDA does not believe that the regulation as

revised will result in decreased compliance with the GLP regulations or that the term "critical phase" needs to be defined.

19. Eight comments addressed FDA's proposal to delete § 58.35(b)(4), which currently requires the QAU to submit periodic written status reports to management and to the study director. One of the comments supported the proposal on the basis that the provisions of § 58.35(b)(3), which require reports to management on problems likely to affect study integrity, are adequate to assure study quality. Several comments questioned whether deleting § 58.35(b)(4) would provide any practical benefit to testing facilities, noting that management is likely to continue to expect periodic reports. One comment noted that elimination of the requirement for status reports could allow management to disregard quality assurance problems if management is only marginally supportive of good laboratory practice and quality assurance. Three comments argued that, by deleting the provision, FDA would inappropriately place on the QAU rather than on the study director the obligation of determining what constitutes a problem likely to affect the integrity of a study. One comment argued that, because management is required to be involved in corrective actions under the provisions of §§ 58.31(g) and 58.35(b)(3), management must be kept informed respecting the status and the progress of any study inspected by the QAU. Another comment suggested that FDA delete the requirement that status reports be provided to the study director but retain the requirement that management receive such reports.

After careful consideration of these comments, FDA has concluded that § 58.35(b)(4) should be retained in its current form. The agency proposed to delete the paragraph based on its tentative conclusion that routine reports of unremarkable findings by the QAU are not essential to study quality. The comments, however, are persuasive in that such reports are necessary to demonstrate to management that the QAU is functioning properly. It is also necessary that the study director continue to receive such reports because that individual is responsible for all aspects of any study being conducted by a facility, including GLP compliance.

20. One comment suggested that, in lieu of deleting the entire paragraph, § 58.35(b)(4) be modified by removing the requirement for status reports on each study, thereby reducing paperwork.

In accord with the conclusions stated in paragraph 19 of this preamble, FDA

believes that it is inappropriate to eliminate the requirement for status reports for each study. Without status reports on each study, there would not be adequate assurances concerning the quality of the ongoing studies.

21. One comment urged FDA to revise current § 58.35(b)(5) to hold the QAU responsible only to (1) determine that known deviations from approved protocols or standard operating procedures were not made without proper documentation, and (2) require authorization for anticipated deviations. The comment argued that the current wording of the regulation implies that the QAU shall have prior knowledge of any deviations and shall approve such deviations, which is not the case in most instances.

FDA would not consider a laboratory to have violated § 58.35(b)(5) if a deviation was not authorized in advance because it was unanticipated. For example, as recognized in the preamble to the final rule (43 FR 59998), a fire in the facility would necessitate immediate action. Also, as discussed at length at 43 FR 59998, FDA does not intend that the QAU is responsible for authorizing any deviations from the protocol or standard operating procedures, rather it is responsible for detecting any such deviations by its inspection and audit procedures. The revision suggested by the comment would remove the accountability of the QAU for detecting deviations and would undermine the requirements for quality assurance.

22. FDA proposed to revise current § 58.35(b)(7) to provide that the statement which the QAU prepares to accompany the final report would be required to identify the phases of the study inspected and the number of inspections conducted. Eleven comments objected to the proposed change to the regulation, which currently requires only that the statement by the QAU specify the dates that inspections of the study were made and the dates that findings were reported to management and to the study director. Most of the comments were concerned with the additional reporting burden imposed by the proposed revision. Some of the comments argued that the information sought by FDA through the proposed revision in § 58.35(b)(7) is currently required under the provisions of § 58.35(b)(3) and (c). These comments pointed out that requiring additional documentation would be duplicative and contrary to the stated purposes of the proposed revisions to the GLP regulations.

FDA has carefully reevaluated its proposal to require that the QAU

statement identify the phases of a study inspected and the number of inspections conducted. The agency is persuaded that the proposal would have provided information redundant to that which is available under other provisions of the GLP regulations. Accordingly, FDA has decided not to change § 58.35(b)(7) and is retaining this provision in its current form. Proposed § 58.35(b)(6) (as § 58.35(b)(7) would have been renumbered) is not being adopted.

Animal Care Facilities

23. One comment objected to the proposed modification to § 58.43(c), which would delete the current requirement that all laboratory facilities include separate areas for the diagnosis, treatment, and control of laboratory animal diseases. The comment noted that animal health is a major problem in toxicology testing. For this reason, the comment argued that any relaxation of the current requirements in the GLP regulations for animal care is ill-advised and contradictory to FDA's responsibility for the welfare of animals.

As discussed in the preamble to the proposed amendments to the GLP regulations (49 FR 43532), a laboratory may elect to dispose of diseased animals, thereby obviating the need for dedicated areas for such animals. FDA believes that it is not cost-effective to require separate areas in every case and has concluded that the decision concerning appropriate separation of animals should be made by the study director in consultation with other scientific personnel. The agency does not believe that providing for dedicated laboratory areas as appropriate compromises FDA's continuing commitment to animal welfare, which is specifically dealt with in § 58.90. Indeed, FDA believes that the GLP regulations foster quality animal testing under defined conditions so that fewer animals are required to establish product safety.

Animal Supply Facilities

24. FDA proposed to revise § 58.45 to permit laboratories to store perishable supplies or feed by methods most appropriate to the characteristics of the materials. One comment urged FDA to amend § 58.45 further to permit storage of animal feed in rooms housing small animals or small groups of animals that are isolated from other studies.

