

1. Transmitted is a revision to the Department of Veterans Affairs, Veterans Health Administration manual M-2, "Clinical Programs," Part IV, "Medical Service," Chapters 1 through 8.
2. Principal changes are:
 - a. Chapter 1: Delegates general supervision of the Medical Officer of the Day to the Chief of Staff.
 - b. Chapter 2: Revises and updates policies regarding cardiology.
 - c. Chapter 3: Defines policy for Intensive Care Units.
 - d. Chapter 4: Revises and updates policies on the Dialysis Program including new 38 United States Code (U.S.C.) citations.
 - e. Chapter 5: Establishes policy for providing outpatient oxygen therapy.
 - f. Chapter 6: Amended to include the Infection Control Program.
 - g. Chapter 7: Defines ethnic origin of applicant and includes new 38 U.S.C citations.
 - h. Chapter 8: Defines policy for providing Allergen Therapy.

3. Filing Instructions

Remove pages	Insert pages
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4. RESCISSIONS: M-2, Part IV, dated October 23, 1990, chapters 1 through 8.

~~S/ 4/29/94 by Lydia Marvidis for~~
John T. Farrar, M.D.
Acting Under Secretary of Health

(Logo) Department of
Veterans Affairs

CLINICAL PROGRAMS
Medical Service

April 29, 1994

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

Department of Veterans Affairs, Veterans Health Administration manual M-2, "Clinical Programs," Part IV, "Medical Service," is published for the compliance of all concerned.

~~S/ 4/29/94~~ by Lydia Mavridis for
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December 4, 1950	Reporting of Cases of Syphilis to Health Authorities
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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part IV, Chapter 1, dated October 23, 1990.

CHAPTER 1. ADMINISTRATIVE

1.01 POLICY

It is the Department of Veterans Affairs (VA) policy that each Veterans Health Administration (VHA) element have written administrative policies and procedures available for reference at all times.

1.02 MEDICAL OFFICER OF THE DAY (MOD)

a. The Chief of Staff (COS) will develop and issue written guidelines to provide continuous, appropriate and effective medical supervision 24 hours a day, 7 days a week. The guidelines will specify the authorizations, responsibilities, duties, schedules and assignments which are elements of the arrangement.

b. In determining the pattern of medical supervision, due consideration will be given to the type of patients, the number of beds, the number and spatial arrangement of buildings in the hospital complex, and all other factors influencing patient care.

c. One or more duly licensed physicians, with appropriate clinical credentials and privileges, will be assigned to provide medical coverage during evenings, nights, weekends and holidays when the regular medical staff is not on duty.

(1) This physician shall be referred to as the MOD, when serving as a general practitioner.

(2) When more than one physician is scheduled (as at many affiliated medical centers due to the volume or complexity of the patients being covered), specialty and/or subspecialty titles should be used, as in Psychiatry Admitting Officer of the Day (POD) or Surgical Officer of the Day (SOD).

(3) Call schedules need to be clearly posted for use by the triage area, nursing stations and page operators.

d. MODs responsible for performing resuscitations (e.g., no separate code team), will have current Advanced Cardiac Life Support (ACLS) certification.

e. The MODs will not leave the facility grounds during their call shift without the permission of the COS, at which time another physician will be designated.

1.03 RESPONSE TO CODES

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a. Medical center physicians will ensure swift response times to codes i.e., cardio-pulmonary arrest episode, by skilled personnel. All members of code teams must have beepers and will be reached via designated pagers.

b. In order to ensure consistent resuscitation procedures, VA supports the use of the most current ACLS guidelines written and updated by the American Heart Association (AHA). ACLS certification is required to run or supervise any code at a VA medical center.

NOTE: Cardiac Pulmonary Resuscitation (CPR) should be initiated by staff witnessing a code until the code team (ACLS-trained personnel) arrives.

c. Physicians on the Code Team

(1) Daytime coverage. Daytime coverage at the medical center includes:

(a) A ACLS-certified Chief Resident, post-graduate year (PGY) 4 fellow, or staff physician as the supervisor to ensure that the ACLS protocol is correctly applied (some medical centers rely on fellows). A PGY 4 fellow, Chief Resident, or staff physician is given a code beeper for daytime codes (8:00 a.m. to 4:30 p.m.), and will supervise all daytime codes. This provides for the teaching of house officers and non-ACLS staff physicians, as well as ensuring appropriate interventions.

(b) A house officer or staff physician will run the code, subject to the advice and concurrence of the supervisor. Running the code requires ACLS certification.

(c) A fully trained individual (surgical or anesthesia house officer, attending staff, respiratory therapist or nurse anesthetist) will intubate the patient and remain present to assist with any needed IVs.

(d) Additional house officers, students, or attending staff responsible for the patient, will assist in the performance of the code under supervision. They are the only physician members of the team who may participate without current ACLS certification.

(2) Other than daytime coverage at the medical center. The medical team on call will perform off hours codes; this includes night-time, weekend, and holiday coverage. Current ACLS certification is required. Non-ACLS certified housestaff will perform only under the direct auspices of the code supervisor.

(3) Waiver

(a) A waiver may be granted to those VA medical centers that can document that the requirements listed in preceding paragraphs (1) and (2) do not allow them to provide timely and appropriate care to the patients they serve. NOTE: Although there have been several applications, to date no such waiver has been granted.

(b) An application for the waiver is to include the reasons why the VA medical center cannot comply with the requirements and the mechanisms whereby patients will be served (i.e., activating a community emergency system). The application should include a plan for monitoring, reviewing, and evaluating the system by the VA medical center to ensure that responses provided are timely and appropriate.

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(c) The application for a waiver is to be submitted to the Office of Clinical Programs (11), VA Central Office.

NOTE: These policies are to become effective October 1, 1994.

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RESCISSIONS

The following material is rescinded:

1. Manual

M-2 Part IV, Chapter 2 dated October 23, 1990

CHAPTER 2. CARDIOLOGY

2.01 POLICY

It is the Department of Veterans Affairs (VA) policy that invasive cardiovascular procedures will be performed only in appropriately authorized and equipped laboratories, by experienced, credentialed and privileged staff. Individuals must be board-certified in internal medicine, cardiovascular diseases or radiology. Trainees must be directly supervised by a fully qualified staff member.

2.02 SCOPE

a. Routine cardiac catheterization, angioplasty, valvuloplasty, pacemaker insertions and electrophysiologic studies and treatments are performed in 71 VA medical center laboratories.

b. Trends in average performance over several years are followed to assess compliance with minimum performance requirements. The minimum number of total procedures for a catheterization laboratory is 300; the minimum number of left heart procedures is 250.