FDA declines to amend § 58.45 as recommended by the comment. In developing the current GLP regulations, the agency carefully considered whether animal feed or bedding might be stored within any test areas. FDA concluded at that time that storage areas needed for feed and bedding should be separate

from the areas housing the test system to preclude mixups and contamination of test article-carrier mixtures and inadvertent exposure of the test system to potentially interfering contaminants. FDA continues to believe that separate storage areas for feed and animal bedding should be required and the comment did not provide any data to counter this belief. FDA advises, however, that § 58.45 does not preclude holding of limited quantities of test or control article-feed mixtures for short periods of time in properly constructed and labeled containers in the animal rooms.

25. One comment objected to the proposed changes to § 58.47, arguing that it believed the current requirements respecting facilities for handling test and control articles have resulted in fewer mixups.

Based on the comment, FDA has reconsidered the proposed revision of § 58.47. The agency agrees with the comment, in principle. Indeed, the agency intended the revision to be only editorial to simplify and to make clear that laboratories shall provide separate areas for receipt, mixing, and storage of test and control articles and their mixtures as necessary to prevent contamination or mixups. Inadvertently, however, the proposed revision would have deleted an essential requirement of good laboratory practice, i.e., the need to provide storage areas for test and control article mixtures adequate to preserve the identity, strength, purity, and stability of the mixtures. For this reason, the agency has concluded that the regulation is appropriate as currently stated and existing § 58.47 is retained.

Maintenance and Calibration of Equipment

26. FDA proposed to revise § 58.63(b) to provide that written standard operating procedures respecting maintenance and calibration of equipment would allow laboratories to discard faulty equipment as an alternative to the current provisions of § 58.63(b), which provide only for the repair of equipment that fails or malfunctions. Under FDA's proposal, a testing facility would need to specify remedial action in the event of equipment failure or malfunction only when remedial action is "appropriate" to the particular piece of equipment. Three comments recommended that FDA amend § 58.63(a) to require testing, calibration, and/or standardization of equipment in accord with written standard operating procedures. The comments argued that by changing

current § 58.63(a) in this fashion, FDA might delete § 58.63(b) in its entirety without substantively affecting the requirements of the GLP regulations applicable to laboratory equipment.

FDA advises that § 58.63(b) concerns not only setting forth in standard operating procedures the details of routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, but it also concerns describing remedial actions to be taken when appropriate if the equipment fails or malfunctions. In promulgating existing § 58.63(b), FDA concluded that the specific features set forth in the regulations need to be included in equipment standard operating procedures because of the crucial role that properly used equipment plays in study conduct; a role which pervades every phase of a study and is vital to study quality and final report integrity. The comments did not provide any data that negate FDA's original determination. The agency continues to believe that specification of these features provides useful guidance to persons subject to the GLP regulations and concludes, therefore, that it would be inappropriate to delete § 58.63(b) from the regulations.

27. Section 58.63(b) requires in part that written standard operating procedures designate the person responsible for certain operations respecting equipment, i.e., routine inspection, cleaning, maintenance, testing, calibration, and/or standardization. Although FDA did not propose to revise these requirements of § 58.63(b), three comments stated that by requiring that standard operating procedures designate an individual responsible for performing each operation, FDA obligates testing facilities to change their standard operating procedures frequently. The comments further argued that the requirement to make a copy of the standard operating procedures available to laboratory personnel is redundant to the requirements set forth in § 58.81(c) and should be deleted.

The comments misconstrue the meaning of the word "person" as it is used in § 58.63(b). The second sentence of § 58.63(b) requires, in pertinent part, that "the written standard operating procedures shall designate the person responsible for the performance of each operation * * *." As explained in paragraph 120 of the preamble to the final rule (43 FR 60001), FDA adopted the term "person" as defined in § 58.3(h) rather than the originally proposed term "individual" to allow the standard

operating procedures to designate an organizational unit.

The agency agrees with the comment that § 58.63(b) is redundant to § 58.81(c) insofar as it provides for standard operating procedure availability. Accordingly, FDA is removing the phrase "and copies of the standard operating procedures shall be made available to laboratory personnel" from § 58.63(b).

28. Section 58.63(c) requires that a testing facility maintain written records of all equipment inspection, maintenance, testing, calibration, and/or standardizing operations. Two comments recommended that FDA delete § 58.63(c) in its entirety, arguing that if management is satisfied that the standard operating procedures are adequate, further requirements are unnecessary.

FDA does not agree with the comments. FDA carefully considered the necessity for maintaining the records specified in § 58.63(b) when the agency developed the current GLP regulations. FDA concluded that such records are necessary to reconstruct a study and to ensure the validity and integrity of the data that are obtained from a study (see paragraph 26 of this preamble and 43 FR 60001). The purpose of the record retention requirement is to provide documentation throughout the study of equipment function in accord with design specifications for the equipment, and equipment use in accord with standard operating procedures for maintenance and calibration of the equipment. FDA'S experience in administering the GLP regulations has shown the benefit of maintaining such records. For example, through FDA's laboratory inspection program, the agency has been able to identify the precise period of time of equipment malfunction by an examination of the equipment records. Thus, § 58.63(c) has made it possible to disregard the data collected by a single defective piece of equipment without having to disregard all the data obtained from a specific study.