2.03 CARDIAC CATHETERIZATION LABORATORIES

a. Authority. VA's cardiac catheterization laboratories are governed by regulations that call upon VA and the Department of Defense (DOD) to minimize duplication and underuse of health-care resources, and provides VA, DOD, and Public Health facilities with authority to enter into agreements to "share" health-care resources (see M-1, Pt. I, Ch. 1, Sec. XI).

b. Staffing. Approximately five clinical Full-time Employees (FTE) are required to operate a catheterization laboratory performing the minimum number of procedures. An example is: one Chief, Catheterization Laboratory, who is a physician, two Registered Nurses (R.N.s), and two catheterization laboratory technicians). NOTE: The goal of VA is to achieve 500 procedures per year per lab.

c. Opening a Catheterization Laboratory

(1) Demographic changes have determined where new facilities are opened.

(2) Approval for the concept must be obtained through Veterans Health Administration's (VHA's) formal planning process. The VA medical center Director then submits an application to VA Central Office, Medical Service. Entirely new laboratories will require availability of on-site cardiac surgery. NOTE: No new laboratories will be opened unless nearby Federal government laboratories are performing an average of 500 cases annually.

d. Retaining a Catherization Laboratory. Once established, a laboratory will stay open as long as it conforms to the minimum performance requirements of VA and other guidelines which VA accepts. For persistently borderline performance, (in terms of numbers, or morbidity and mortality status) a VA Central Office site visit team will be sent to evaluate, prior to authorization of new equipment.

e. Closing a Catherization Laboratory. Established criteria are used to determine that a laboratory should be closed. The stages of closure begin with warning letters, then progress to site visits and formal recommendations through channels.

(1) Failure to achieve a minimal performance standard or to report required statistics may result in closure.

(2) Failure to retain or recruit appropriately trained and credentialed staff, unduly high morbidity or a change in the mission of a VA medical center, may result in closure.

(3) Laboratories may be phased out through not replacing their equipment. NOTE: Most catheterization laboratory equipment is replaceable after 8 to 10 years. Once the decision is made to replace equipment, serviceable devices and in some cases, lead-lined rooms, may be retained for electrophysiology or procedure rooms. This permits two rooms, but just one state-of-the-art angiography suite. VA medical centers performing 1,000 total procedures per year could justify two fully equipped new rooms for coronary angiography.

f. Incident Reports

(1) Complications must be recorded at the local laboratory if they occur within 24 hours of the cardiac catheterization or if they are attributable to the catheterization even if remote in time. EXAMPLE: A patient who undergoes an angioplasty and has complications including dissection, myocardial infarction and subsequent renal failure. After a prolonged Intensive Care Unit (ICU) course including hemodialysis, the patient dies. The death is to be listed as an angioplasty related death (complication of procedure). All episodes of surgery that the patient would not have had if the catheterization had not been performed are also listed as complications.

(2) The following list is the minimum for local laboratory record-keeping: NOTE: Other serious complications, (especially those discussed in a staff review, or morbidity and mortality conference) should be included.

(a) Death during or related to catheterization;

(b) Dissection;

(c) Transient ischemic attacks and/or stroke and/or paralysis and/or visual changes;

(d) Myocardial infarction or pulmonary edema within 24-hours of catheterization;

(e) Renal failure (contrast nephrotoxicity);

(f) Perforation and/or tamponade and/or rupture;

(g) Amputation and/or peripheral vascular surgery;

(h) Anaphylaxis;

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- (i) Pseudoaneurysm and/or significant hematoma and/or fistula;
- (j) Hypotension, during and after procedure, requiring intra-aortic balloon pump or sustained therapy;
- (k) Local infection or inflammation, requiring drainage;

- (l) Septicemia; or bacterial endocarditis; or thrombophlebitis, requiring more than 7 days of treatment;
- (m) Unusual catheter problems as breakage or rupture;
- (n) Bleeding of a nature requiring transfusion or surgery; and
- (o) Ventricular fibrillation and/or a complete heart block.

2.04 CORONARY ANGIOPLASTY

VA authorizes the use of percutaneous transluminal coronary angioplasty (PTCA) as an elective and emergent procedure in accord with the following regulations:

a. Eligibility. Only VA medical centers with on-site Cardiac Surgery Programs are eligible to perform elective angioplasty. Due to the nature of VA which includes in-house programs, contracts, and sharing agreements to provide cardiac surgery, VA recognizes circumstances that may merit an exemption. Formal application for an exemption must be made to Medical Service (111A), VA Central Office.

b. Requirements for Training. Many VA cardiologists perform invasive procedures at other institutions. VA requires only that the total number of cases for an individual angioplasty attending comply with nationally accepted guidelines (e.g., 75 per year). VA medical centers with insufficient volume to achieve such a total experience for the individual angioplasty operator should discontinue performing PTCA, unless an experienced angioplasty attending will directly supervise each case (e.g., a fully-qualified university or community affiliated attending, who is present in the cardiac catheterization laboratory).

2.05 PACEMAKERS/IMPLANTABLE DEFIBRILLATORS

a. Registry. Veterans with pacemakers and other implantable devices are registered through the National Pacemaker/Device Registry at the VA Medical Center, Washington, DC.

(1) Currently, 98 VA medical centers implant about 1,000 permanent pacemakers annually. NOTE VA medical centers must implant about 15 pacemakers per year to remain authorized (sufficient volume to keep current).

(2) Patients are followed locally for clinical care and reprogramming, and by telephone for surveillance.

(3) Patients with Automatic Implantable Cardioverter Defibrillators (AICDs) are followed by 21 VA medical centers. They are:

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Region I

Region 2

Region 3

Region 4

New York
Richmond
Washington, DC

Ann Arbor
Columbia
Hines
Indianapolis
Milwaukee
Minneapolis

Gainesville
Houston
Little Rock
Miami
Nashville
Oklahoma City
Tampa

Salt Lake City
San Diego
San Francisco
Tucson
West Los Angeles

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b. Pacemaker Selection

(1) Shipping and/or Returns. Pacemakers appear on the Federal Supply Schedule. Receipt of a pacemaker is accomplished by Acquisition and Materiel Management (A&MM), which maintains a record for pacemaker purchases and returns. Unused pacemakers will be exchanged for credit as authorized, and then deleted from the facility's inventory.

(2) Explants

(a) Explanted pacemakers, which are removed because of evidence of unexplained clinical failure or because of a Food and Drug Administration (FDA) recall, will be sent by the Chief, A&MM, of VA medical centers to the Eastern Cardiac Pacemaker Surveillance Center, VA Medical Center, 50 Irving Street, NW, Washington, DC, 20422. The explanted pacemaker should be accompanied by a completed VA Form 10-0049, Explanted Cardiac Pacemaker Prosthesis (ECP) Data. A shipping label and a request for reimbursement by the manufacturer must be provided.