Standard Operating Procedures

29. Two comments on the requirements for standard operating procedures suggested that § 58.81(a) be amended to permit appropriate supervisory personnel to authorize deviations from the written standard operating procedures, arguing that the study director may not have the technical expertise to evaluate such deviations. One of the comments further argued for the change on the ground that the principles of good laboratory practice established by the Organization

for Economic Cooperation and Development of the World Health Organization do not require study director approval of all standard operating procedure deviations.

FDA does not accept the suggestion. As discussed in paragraph 9 of this preamble, it is not necessary for the study director to be technically competent in all aspects of a study to assure that appropriate action is taken in response to any circumstances that may affect the quality and integrity of a study. The study director, however, has to be aware of and authorize any deviations that could have an impact on the study. FDA does not agree that the responsibility of the study director, as set forth in § 58.81(a), is inconsistent with the Organization for Economic Cooperation and Development principles of GLP. Chapter 2, section 2.3 (Ref. 1, p. 27) of the Organization for Economic Cooperation and Development document defines the responsibilities of the study director, in part, as "ensur[ing] that the procedures specified in the study plan are followed, and that authorization for any modification is obtained and documented together with the reasons for them * * *." Accordingly, both the GLP regulations and the Organization for Economic Cooperation and Development principles of GLP require that the study director make certain that specified procedures are followed and that all modifications to the procedures in the approved study plan (i.e., standard operating procedures) are documented and approved.

30. One comment recommended that FDA amend § 58.81(b) to delete all examples of standard operating procedures that FDA requires a testing facility to establish on the ground that the list is not all-inclusive and may lead to misinterpretation.

FDA disagrees with the recommendation. The examples listed in § 58.81(b) are those minimal laboratory procedures which the agency believes are essential to assuring the quality and integrity of the data generated in the course of any study (see 41 FR 51213). FDA recognizes that circumstances may necessitate establishment of additional standard operating procedures. The list is not intended to be all-inclusive and should not be interpreted as such.

31. Three comments objected to the proposed deletion of examples of laboratory manuals and standard operating procedures required to be in the laboratory under § 58.81(c). The comments argued that the listing of examples serves to spell out the agency's intent, helps laboratories

decide which areas to cover, and that without such guidance a potential exists for misinterpretation of FDA's intent.

FDA does not agree. Section 58.81(c) requires that each laboratory area have immediately available standard operating procedures relative to the laboratory procedures being performed. Unlike the list in § 58.81(b), which represents specific minimal requirements, the examples listed in § 58.81(c) encompass very broad areas. Each of the areas presented would require the preparation of a group of standard operating procedures to cover adequately the operations within that area. Consequently, the agency concludes that the list in § 58.81(c) is too broad to serve as useful guidance.

Reagents and Solutions

32. FDA received five comments that recommended that the agency amend § 58.83. Four comments stated that only those reagents and solutions used in the conduct of nonclinical laboratory studies need to be labeled in accord with the requirements of § 58.83, i.e., "to indicate identity, titer or concentration, storage requirements, and expiration date" of the material. These comments argued that such a modification would allow the laboratory flexibility in designing the most suitable system to assure that deteriorated or outdated reagents and solutions are not used. The fifth comment recommended that FDA insert into the first sentence of § 58.83 the phrase "as appropriate" to make the provision read "all reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and, as appropriate, expiration date." This comment argued that it was not necessary to have expiration dates on certain stable reagents and solutions such as water and saline.

FDA declines to amend § 58.83. The agency continues to believe, as discussed in paragraph 148 of the preamble to the final rule (43 FR 60003), that all reagents and solutions maintained in the laboratory area for use in the conduct of nonclinical laboratory studies should be labeled as required by § 58.83. Accordingly, the label should include the identity, titer or concentration, storage requirements, and expiration date. This label information is the minimum information necessary to make clear to the laboratory personnel that the reagents and solutions are suitable for use in the procedures specified in the protocol and to protect against inadvertent mixups of reagents and solutions that are used in nonclinical laboratory studies with those that are not intended for such use.

Further, FDA disagrees with the comment that suggested that expiration dating is not necessary for some reagents and solutions. FDA believes that expiration dates should be required on all reagents and solutions, without regard to their stability so that there is no doubt about the suitability of the materials for use in nonclinical laboratory studies.

Animal Care

33. One comment recommended that FDA delete § 58.90(a) on the basis that requiring standard operating procedures for housing, feeding, handling, and care of animals is redundant to other provisions of the GLP regulations.

FDA recognizes that § 58.81(b)(2) requires testing facilities to establish standard operating procedures for animal care. Section 58.90(a), however, expressly specifies that standard operating procedures shall also cover animal housing, feeding, and handling. The agency believes that these items are essential features for providing adequate humane treatment of animals and, therefore, is retaining § 58.90(a).

34. Two comments objected to the proposed amendment of the requirements under §§ 58.90 (b) and (c) to provide that animals may be isolated rather than quarantined. The comments argued that allowing laboratories to develop isolation and health status evaluation procedures in lieu of quarantine may not provide adequate assurance of test animal health because such evaluations are done only on a small randomly selected number of animals and are not as reliable as an adequate quarantine period. One comment suggested that the term "segregated" or the term "separated" may more accurately reflect FDA's intent in amending §§ 58.90 (b) and (c) than does the term "isolated."

As discussed in the preamble to the proposed amendments (49 FR 43533), substitution of a requirement for isolation and health status evaluations in lieu of quarantine of newly received animals will permit laboratories to develop specific isolation and health status evaluation procedures in concert with the age, species, and class of animals, and with the type of study to be done. As used in current § 58.90(b), the term "quarantine" connotes a rigid set of prestudy procedures which a facility is obligated to follow, including a mandatory holding period, specified diagnostic procedures, and the use of specialized facilities and animal care practices. The agency has concluded that isolation and health status evaluations should provide adequate precautions against entry of unhealthy

animals into a study. Health status evaluations may be performed during the prestudy acclimation period. Under § 58.90(b), the health status of each animal is to be evaluated soon after receipt. Section 58.90(c) prohibits the entry of any diseased animal into the study.

The agency has also concluded that a devoted area equipped to provide isolation of diseased animals is not necessary in all cases. As discussed in the preamble to the proposal (49 FR 43533), FDA believes that it should allow certain options for handling diseased animals, thereby permitting increased flexibility in laboratory operation. FDA agrees that the term "segregate" or the term "separate" rather than the term "isolate" could be used in as much as each term connotes "to set apart." Because "isolate" is a term commonly used and understood in contemporary veterinary medical practice, however, FDA will continue to use that term in these regulations.

35. One comment recommended that FDA amend § 58.90(d) to permit procedural means to provide "appropriate identification" of individual animals in a study.

FDA does not accept the recommendation. The agency notes that proper animal identification throughout a study is essential to study integrity. When animals are housed individually in cages, procedural means can be used to identify each individual animal, i.e., a cage card may be used if it provides all the information necessary to identify the animal specifically, and the animal handling standard operating procedures specify detailed procedures for preventing animal mixups. The agency is not aware, however, of any procedural means that could be used to identify adequately individual animals that are housed within a group in a cage. FDA advises that § 58.90(d) does not preclude identification by means other than the examples enumerated in that section provided that individual identification can be maintained and documented throughout a study.

Test and Control Article Characterization

36. One comment urged the agency to delete the requirement in § 58.105(b) for stability determination of test and control articles before initiation of the study. The comment argued that changing § 58.105(b) as recommended would make it consistent with FDA's proposed changes to § 58.105(a), which would allow test and control article characterization after completion of the study.

FDA disagrees with the recommendation. As discussed in the preamble to the proposal (49 FR 43533), FDA has concluded that characterization of test and control articles need not be performed until initial toxicology studies with the test article show reasonable promise of the article's reaching the marketplace. In arriving at this conclusion, the agency considered that prior knowledge of the precise molecular structure of a test article is not vital to the conduct of a valid toxicology test. It is important, however, to know the strength, purity, and stability of a test or control article that is used in a nonclinical laboratory study.

A stability determination of a test or control article conducted after completion of the nonclinical laboratory test with the article does not provide any information about the continued strength of either the test or control article previously given to the test system. Determining that the test and control articles are stable for the duration of the study is fundamental to interpreting the results of the study. For this reason, it would be inappropriate to allow for stability determinations only after-the-fact.

The agency does believe, however, that the continued strength of the test or control article may adequately be determined either by stability testing before initiation of the study or through appropriate periodic analysis of each batch. Section 58.105(b) currently allows stability testing of the test and control articles through periodic analysis only if it is not possible to determine their stability before study initiation. Because experience has shown that it is adequate either to determine stability of the test and control articles before initiation of a study or by periodic analysis of the articles while the study is in progress, the agency on its own initiative is revising § 58.105(b) to provide facilities and sponsors the flexibility to use either approach. Therefore, § 58.105(b) has been revised to provide for determination of the stability of the test or control article either before study initiation or through periodic analysis of each batch according to established standard operating procedures.

37. One comment observed that § 58.105(a) provides that testing facilities may rely on the labeling of marketed products for purposes of characterizing such products used as control articles in a study. The comment recommended that the agency also revise § 58.105(b) to allow product labeling to serve as documentation of

stability for marketed products used as control articles.

FDA declines to adopt this recommendation. The only stability information typically included on the labeling of marketed products is the expiration date. The manufacturer's expiration dating on a marketed product is not adequately precise to provide data on the strength of the control article used throughout a nonclinical laboratory study. Lacking precise stability information respecting the control article could raise doubts concerning whether the test and control articles are comparable. Furthermore, mixing the marketed product with a carrier or use of the product in a manner not in accord with its labeling could alter the stability characteristics of the product. For these reasons, FDA concludes that determination of the stability in accordance with the procedures in § 58.105(b) still is appropriate for any products used as control articles.

38. Several comments recommended that FDA revise § 58.105(c) to remove the current requirement that storage containers be assigned to a test article for the duration of a nonclinical laboratory study. The comments argued that the requirement is unnecessary and is inconsistent with the Organization for Economic Cooperation and Development principles of GLP. One comment alleged that the statement is vague and questioned whether the provision would permit a storage container that a laboratory emptied during the conduct of, but before completion of, a study to be destroyed or reused. The same comment also questioned whether, as the test article is depleted during the conduct of a study, the provision would permit a laboratory to transfer the test article into a container smaller than that originally assigned to the article.

FDA does not believe that it would be appropriate to eliminate the storage container provision in § 58.105(c). FDA advises that the provision simply requires that each test article storage container be assigned to a test article at the beginning of a study and remain so assigned until the study is completed, terminated, or discontinued. The test article may not be transferred to different sized storage containers as a study progresses, nor may assigned storage containers be destroyed while a study is in progress.