(b) Explanted pacemakers removed due to replacement or cremation can be tested locally and returned to the manufacturer for credit or sent in accordance with subparagraph b(1). If an individual medical center lacks the capability to evaluate an explanted model, it should be returned as stated in subparagraph b(1).

(c) All VA medical centers need to ensure that credit is sought for explanted pacemakers still under warranty. If sent to the Eastern Pacemaker Surveillance Center, use the mailing label provided and include the request for reimbursement. A report on the operating characteristics of the explanted pacemaker will be sent to the originating VA medical center, to the manufacturer, and to the FDA. If evaluated at the individual medical center and found lacking, the pacemaker should be returned directly to the manufacturer for possible credit. All generators should be non-invasively analyzed so that VA can obtain credits toward new devices.

(3) Cremation. When an autopsy is performed, Standard Form (SF) 523, Authorization for Autopsy, will document the removal of the pacemaker. Otherwise, the Chief, Pathology Service, or designee, shall seek authorization (documented on SF 507, Clinical Record Report) from the family to remove the pulse generator. If the pulse generator is not removed from the body, the Death Certificate must clearly state its presence. For example:

NOTE: BODY CONTAINS A PACEMAKER WHICH INCLUDES A BATTERY OR POWER SOURCE.

(4) Other Equipment. Veterans electing pacemaker follow-up through VA will be supplied with attachments necessary for telephone surveillance (considered a prosthetic appliance). VA medical centers may not use any free monitoring services offered by vendors or manufacturers directly or indirectly (this does not apply to loaned programmer equipment).

c. Pacemaker Surveillance Centers

(1) There are two pacemaker surveillance centers for telephone monitoring:

(a) The Eastern Pacemaker Surveillance Center, VA Medical Center, Washington, DC, serves pacemaker recipients East of the Mississippi River. It is the location of the National Pacemaker/Device Registry and will analyze explanted cardiac pacemakers as needed. For clinical issues call: FTS 8-700-921-8398 or 1-800-543-PACE (7223).

(b) The Western Pacemaker Surveillance Center, VA Medical Center, San Francisco, CA, serves pacemaker recipients West of the Mississippi River. For clinical issues call FTS 700-470-2079, or (415)-750-2077.

(2) The surveillance centers save time and effort for VA medical centers, as well as providing pacemaker expertise to remote and/or underserved areas on a device-specific basis.

NOTE: The VA medical center where the implant is performed or where the patient is followed, is responsible for making sure that stable pacing parameters are achieved.

(a) Telephone surveillance decreases the need for pacemaker clinic appointments. Most VA medical centers now defer telephone monitoring to the surveillance centers, which provide computerized reports back to the clinicians.

NOTE: Clinical follow-up is provided at VA medical centers or via fee-basis if not otherwise available locally.

(b) All veterans with pacemakers will continue to be offered telephone surveillance, from one of the two (Eastern or Western) pacemaker surveillance centers, even if they are no longer followed in a VA clinic.

(c) VA medical centers discharging patients from their clinics, or discontinuing clinics, must ensure that all pacemaker patients continue to be offered telephone surveillance. Any alternative method (to follow-up by one of the pacemaker surveillance centers) requires specific approval, with individual requests directed to Medical Service (111A), VA Central Office.

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RESCISSIONS

The following material is rescinded:

1. Manuals

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CHAPTER 3. SPECIALIZED MEDICAL PROGRAMS

3.01 POLICY

It is the Department of Veterans Affairs (VA) policy to provide Specialized Medical Programs to meet the critical health care needs of the eligible veteran patient.

3.02 INTENSIVE CARE UNITS (ICUs)

a. VA medical centers with ICUs must provide certain minimal services. Not all medical centers have ICUs. Depending on the patient population served by a given facility, critical care may be provided on-site, by transfer to another VA medical center, or by fee-basis or sharing agreement. In all cases, the object is to provide the best possible critical care for the individual patient.

b. Each ICU will have a designated physician chief who is a member of the VA staff with appropriate Board certification and clinical privileges. The ICU Chief, is administratively responsible for all aspects of the care given in the ICU around the clock, and should have an office near the ICU. At times when the ICU Chief is not available (e.g., sick or annual leave, national meetings or conferences), a qualified physician will be designated by the Chief of Staff (COS) to act for the ICU Chief.

c. The ICU Chief is responsible for directing all aspects of the operation of the unit, as well as for developing operating policies including admission criteria. The ICU Chief will be assisted by a multidisciplinary ICU committee that meets at least quarterly. This committee is composed of representatives from all subspecialties involved in critical care.

d. Only licensed physicians will function independently in ICUs. Physicians-in-training must be directly supervised by qualified, licensed physicians (e.g., post-graduate year (PGY) 2 or above) for all procedures. Physician assistants will act only in accord with physician orders and specific clinical privileges. Physicians working with intensive care patients must have individual beepers. Only appropriately trained physicians will perform invasive procedures in ICUs. NOTE: This includes central venous access and arterial cannulations in all forms.

e. Each ICU must have fully qualified critical care nurses to provide nursing care.

(1) At least one ICU nurse per shift must be fully trained in cardiac output determinations, and privileged to perform same if the ICU has capability for Swan-Ganz monitoring.

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(2) In tertiary care centers, at least one nurse per shift must be privileged to care for patients with temporary transvenous pacemakers and intra-aortic balloon pumps if these modalities are within the unit's capabilities.

(3) Lack of such staff is a sufficient reason to transfer a critically ill patient to another facility.

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part IV, Chapter 4, dated October 23, 1990.

CHAPTER 4. DIALYSIS PROGRAM

4.01 PURPOSE

The purpose of this chapter is to establish policy and provide guidelines for the operation of the Dialysis Units.

4.02 POLICY

a. Department of Veterans Affairs (VA) will appropriately treat patients with End Stage Renal Disease (ESRD) as indicated by competent professional judgment. This may include conservative therapy, hemodialysis and peritoneal dialysis in a medical facility or at home, and renal transplantation.

b. The extensive professional expertise and other resources necessary to provide proper ESRD care require that designated dialysis units be located and operated for maximum effectiveness and efficiency.

c. Only VA facilities having the approval of the appropriate Regional Director with concurrence of Medical Service, VA Central Office, should undertake chronic dialysis care. No VA medical center with the necessary expertise is barred from performing acute dialysis when medically necessary.

4.03 ELIGIBILITY FOR CARE - GENERAL CONSIDERATIONS

a. Priorities for treatment of patients will conform to established beneficiary priorities for VA hospital care and outpatient care.

b. Within beneficiary priority classes highest priority for dialysis treatment will be given to seriously ill, or unstable patients urgently in need of care, and lowest priority will be given to clinically stable patients receiving ESRD care in a non-VA program who seek elective transfer into a VA program.

(1) Veterans who are nonservice-connected (NSC) for renal disease and who are stable and receiving care in a non-VA program may be accepted for transfer into a VA dialysis unit on a space-available basis in accordance with pertinent eligibility regulations.

(2) Such NSC patients seeking VA care should be informed by the dialysis and/or medical administrative staff that the VA ordinarily will not pay for subsequent care in a non-VA unit (such as if they live too far from a VA medical center having a dialysis program, or if the VA Dialysis Program becomes overtaxed) unless the patient's other resources, such as Medicare, are clearly inadequate to support such treatments.

(3) Veterans shall not be admitted for the sole purpose of placing them on outpatient nonservice-connected (OPT-NSC) care. (See par. 4.07 for further information on VA support of patients in non-VA dialysis units.)

(4) When a veteran patient is denied acceptance into a VA Dialysis Program because of lack of capability, the VA staff should assist the patient in identifying an alternate source or sources of dialysis treatment.

4.04 PROGRAM COMPONENTS

a. Dialysis Center. A VA medical center designated as a Dialysis Center is capable of providing the full spectrum of dialysis related diagnostic and therapeutic services required by patients with end stage renal disease:

(1) Each VA Dialysis Center will have appropriate arrangements for evaluating patients as transplantation candidates, and for appropriate referral for transplantation.

(2) Transplantation may be performed either within the VA medical center, at another VA medical center, or in a non-VA facility depending on local circumstances, e.g., available resources, sharing agreements, patient preference and other eligibilities such as Medicare, etc. (see Ch. 7.)

b. VA Satellite Dialysis Unit. A Satellite Dialysis Unit is a designated program in a VA medical center initially intended to provide continued dialysis treatment to stable ESRD patients.

(1) The exact responsibilities carried out by a Satellite Dialysis Unit will depend upon the local needs and the resources at the Satellite as outlined in a formal written affiliation agreement with an affiliated VA dialysis center.

(2) Some Satellite Dialysis Units with the necessary expertise have been authorized to function independently as Interim Dialysis Centers.

4.05 SCOPE OF VA DIALYSIS PROGRAM ACTIVITIES AND ADMINISTRATIVE CONSIDERATIONS

a. Diagnostic Study, Initial Stabilization and Formulation of Treatment Plan, Periodic Review and Reevaluation of Therapy. Dialysis center staff will ordinarily carry out these activities which require multidisciplinary professional expertise.

b. Maintenance Assisted (Full-Care) Dialysis. Patients who are not suitable for home dialysis, or limited and/or self-care dialysis, may require continued assisted full-care dialysis either at a Dialysis Center or satellite. Decisions on mode and location of dialysis treatment will be made by the dialysis center staff.

c. Home Dialysis. Suitable patients and their assistants may be trained to perform dialysis at home.

(1) All VA Dialysis Centers will provide home and/or self dialysis training so that selected patients can continue their dialysis treatments at home; or perform limited and/or self-care dialysis at dialysis centers or satellites, if home dialysis is not feasible. VA encourages home dialysis which permits dialysis facilities to treat additional patients, may offer potential rehabilitation benefits to the patient, and is less costly than continued dialysis in a medical center.

(2) Selection of home dialysis treatment is based on professional determinations of patient suitability by the Dialysis Program staff and consent of the patient.

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(3) In home dialysis, VA provides support services, including supplies and ongoing technical and professional assistance, and placement and installation of dialysis equipment in the patient's home.

(4) Home dialysis equipment will be provided only after there is assurance that the dialysis patient and the attendant are adequately trained, and trained VA personnel are available to provide backup consultation and assistance.

d. Home Dialysis Attendants. VA provides instruction, and may provide financial support for home dialysis attendants during the instruction period. Such support can be provided either by appointment of the attendant as a "without compensation employee" for the training period, with payment for travel and per diem during the training period, or by use of a contract with the person to be trained.

(1) VA does not encourage the use of paid home dialysis attendants in lieu of family members. However, under extraordinary circumstances, such as when a family member is not available to assist with dialysis care, use of such an attendant may be the most satisfactory alternative for the patient, and preferable to other alternatives from a cost effectiveness standpoint.

(2) In such cases, VA will continue to exercise overall professional responsibility for the patient's care, including assessing the performance capability of the proposed attendant, and periodically monitoring and evaluating the actual performance of the home dialysis attendant.

(3) The VA patient and potential dialysis attendant should be informed that VA does not assume responsibility for the performance of the dialysis attendant or for any untoward effect (such as hepatitis) that the attendants may develop.

(a) The use of a formal agreement for the functioning of the dialysis attendant is encouraged.

(b) The patient and VA-trained attendant might properly be parties to such agreement, which should include:

1. Provision for listing the risks to the patient entailed in dialysis,
2. The responsibilities of the attendant, and
3. The fact that the attendant is not considered to function as an employee of VA.

NOTE: The Office of District Counsel is available to assist in drafting such agreements.

(4) Dialysis attendants may be recruited directly by the patient, with assistance of the Dialysis Unit, or existing community resources may be utilized.

e. Limited and/or Self-Care Dialysis. It has been found that limited and/or self-care dialysis programs are more successful if such activities are carried out separately from the assisted full-care dialysis treatment.

(1) Selected patients for whom home dialysis is not feasible may be trained to participate actively, to the extent possible, in dialysis treatment provided

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at a dialysis facility. Thus, only the minimum amount of staff assistance will be necessary.

(2) VA encourages such limited and/or self-care dialysis where appropriate, and additional resources in support of such activities have been provided to many dialysis programs.

4.06 GUIDELINES FOR VA DIALYSIS UNIT OPERATION

a. Introduction. Operation of a dialysis program requires consideration of various distinct functions including:

- (1) Formulation and modification of basic policies and procedures,
- (2) Ongoing clinical decision making, and
- (3) Conducting quality assurance studies.

NOTE: These functions must be distinguished since the necessary participants and their roles vary.

b. ESRD Committee. A medical center ESRD Committee will be established in each dialysis center to formulate basic policies and procedures, accept patients into the renal replacement program and oversee program activities. The medical center Director will establish the ESRD Committee and approve its membership:

(1) Membership

(a) The Chief, Renal Section, Medical Service, and the Chief, Transplant Section, Surgical Service, will serve on this committee and jointly recommend appointment of the members. The surgeon responsible for surgical problems of ESRD patients will be a member. Non-physician participants including a nephrology nurse, nephrology social worker, and dietitian will be appointed to the committee. At least three physicians will serve on the ESRD Committee, one of whom will serve as chairperson.

(b) Either the Chief, Renal Section or Chief, Transplant Section, may serve as chairperson. In hospitals where only dialysis facilities exist, the Chief, Renal Section, Medical Service, will serve as chairperson of the committee and recommend appointment of the other members.