The agency recognizes that it may be inconvenient for laboratories, especially small laboratories, to devote space to a test article container which is emptied before a study is completely terminated,

or discontinued, or which might be replaced by progressively smaller containers while a study is in progress. Destroying or reusing or otherwise substituting for originally assigned, identified test article storage containers, however, could adversely affect the integrity of the study. FDA established the current provision because the agency observed a lack of accountability for test materials, ostensibly due to the very acts proscribed by the regulation, i.e., transfer of test articles to different sized containers and destruction of empty containers during the progress of nonclinical laboratory studies.

FDA continues to believe that the requirement concerning assignment of storage containers is necessary to ensure the integrity of a study. For example, the mere act of transferring a test article from one storage container to another introduces the opportunity for contamination of the test article by other laboratory materials or for mix-ups with other laboratory materials. In addition, during a transfer the test article would be exposed to air-borne contaminants as well as to moisture, either of which may compromise the integrity of the test article.

FDA also believes that requiring that containers be assigned to a test article for the duration of a study is fully consistent with the Organization for Economic Cooperation and Development principles of GLP. Chapter 2, section 2.3 (Ref. 1, p. 31) of the Organization for Economic Cooperation and Development document states that "storage container(s) should carry identification information, earliest expiration date, and specific storage instructions." Although the Organization for Economic Cooperation and Development document does not further characterize storage instructions that the Organization for Economic Cooperation and Development would recommend be included on containers, FDA concludes that its regulation identifies a "specific" storage instruction that is necessary to assure the integrity of the test article.

Mixtures of Articles with Carriers

39. Two comments argued that the requirements in § 58.113(a) to determine the uniformity, concentration, and stability of test and control articles in mixtures is unnecessarily burdensome for short-term studies. One comment stated that such tests are not necessary for test articles that are prepared and dispensed on the same day as used in single-dose acute toxicity tests. The comments suggested that the agency

revise § 58.113(a) to require that tests of mixtures of test and control articles need be conducted only "for studies other than short-term."

Section 58.113(a) requires, for all test or control articles mixed with a carrier, a determination of the uniformity of the mixture and a periodic analysis of the concentration of the test or control article in the mixture. In addition, § 58.113(a)(2), as amended, requires a determination of the stability of the test or control article in the mixture adequate to support time of use. Each of these analyses is necessary to assure that the test system is exposed to the test or to the control article in the amounts specifically designated in the protocol for a study. Determination of the uniformity of a mixture assures that each member of the test system receives the intended dose of test or control article. Periodic analysis of the concentration of the test or control article serves as a spot check to assure that the test or control article mixture has been prepared properly and in accord with the protocol and with applicable standard operating procedures. Determining the stability of the test or control article in the mixture helps to determine the period of time during which the test or control article mixture may be suitable for administration to the test system. FDA believes that knowledge of the dose of test or control article used in any test is essential for the proper evaluation of the results of that test. For these reasons, FDA has concluded that the requirements of § 58.113(a) should continue to apply to short-term tests as well as to studies other than short term.

As discussed in paragraph 36 of this preamble, however, FDA has decided to allow facilities and sponsors the flexibility to determine the stability of test and control articles either before study initiation or through periodic analysis of each batch according to established standard operating procedures. The agency believes that it is appropriate to allow similar flexibility with respect to determining the stability of mixtures of articles with carriers. For this reason, on its own initiative, FDA has revised § 58.113(a)(2) to allow determination of the stability of test and control articles in the mixture either before study initiation or through periodic analysis of the mixture according to established standard operating procedures.

40. One comment recommended that FDA delete § 58.113(a)(1), alleging that periodic determinations of the test or control article in mixtures is routine and provisions respecting such

determination would more appropriately be included in § 58.35(b)(3).

The comment misconstrues the function of the QAU (see especially paragraphs 12 and 18 of this preamble). Current § 58.35(b)(3), as well as § 58.35(b)(3) as revised by this final rule assigns responsibility for periodic inspection of laboratory operations to the QAU. The QAU does not, indeed, under § 58.35(a), the QAU may not conduct any portion of a study. Rather, it is responsible for assuring that a study is conducted according to the protocol, the standard operating procedures, and the GLP regulations.

Protocol

41. A comment urged the agency to delete the provision in current § 58.120(a)(14) (final § 58.120(a)(10)) that requires that the protocol for each study identify the records for the study to be maintained. The comment argued that the requirement in renumbered § 58.120(a)(10) is redundant to the same requirements in §§ 58.33(f), 58.190(a), and 58.195(b).

FDA recognizes that §§ 58.33(f), 58.190(a), and 58.195(b) address records that the GLP regulations require a testing facility to retain in all events. As the authorized master plan for a study, however, the protocol should identify all records of the study to be maintained by the testing facility to inform all study participants fully of recordkeeping obligations. The agency believes that inclusion of this information in the protocol is essential to ensure adequate documentation of the conduct of the study.

For these reasons, FDA declines to remove § 58.120(a)(10) from the GLP regulations.

42. One comment recommended that FDA delete the provision in current § 58.120(a)(16) (final § 58.120(a)(12)) that requires that the protocol for each study include a statement of the proposed statistical methods to be used in the study. The comment argued that a determination of the statistical methods used to evaluate data can, in many cases, be made only after data have been reviewed.

FDA recognizes that circumstances occasionally require a testing facility to modify the proposed statistical methods for analysis of the data in a given study. Good scientific practice, however, requires consideration of the statistical analysis of a study as part of the design of the study to assess whether the objectives of the study can be met. FDA concludes that the requirement is appropriate.