(2) Responsibilities. The ESRD Committee will:

- (a) Formulate basic policies and procedures for the dialysis program.
- (b) Approve the program's policy and procedure manual.

(c) Accept patients into the renal replacement program. Patient criteria include:

1. The likely quality of life and outcome of dialysis therapy should be considered when formulating medical admission criteria.

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2. Each patient will be considered on an individual basis and no patient should be excluded from the consideration process solely because of a specific diagnosis.

(d) Periodically review clinical care, outcome of therapy, and complications.

(e) Take such actions as are appropriate and/or offer its recommendations to the medical center Director through the Clinical Executive Board to improve ESRD patient care.

(f) Provide minutes of all meetings; these minutes will include a listing of individuals attending and actions taken.

(3) Since multidisciplinary professional expertise must be available to implement proper ESRD policies, the function for satellite units will ordinarily be carried out at the parent center. If the requirements are met, existing dialysis and transplant committees whether in combination with a university committee or existing totally within VA may be used.

c. Policy and Procedure Manual. Each Dialysis Unit will develop and maintain a manual approved by the ESRD Committee outlining operational objectives, basic policies and approved procedures adopted to assure a high level of patient care:

(1) National guidelines and/or standards developed by recognized agencies and organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), Center for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Surgeon General, and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) should be considered and incorporated as appropriate.

(2) Areas covered in this manual will include:

(a) Admission criteria and procedures to ensure equitable access to ESRD care in accordance with general VA policies and priorities.

(b) Staffing policies for physician and nonphysician personnel in cooperation with other involved services, such as Nursing, Social Work, and Dietetics.

(c) Procedures for ensuring health and safety of patients and staff including:

1. Hepatitis and other infectious disease control, including information, instructions and precautions for home dialysis patients and attendants.

2. Air embolism prevention and treatment.

3. Policy and procedures for dialyzer use (including reuse if any).

4. Standards for dialysate composition, conductivity and temperature.

5. Water purification standards and testing requirements.

6. Blood leak detection and control.

7. Use of monitoring devices, alarms, and other safeguards.

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8. Provisions for emergency medical care.
9. Provisions for power failure, fire, and other nonmedical emergencies.
10. Provisions of social services to help maintain normal social functioning of the patient and the family.

(d) Procedures for ongoing monitoring and modifying of individual short-term and long-term patient care plans including:

1. Dialysis treatments,
2. Medications,
3. Diet,
4. Suitability for transplant,
5. Psychosocial evaluations,
6. Special treatment, and
7. Continuing care.

NOTE: Such ongoing decision-making will include input from the various professionals involved in the care of the individual patients.

(e) Patient rights, including right to privacy and confidentiality, right to information about medical condition and treatment, and right to participate in selection of treatment options.

(f) Relationship to other VA, or non-VA dialysis, or transplant facilities including affiliated VA satellite unit or center, if any, and to community ESRD organizations.

d. Quality Assurance (QA). QA activities relating to ESRD care including medical audit and utilization review will be integrated into the hospital's overall QA Program.

(1) Recommended elements for dialysis-specific QA include the following:

- (a) Qualified physician director;
- (b) Functioning ESRD committee;
- (c) Written plan including policy and procedure manual;
- (d) Monitoring use, for conformance to national guidelines, of:

1. Safeguards,
2. Alarms, and

3. Monitors and procedures (e.g., relating to water quality, dialysis equipment and supplies, dialyzer reuse and including home dialysis patients);

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- (e) Review of all deaths and serious complications relating to dialysis;
- (f) Periodic review of patient data for maintenance of pre-set targets for clinical, hematological and blood chemistry values;
- (g) Participation in local ESRD network (strongly encouraged by the VA Ad Hoc Advisory Group on Renal Disease and Dialysis);

(h) Periodic review of mortality statistics and comparison to national data and periodically review experience, which may reflect on quality of care, relating to:

1. Staff physician supervision of residents and non-physician staff,
2. Vascular access,
3. Infections,
4. Rehospitalization,
5. Use of consultations,
6. Patient complaints, and
7. Litigation, etc.

(2) Results of ESRD QA studies will be reviewed by the medical center ESRD Committee and appropriate actions undertaken or recommended.

e. Relations of VA ESRD Programs to Community ESRD Organizations and local ESRD Networks

(1) VA data for the United States Renal Data System (USRDS) will be submitted through the local ESRD "Network."

(2) VA medical centers which provide ESRD care to non-VA patients through sharing agreements, and which have been authorized by agreement between VA and the Department of Health and Human Services, and approved as a Medicare ESRD provider will be accorded full membership rights in the local ESRD "network," and will conform to the Medicare Patient Information System, Medical Review Boards, and other requirements with regard to Medicare (but not VA) patient care.

(a) Aggregate VA data, provided for both VA and non-VA patients use, will be included in calculating utilization rates. VA patient data identified by individual and care provided to individual VA patients will not be subject to any mandatory review or external control.

(b) Release of patient data will be in accordance with established policies and procedures governing disclosure of medical information, based upon the Privacy Act of 1974 (5 United States Code (U.S.C). 5552a, and VA confidentiality status (38 U.S.C. 5701 and 7332). NOTE: In this subparagraph the term "patient data" refers to individually identifiable information while the term "aggregate VA data" refers to statistical, nonindividually identifiable information.

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(3) VA medical centers where Medicare patients are not treated, are encouraged to participate voluntarily in local network activities, to the extent possible, in the interest of improved patient care.

(a) As with those VA facilities that do treat Medicare patients, aggregate VA data may be provided, but patient data identified by individual and care provided to individual VA patients will not be subject to any mandatory review or external control.

(b) Release of patient data will be in accordance with established policies and procedures governing disclosures of medical information, based upon the Privacy Act of 1974 (5 U.S.C. 552a) and VA confidentiality status (38 U.S.C. 5701 and 7332).

(4) VA employees designated to serve in network activities should avoid participation that would conflict with, or give the appearance of conflicting with, their duties as VA employees. VA Standards of Ethical Conduct and Related Responsibilities, set forth in pertinent in part 38 CFR (Code of Federal Regulations) 0.735-1 through 0.735-23, should serve as guidelines. Further guidance may be sought from the District Counsel.