Conduct of a Nonclinical Laboratory Study

43. Section 58.130(c) provides that materials derived from a test system for examination or analysis (specimens) are to be identified by test system, study, nature, and the date of collection, and requires that such identification is to be located on the specimen container or is to accompany the specimen in a manner that precludes error in the recording and storage of data. Five comments argued that the requirements under § 58.130(c) for specimen identification are overly restrictive and suggested that management should be responsible for determining methods for identifying specimens.

The identification requirements specified in § 58.130(c) are designed to preclude error during the conduct of a nonclinical laboratory study. FDA has reviewed the requirements and has concluded that the identifying information specified in the regulation is the minimum information needed to distinguish each specimen from all others that have been collected in the facility thereby protecting against mixups and permitting orderly storage of specimens. Such information also shows whether the data collected on each specimen are assigned to the correct component of the test system.

FDA has always provided flexibility in the methods to be used for identifying the specimens in that the identifying information can be encoded through, for example, the use of accession numbers affixed to the specimen with the numbers decoded in accompanying information (see, e.g., paragraph 205 of the preamble to the final rule (43 FR 60008)). The agency believes that the requirements with respect to specimen identification are the minimum requirements necessary to prevent mixup of specimens or lost specimen identity.

44. Two comments disagreed with FDA's proposal to revise § 58.130(d), which currently requires that records of gross findings for a specimen from postmortem (necropsy) observations shall, in all cases, be provided to a pathologist during study of the specimen. The proposed revision provides only that such records "should" be made available to the pathologist. Four comments supported the proposed change on the ground that the resulting flexibility allows "blinding" of the pathologist. One comment suggested that § 58.130(d) be deleted in its entirety or, alternatively, modified by specifying that the records

are to be provided to the pathologist "if required by the protocol."

FDA established § 58.130(d) in the belief that the provision would increase the pathologist's ability to describe correctly microscopic findings and to relate such findings properly with the gross postmortem observations (41 FR 51214). FDA continues to believe that for most studies it is important for the pathologist to have available the records of gross findings when examining a specimen histopathologically. The agency recognizes, however, that for certain nonclinical laboratory studies it may be appropriate for pathologists to evaluate the histopathological specimens without being informed of the necropsy findings. The change made in the regulation will permit the study director, in concert with management, to determine the need for "blinding" in relation to the specific objectives of the study.

FDA advises that it continues to believe that for most studies it is a preferred practice not to use "blinding" in histopathological evaluation. For this reason, the agency is not deleting § 58.130(d) as suggested by one comment. The alternative phrase "if required by the protocol" suggested by the comment would serve the same purpose as the modification proposed by the agency. Therefore, the agency is adopting § 58.130(d) as proposed.

45. One comment on § 58.130(e) requested that FDA clarify the meaning of the term "automated data collection systems," stating that it is unclear whether § 58.130(e) applies to tabulation of source data from "hard" copy by automated systems.

As discussed in paragraph 7a. of this preamble, hand-recorded data collected during a study are "raw data." The subsequent entry of these hand-recorded data into a computer system, for example, by data processing clerks or through the use of optical readers, does not alter the status of the hand-recorded data as "raw data." The processing of these data by the computer, e.g., tabulation, is not "direct data input" and is, therefore, not encompassed by the requirements of § 58.130(e).

Reporting of Nonclinical Laboratory Study Results

46. Section 58.185(a) requires that a final report be prepared for each nonclinical laboratory study conducted and specifies the minimum information that shall be included in a final report. One comment urged that § 58.185(a) should be modified to require final reports to include the specified information only "where appropriate" to

make the requirements respecting final reports consistent with FDA's proposal to change § 58.120(a) respecting protocols. Alternatively, the comment urged that, at the least, § 58.185(a)(8), which requires that any final report shall include a description of the dosage, dosage regimen, route of administration, and duration, should be so modified. The comment argued that some of the information required under this paragraph is not applicable to certain studies involving medical devices.

FDA proposed to change § 58.120(a) in recognition of the fact that certain of the enumerated items are not necessary for the protocols for all studies. FDA has carefully reviewed each of the items listed in § 58.185(a) and has concluded that the information required by this section to be included in a final report for a nonclinical laboratory study is necessary to evaluate any such study. FDA notes that § 58.185 currently allows certain appropriate flexibilities where specified information is determined by the laboratory not to be relevant to a study. For example, § 58.185(a)(4) provides that test and control articles may be identified by "other appropriate characteristics" and § 58.185(a)(7) includes the term "where applicable." The agency believes that the information required by § 58.185(a)(8) is applicable to studies involving medical devices. For example, "dosage" and "dosage regimen" for devices may be expressed in units used per animal at a designated frequency of use. "Route of administration" may describe the means by which the device is used in relation to the animal. "Duration" would pertain to the period of time the device was tested in the animal. These clarifications should permit nonclinical laboratory studies on medical devices to be reported properly.

47. Section 58.185(a)(10) requires that each final report of a nonclinical laboratory study include the name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study. One comment recommended that FDA revise § 58.185(a)(10) to require identification only of the study director and of the principal scientists involved in the study.

FDA disagrees with this suggestion. Supervisors play an important role in the data collection process. They supervise those who perform the procedures, may recommend or actually provide training, and assure that data collection is carried out in accordance with the protocol, the standard operating procedures, and the GLP regulations. The names of all scientists,

professionals, and supervisors are needed to assure the accountability of all of those individuals responsible for the integrity of the study. The comment did not provide any data or information to support its recommendation to revise § 58.185(a)(10) and the agency concludes that it should retain the current requirement.