4.07 FEE-BASIS AND CONTRACT DIALYSIS IN NON-VA DIALYSIS FACILITIES

a. General Policy. Subject to eligibility limits on non-VA provided care, if the required dialysis care cannot be provided directly to a VA patient (such as if the patient lives too far from the VA dialysis unit to return for treatments, or the VA dialysis unit is overtaxed) or by another Federal Government facility under contract with VA, treatments may be provided in non-VA facilities, such as fee-basis or contract dialysis, or by using VA equipment placed in a non-VA hospital by means of a revokable license.

b. Conditions for Provision of Contract/Fee-Basis Dialysis

(1) Fee-basis or contract dialysis for a patient on OPT/NSC status without any other special eligibility for outpatient care supported by VA will not be authorized until full consideration has been given to other possibilities of financial support, such as Medicare and other third-party payers. Where such resources are adequate the NSC patient will be discharged to continue care in a non-VA unit not at VA expense.

(2) Only if it is determined by the facility staff that resources such as Medicare would be clearly insufficient, should approval of fee-basis or contract dialysis care for a veteran who is otherwise eligible for non-VA care be made by the Director of a VA facility with a designated dialysis program.

(3) Any NSC patient placed on contract and/or fee basis dialysis should be reevaluated periodically to determine eligibility (if the patient has become eligible) for other modes of support (such as Medicare) which may permit discharge from the VA program.

(4) A 1-year limitation is placed on OPT/NSC care unless an extension is authorized. Hospitalization of OPT/NSC patients in non-VA facilities (such as for treatment of serious complications during contract dialysis) ordinarily cannot be authorized and paid for by VA.

(5) No person will be admitted to a VA medical center for the sole purpose of placement on OPT/NSC treatment.

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NOTE: VA patients, or potential patients, on contract or fee dialysis should be informed of such limitations.

c. Limitations on Authority for VA Medical Centers Without Dialysis Programs to Authorize Contract or Fee Dialysis

(1) VA medical centers without a dialysis program will not independently authorize fee-basis or contract dialysis care despite clinic of jurisdiction or similar authority,

except in connection with ongoing contract hospitalization, or in order to provide authorized emergent medical care to veterans eligible for such contract care under provisions of 38 U.S.C. 1703.

(2) Individuals inquiring about care in the VA Dialysis Program will be informed of the limitation on VA payment for care in non-VA facilities, and will be referred to the closest VA Dialysis Program for evaluation of administrative eligibility using established criteria and priorities, and medical assessment.

(3) The VA facility closest to the patient's home, or the clinic of jurisdiction, may carry out administrative aspects of contract or fee-basis dialysis after such treatment is authorized by the Director of a VA medical center having a Dialysis Program.

4.08 REPORTING

a. Automated Management Information System (AMIS) Report. (Segment J-19. 8JD2, RCS 10-0049). Each VA facility with an authorized Chronic Dialysis Program and/or supporting patients on contract/fee-basis dialysis will submit the appropriate AMIS report quarterly summarizing the Dialysis Program activity for the report period. Care must be taken to avoid "double-counting" or other duplicate reporting of the same patients cared for in several VA programs (e.g., a center and its satellite).

b. USRDS. VA has agreed to participate in the USRDS being developed for the National Institutes of Health (NIH) with the cooperation of the Health Care Financing Administration (HCFA). ESRD patient information should be submitted in accordance with instructions.

4.09 BUDGETING CONSIDERATIONS

When fee-basis or contract dialysis is utilized, VA payment will ordinarily be limited to the amount that Medicare has authorized that facility to receive for providing the same service to Medicare beneficiaries. VA may pay 100 percent of the approved charge while Medicare may deduct coinsurance and deductible amounts.

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RESCISSIONS

The following material is rescinded:

1. Manual

M-2, Part IV, Chapter 5, dated October 23, 1990

CHAPTER 5. OUTPATIENT OXYGEN THERAPY

5.01 POLICY

It is the Department of Veterans Affairs (VA) policy to provide outpatient oxygen therapy to eligible veterans when medically indicated.

5.02 SCIENTIFIC BACKGROUND

a. The use of oxygen therapy in the home on a long-term basis is common practice and can benefit patients with chronic hypoxemia while decreasing their medical care costs.

b. Complications of hypoxemia usually occur below an arterial oxygen tension of 55 mm Hg. A number of beneficial effects of long-term oxygen therapy have been clearly documented:

- (1) Reduction in pulmonary arterial pressure and polycythemia,
- (2) Improvement in neuropsychologic performance,
- (3) Increase in exercise tolerance,
- (4) Reduction in the number of hospitalizations, and
- (5) Improvement of the quality of life.

c. In patients with hypoxemic chronic obstructive lung disease (COPD) it has been shown that mortality rate is improved by oxygen with the best prognosis in those using oxygen 24 hours a day.

NOTE: In conditions other than COPD, the same guidelines for oxygen use are generally accepted. Oxygen is usually effective when delivered at rates between 1 and 4 liters per minute.

c. Patients may develop marked hypoxemia only during exercise or sleep. Oxygen supplements during sleep and exercise may be helpful to people who have hypoxemia only during these activities.

5.03 POTENTIAL PROBLEMS IN OUTPATIENT OXYGEN THERAPY

a. Patients with hypercapnia (elevated PaCO₂) may have further elevation of PaCO₂ associated with uncontrolled oxygen use. This is usually not a problem in the chronic stable patient, but only in the setting of acute illness.

b. The effectiveness of oxygen therapy may be reduced and associated risks are increased in patients who continue to smoke. Careful evaluation of the

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risk and/or benefit ratio should be done before starting or renewing oxygen therapy for smokers.

5.04 PATIENT SELECTION AND CLINICAL INDICATIONS

a. The patient should be on an optimal complete medical regimen. The determination to prescribe supplemental oxygen should be made by a physician knowledgeable in the treatment of chest diseases. Smoking cessation should be strongly recommended.

b. Documentation of one or more of the following indications for chronic oxygen supplementation should exist before oxygen is prescribed:

(1) Resting arterial oxygen tension (PaO₂) below 55 mm Hg while the patient is breathing room air for 20 to 30 minutes, in a stable clinical state. Thus a patient at time of discharge from hospital with an acute respiratory illness would not be considered "stable". In such a situation it will be appropriate to repeat pO₂ or saturation measurement in 3 or 4 weeks after discharge on room air before making commitment to long term oxygen therapy. Short term oxygen therapy until stability is achieved may be appropriate in some of these patients.

(2) Desaturation by oximetry with a saturation below 88 percent at rest, with exercise, or during sleep, also in a stable clinical state as defined.

(3) Resting arterial oxygen tension (paO₂) of 60 mm Hs or less with hypoxic organ dysfunction such as cor pulmonale, erythrocytosis, or hypoxia associated altered mentation.

5.05 MODE AND DURATION OF THERAPY

a. Most patients show an acceptable improvement of arterial oxygen tension on oxygen at 1 to 4 liters per minute. A few patients, particularly those with restrictive lung disorders, may require higher flow rates (e.g., 5 to 8 liters per minute). In these patients, the need for higher oxygen flow rates should be documented by an arterial blood gas or saturation measurement with the patient receiving oxygen.

b. Patients with chronic lung disease and hypoxemia who have been appropriately selected for long term oxygen therapy by establishing that they are in a stable state, usually require treatment permanently.

5.06 TYPES OF OXYGEN EQUIPMENT AND SERVICES

a. The physician responsible for the Respiratory Care Program should be familiar with both the medical and economic aspects of the various methods of delivery. When low flow oxygen is prescribed, it is usually more economical to use an oxygen concentrator. The use of certain fixed flow gauges may prevent waste through unnecessarily high flow rates when tank oxygen is used.

b. Oxygen conserving cannulae, pulse dose delivery devices, and transtracheal catheters are reported to reduce the oxygen consumed by 50 to 75 percent and may be particularly useful with portable systems. It has been demonstrated in several locations that the purchase of concentrators is more economical than rental contracts. The use of liquid oxygen systems, which are substantially more costly, should be limited to those whose activity level will allow them to benefit.

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5.07 PERIODIC REVIEW

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These patients should be clinically and physiologically reevaluated for oxygen therapy every 6 months for the first year and at least yearly thereafter in conjunction with the patient's regular medical evaluation. Since most properly selected patients with chronic lung diseases require treatment indefinitely, these evaluations will confirm and document the need for oxygen and the appropriate continuing flow rates.

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RESCISSIONS

1. Manuals

M-2, Part IV, Chapter 6 dated October 23, 1990

CHAPTER 6. INFECTIOUS DISEASES

6.01 POLICY

It is the Department of Veterans Affairs (VA) policy that treatment, control, and prevention of infectious diseases in all VA health care facilities be similar.

6.02 THE ADVISORY COMMITTEE ON INFECTIOUS DISEASES

a. A VA Central Office Advisory Committee on Infectious Diseases exists to advise the Associate Deputy Chief Medical Director (ADCMD) for Clinical Programs on policy.

(1) The Director, Medical Service, acts as liaison through the Program Director in Infectious Diseases.

(2) The committee ordinarily consists of the Infectious Disease Field Advisory Group (Medical Service) under the direction of the Program Director in Infectious Diseases, who is specially trained in this medical subspecialty.

b. Some of the areas in which the committee might make recommendations include:

(1) Work force;

(2) Design of health care and extended care facilities, including the Microbiology Laboratory;

(3) Policies on prevention and control of communicable diseases;

(4) Policies on the use of antimicrobials and anti-infectious biologics;

(5) Training recommendations;

(6) Policies on methods of infection surveillance and data analysis;

(7) Infection Control Program;

(8) Advice on the development and adoption of new laboratory procedures;

(9) Development of specialized resources within selected laboratory Services;

(10) Acquired Immunodeficiency Syndrome (AIDS) (in conjunction with the AIDS Service); and,

(11) Tuberculosis (TB).

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6.03 HOSPITAL INFECTION CONTROL COMMITTEE

Each health care facility should establish an Infection Control Committee (see M-1, Pt. I, Ch. 26 , par. 26.07 and App. 26A; and MP-3, Pt. III, Ch. 32, par. 32.29). A physician, specially trained in Infectious Diseases, should be chairperson of this committee. The Hospital Infection Control Committee may serve as a consultant to the Safety, Occupational Health and Fire Protection Committee on matters relevant to infection control.

6.04 INFECTIOUS DISEASES SECTIONS

a. Infectious Diseases Sections should be formed as a subspecialty under Medical Service at all health care facilities where feasible. The functions of such a section are to:

(1) Provide optimal patient care with relation to infectious diseases by consultation throughout the facility. This would include the consideration of inpatient and outpatient problems.

(2) Conduct the business of the Infection Control Committee, including policy recommendations in such areas as:

(a) Procedures for isolation and prevention of infection,

(b) Environmental sanitation,

(c) Infection surveillance,

(d) Epidemiologic studies,

(e) Employee health (where communicable diseases and/or infection is involved), and,

(f) Immunization programs.

(3) Advise appropriate local facility committees regarding:

(a) Selection and control (restriction) of antimicrobials, and,

(b) Audit of antimicrobial usage.

(4) Provide guidance for activities under the Infection Control Program.

b. The Chief, Infectious Diseases Section, or designee, should have close liaison with Pathology and Laboratory Medicine Service, and work actively with the Chief, Pathology and Laboratory Medicine Service, on the development and implementation of programs and policies in the Microbiology Section, Pathology and Laboratory Medicine Service, particularly with regard to staffing, space, and equipment. The Chief, Infectious Diseases Section, should consult with appropriate members of Pathology and Laboratory Medicine Service regarding:

(1) The collection of specimens, the establishment of priorities for collection of specimens,

(2) The establishment of priorities for cultures, susceptibility tests, new diagnostic procedures, and

(3) The compilation of laboratory data for epidemiologic evaluation.

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c. The Section Chief should work with the Associate Chief of Staff for Education, or appropriate staff of other services, to maintain a program of inservice education. This program will provide improved knowledge of infectious diseases to appropriate medical center personnel.

NOTE: The Section Chief should maintain a liaison function with other local hospitals and public health authorities in the community regarding infectious disease problems.

6.05 INFECTION CONTROL PROGRAM

The prevention and control of infections in all VA health care facilities will be addressed through Infection Control Programs that are similar in design. The regional offices may review each medical center's Infection Control Program in conjunction with a planned systematic review process, utilizing criteria developed in concert with the Infectious Diseases Program Office. The Infection Control Programs must meet current requirements from external regulatory agencies and comply with written VA requirements and guidelines.

a. Each VA health care facility will institute an Infection Control Program. The Infection Control Program is under the auspices of Medical Service, specifically under the Infectious Diseases section, if feasible, with oversight function provided by a multidisciplinary hospital Infection Control Committee.

b. Control activities directed toward the prevention of nosocomial infections and the control of infections are integral components of the Infection Control Program. Control functions are performed by the Infection Control staff and other facility personnel through a cooperative effort to prevent and/or control infections in patients, personnel, families, and visitors. Considering that an Infection Control Program cannot be effective without control activities, each facility must have in place control activities to include, but not limited to:

(1) Written policies and/or procedures that:

(a) Define the indications for specific precautions to prevent transmission of infection;

(b) Give authority to person(s) in infectious diseases control and registered nurses to implement isolation procedures in an emergency without a physician's order;

(c) Describe the role and scope of each service in infection prevention and control activities;

(d) Describe the handling and disposal of refuse considered by regulation(s), laws, or statutes to be regulated medical waste and/or infectious waste;

(e) Identify the role and scope of employee health (see MP-5, Pt. I, Ch. 792; MP-3, Pt. III, Ch. 32; and M-1, Pt. III, Ch. 4) for reporting infections, evaluation and intervention as appropriate for exposure of employees to a potentially communicable agent;

(f) Address cleaning, disinfection, decontamination and sterilization issues;

(g) Address separation of soiled and contaminated supplies from clean and sterile supplies; and

(h) Handle the purchase of chemical supplies and equipment related to infection control in the facility.