48a. Section 58.185(a)(12) requires that the final report of a nonclinical laboratory study include the signed and dated reports of each of the individual scientists or other professionals who were involved in the study. Two comments recommended that FDA revise § 58.185(a)(12) to allow for combined reports signed by the principal scientists. According to the comments, allowing for such combined reports would be consistent with the Organization for Economic Cooperation and Development principles of GLP.

The agency does not believe that a combined report from scientists of different disciplines would be appropriate. Each individual scientist involved in a study has to be accountable for reporting data, information, and views within his or her designated area of responsibility. Reports which combine the data, information, and views of more than one such person would obscure the individual's accountability for accurate reporting. Furthermore, FDA believes that the comment has misinterpreted the standard that the Organization for Economic Cooperation and Development established respecting reports of persons involved in a nonclinical laboratory study. Chapter 2, section 2.3 (Ref. 1, p. 36) of the Organization for Economic Cooperation and Development document provides that "if reports of principal scientists from co-operating disciplines are included in the final report, they should sign and date them." It provides further that the final report should contain the "names of other principal personnel having contributed reports to the final report." These provisions do not imply that combined reports would be appropriate. Rather, they support the need for individual accountability. The Organization for Economic Cooperation and Development provisions are entirely consistent with the provisions of § 58.185(a)(12).

48b. On its own initiative, FDA is amending § 58.185(b) to provide that the final report shall contain the dated signature of the study director to conform the provision to the definition of "study completion date" being added by this final rule (see paragraph 6 of this preamble).

Storage and Retrieval of Records and Data

49. FDA proposed to revise § 58.190(a) to allow wet specimens and specimens from mutagenicity tests to be discarded after evaluation and recording. The agency's proposal was supported by several comments. One comment, however, requested that the agency clarify the meaning of "mutagenicity tests" as the term is used in § 58.190(a). The comment asked whether, for example, *in vitro* cell transformation is interpreted to be a mutagenicity test under this provision.

FDA advises that, for the purpose of § 58.190(a), the agency considers mutagenicity tests to be those tests designed to assess the capacity of a test or control article to induce heritable changes in a test system. Accordingly, FDA considers *in vitro* cell transformation to be a mutagenicity test as the term is used in the GLP regulations.

50. One comment recommended that FDA further revise § 58.190(a) to assure that the regulation makes clear that final reports must be retained.

As discussed at length in the preamble to the proposal (49 FR 43534), FDA intended to exclude from the retention requirements of the GLP regulations specimens that are relatively fragile or contribute only in a minor way to safety evaluation. FDA did not intend to change the current requirement that final reports of any nonclinical laboratory study are to be retained in accordance with § 58.195. To preclude any possible confusion regarding the requirement that final reports must be retained, FDA is rewording § 58.190(a) to read "all raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained."

Retention of Records

51. FDA proposed to delete from current § 58.195(c) the listed examples of materials that the agency believes need to be retained only so long as the quality of the preparation affords evaluation. One comment noted that § 58.195(c) should be further revised to delete wet specimens to be consistent with the proposed revisions in § 58.190(a) (see paragraph 50 of this preamble).

FDA agrees with the comment and in this final rule is conforming § 58.195(c) to revised § 58.190(a). In pertinent part, § 58.195(c) now reads "Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of

blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material * * *"

52. Two comments suggested that FDA should specifically provide in new § 58.195(g) that records to be retained under the GLP regulations may be retained as magnetic media.

Section 58.195(g), which is being added to Part 58 by this final rule, provides that records respecting a nonclinical laboratory study may be retained as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Magnetic media could qualify as either "original records" or "accurate reproductions of the original records." This conclusion is consistent with § 58.3(k), which includes "magnetic media" within the meaning of "raw data." Consequently, the agency does not believe that it is necessary to change new § 58.195(g) in order to achieve the result desired by the comments.

Reference

The following reference has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. "Good Laboratory Practice in the Testing of Chemicals," Organization for Economic Cooperation and Development Publications, Paris, France, 1982.

Economic Assessment

As announced in the proposal, FDA has examined the economic consequences of this final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). At that time, the agency concluded that the changes would not constitute a major rule as defined in the Order and that no regulatory flexibility analysis would be required. The agency also certified that the revisions would not have a significant impact on a substantial number of small entities. The agency has not received any new information or comments that would alter its previous determination.

Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Paperwork Reduction Act of 1980

Sections 58.35(b) (1), (3), and (6), 58.63(b), 58.90(c), 58.105(a), 58.120(a), 58.130(e), and 58.190 (a) and (e) of this final rule contain collection of information requirements. FDA submitted a copy of the proposed rule containing the same requirements to the Office of Management and Budget (OMB). These collection of information requirements were approved under OMB Control No. 0910-0203.

List of Subjects in 21 CFR Part 58

Laboratories.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under 21 CFR 5.11, Part 58 is amended as follows:

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

1. The authority citation for 21 CFR Part 58 is revised to read as follows:

Authority: Secs. 306, 402(a), 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 701(a), 706, 801, Pub. L. 717, 52 Stat. 1045-1046 as amended, 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 336, 342(a), 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360f, 360h-360j, 371(a), 376, 381); secs. 215, 351, 354-360f, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n); 21 CFR 5.11.

2. In § 58.1 by designating the existing text as paragraph (a) and adding new paragraph (b), to read as follows:

§ 58.1 Scope.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

3. In § 58.3 by removing the phrase "of this chapter" wherever it appears; by revising paragraphs (c), (d), and (e)(8); by removing and reserving paragraph (e)(12); by replacing "in section 513 of the act" with "in Part 860" in paragraph (e)(17); by replacing "section 514 of the act" with "in Part 861" in paragraph (e)(18); and by adding new paragraphs (o) and (p), to read as follows:

§ 58.3 Definitions.

(c) "Control article" means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system in the course of a nonclinical laboratory

study for the purpose of establishing a basis for comparison with the test article.

(d) "Nonclinical laboratory study" means *in vivo* or *in vitro* experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.

(e) * * *
(8) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in Parts 109 and 509.

* * * * *
(12) [Reserved]
* * * * *

(o) "Study initiation date" means the date the protocol is signed by the study director.

(p) "Study completion date" means the date the final report is signed by the study director.

4. In § 58.31 by revising paragraph (b), to read as follows:

§ 58.31 Testing facility management.

* * * * *

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

* * * * *

5. In § 58.35 by removing paragraph (e), by revising paragraphs (a) and (b) introductory text, (1) and (3), and by adding an OMB number at the end of the section to read as follows:

§ 58.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) The quality assurance unit shall:
(1) Maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of

each study, identity of the sponsor, and name of the study director.

* * * * *

(3) Inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately.

* * * * *
(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

6. By revising § 58.41, to read as follows:

§ 58.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

7. In § 58.43 by removing paragraph (e) and by revising the first sentence of paragraph (c) to read as follows:

§ 58.43 Animal care facilities.

* * * * *

(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. * * *

* * * * *

8. In § 58.45 by revising the last sentence, to read as follows:

§ 58.45 Animal supply facilities.

* * * Perishable supplies shall be preserved by appropriate means.

9. By revising § 58.49, to read as follows:

§ 58.49 Laboratory operation areas.

Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by nonclinical laboratory studies.

§ 58.53 [Removed]

10. By removing § 58.53
Administrative and personnel facilities.

11. By revising § 58.61, to read as follows:

§ 58.61 Equipment design.

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

12. In § 58.63 by revising paragraph (b) and by adding an OMB number at the end of the section, to read as follows:

§ 58.63 Maintenance and calibration of equipment.

* * * * *

(b) The written standard operating procedures required under § 58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

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(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

13. In § 58.81 by revising the first sentence of paragraph (c), to read as follows:

§ 58.81 Standard operating procedures.

* * * * *

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. * * *

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14. In § 58.90 by revising paragraphs (b) and (c) and by adding an OMB number at the end of the section, to read as follows:

§ 58.90 Animal care.

* * * * *

(b) All newly received animals from outside sources shall be isolated and their health status shall be evaluated in accordance with acceptable veterinary medical practice.

(c) At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary. These animals may be treated for disease or signs of disease provided that

such treatment does not interfere with the study. The diagnosis, authorizations of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

15. In § 58.105 by revising the first sentence of paragraph (a), by revising paragraph (b), and by adding an OMB number at the end of the section, to read as follows:

§ 58.105 Test and control article characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented.

(b) The stability of each test or control article shall be determined by the testing facility or by the sponsor either:

- (1) Before study initiation, or
- (2) concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

16. In § 58.113 by revising paragraph (a)(2), to read as follows:

§ 58.113 Mixtures of articles with carriers.

(a) To determine the stability of the test and control articles in the mixture as required by the conditions of the study either (i) before study initiation, or (ii) concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture.

17. In § 58.120 by revising paragraph (a) and by adding an OMB number at the end of the section, to read as follows:

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain, as applicable, the following information:

- (1) A descriptive title and statement of the purpose of the study.
- (2) Identification of the test and control articles by name, chemical abstract number, or code number.
- (3) The name of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(5) The procedure for identification of the test system.

(6) A description of the experimental design, including the methods for the control of bias.

(7) A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(8) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.

(9) The type and frequency of tests, analyses, and measurements to be made.

(10) The records to be maintained.

(11) The date of approval of the protocol by the sponsor and the dated signature of the study director.

(12) A statement of the proposed statistical methods to be used.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

18. In § 58.130 by revising paragraphs (d) and (e) and by adding an OMB number at the end of the section, to read as follows:

§ 58.130 Conduct of a nonclinical laboratory study.

(d) Records of gross findings for a specimen from postmortem observations should be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data

input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

19. In § 58.185 by revising paragraph (b), to read as follows:

§ 58.185 Reporting of nonclinical laboratory study results.

(b) The final report shall be signed and dated by the study director.

20. In § 58.190 by revising paragraphs (a) and (e) and by adding an OMB number at the end of the section, to read as follows:

§ 58.190 Storage and retrieval of records and data.

(a) All raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0203.)

21. In § 58.195 by revising paragraph (c), redesignating paragraph (g) as paragraph (h), and adding new paragraph (g), to read as follows:

§ 58.195 Retention of records.

(c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.

(g) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

§ 58.204 [Amended]

22. In § 58.204 *Notice of and opportunity for hearing on proposed disqualification* in paragraph (b) by removing "of this chapter"

§ 58.213 [Amended]

23. In § 58.213 *Public disclosure of information regarding disqualification* in paragraph (b) by removing "of this chapter."

§ 58.219 [Amended]

24. In § 58.219 *Reinstatement of a disqualified testing facility* by removing "of this chapter."

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: August 10, 1987.

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