(2) Monitoring staff compliance with specific patient care practices and/or procedures and/or policies as they relate to infection control issues.

(3) Mechanisms for obtaining consultation from person(s) in infectious diseases control regarding equipment, supplies, renovation and construction with infection control implications.

(4) Educational efforts directed toward infection control topics for orientation classes for new employees and in-service training for relevant employees.

c. Control activities will be reviewed to determine effectiveness, revised, modified, and changed, as necessary, since the appropriateness of control activities depends heavily on the surveillance findings and the circumstances within the individual facilities.

d. Written infection control documents will be updated at the facility level when clinically indicated, or based, on most current written rules and regulations generated by the VA and/or valid oversight regulatory bodies.

e. Surveillance activities. The major goal of an Infection Control Program is to lower the risk of a hospital acquired or associated infection. Surveillance activities have a significant influence on the control activities employed to achieve the goal of a lower risk for a hospital acquired or associated infection. NOTE: Surveillance, when applied to disease, may be defined as "the continuing scrutiny of all those aspects of the occurrence and spread of disease that are pertinent to effective control."

(1) Such a surveillance system, designed to establish and maintain baseline infection rates, gives a facility an indication of its endemic infection rates. These rates represent the frequency with which a specific type of infection occurs within the total or targeted population in a particular facility based on past surveillance. Knowledge of the endemic rate(s) enhances recognition of a situation to be reviewed when the infection rate(s) rise above the endemic rate(s). Equally true, the drop of infection rate(s) below the endemic rate(s) may signify the effectiveness of in place infection control activities.

(2) An ongoing system of surveillance is an integral component of an Infection Control Program. Inherent in the system should be detection of and control of outbreaks of infections. Being mindful of the major infection sites (bloodstream, lungs, surgical wound, and urinary tract), the surveillance system should be so planned to provide baseline data on each over a designated period of time.

(3) Each facility will establish a written system of surveillance to include, but not be limited to, the following elements:

(a) Definition of the events to be surveyed;

(b) Definitions of nosocomial infections with criteria for determining presence or absence of infection;

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- (c) Systematic collection of relevant data;
- (d) Tabulation of the data;
- (e) Qualitative and quantitative (if appropriate) analysis and interpretation of the data; and

(f) Preparation and dissemination of findings to individuals, groups, and/or committees, as appropriate.

NOTE: A critical element of the program is feedback of accumulated data to those individuals, groups, and committees who can most benefit from this information.

f. The determination of rates is a key factor in the analysis portion of the surveillance system. Consistency in the use of the term and calculation of rates is a crucial issue.

(1) Rate is a numerical statement of the frequency of an event per unit of time obtained by dividing the number of events or the number of individuals experiencing the event (numerator) by the total number capable of experiencing the event (denominator or population at risk during the specific time interval) and multiplying by a constant such as 100, 1,000 or 10,000.

(2) A rate measures the probability of occurrence in a population of some particular event, such as cases of disease. The following is the basic formula for rates:

$$\text{Rate} = \frac{\text{Numerator}}{\text{Denominator}} \times \text{Constant}$$

(a) Numerator = the number of times the event (e.g., infections) has occurred during a specified time interval.

(b) Denominator = a population (e.g., number of patients at risk) from which those experiencing the event were derived during the same time interval.

(c) Constant = a whole number (100, 1,000, 10,000 usually used). Selection of the whole number is usually made so that the smallest rate calculated has at least one digit to the left of the decimal point.

(d) Incidence density is determined by making the denominator the number of patient-days at risk during the period of surveillance.

g. Data can be expressed using analytical statistical methodologies or other descriptive statistical methods such as:

(1) Ratio is the expression of the relationship between a numerator and denominator which may involve either an interval in time or may be instantaneous in time;

(2) Proportion is an expression in which the numerator is always included in the denominator, and the base is equal to 100. Therefore, a proportion is expressed as a percent; and

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(3) Index is the best available approximation to a true rate. This occurs when one is unable to count directly the number at risk (denominator) and something else is used which one can count to give an impression of the number at risk.

h. Through the utilization and implementation of standing requests (see M-1, Pt. I, Ch. 9) VA facilities will report diseases (disclosure of information related to infection with the Human Immunodeficiency Virus (HIV) to public health authorities will be discussed

as a separate issue, (see M-1, Pt. I, Ch. 9) as required by State law for State, county, and city health departments in accordance with the provisions of the Privacy Act of 1974 (5 United States Code (U.S.C.) 522a), and the VA confidentiality statutes, 38 U.S.C. 5701 and 7332.

(1) A purpose of this disclosure is to cooperate with a state reporting requirement.

(2) The required data will be furnished without the written consent of the patient.

(3) Disclosure of information related to infection with HIV will be made to public health authorities, providing the disclosure is in accordance with M-1, Part I, Chapter 9, and M-2, Part I, Chapter 23. Disclosure of the information will be so documented in the patients' medical record as required by the Privacy Act and 38 Code of Federal Regulations (CFR) 1.576(c).

(4) Each facility will develop in writing a system for reporting diseases to include but not limited to:

(a) Administrative management of the standing request and facility responses (see M-1, Pt. I, Ch. 9);

(b) Designated responsibility for report submission;

(c) Notification within the facility to the facility designated reporting official of a disease to be reported; and

(d) Documentation expectations at the facility level.

6.06 STAFFING GUIDELINES

a. Recommendations for staffing of Infectious Diseases Sections should include the following:

(1) A physician section chief (specifically trained in Infectious Diseases and who has taken at the minimum one training course in hospital infection control).

(2) In addition, one staff physician for each 200 to 250 general medical and surgical (GM&S) beds. In areas of high incidence of persons who are HIV positive or with Acquired Immune Deficiency Syndrome (AIDS), additional staffing in accordance with facility need will be necessary.

(3) At least one full-time practitioner of infectious diseases control with the same distribution as staff physicians in subparagraph (2). In areas of high incidence of persons who are HIV positive or with AIDS, additional staffing in accordance with facility need will be necessary.

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(4) Subspecialty resident positions in Infectious Diseases where appropriate and specific infectious diseases training positions in AIDS may be of value.

(5) One unit secretary and at least one clerical support person whose duties include, but are not limited to typing for the Infection Control Program.
NOTE: This is critical to the functioning of the section and the Infection Control Program.

b. If no Infectious Diseases Section exists in the facility, then availability should be ensured by a physician specifically trained in infectious diseases, who has taken at the minimum one training course in hospital infection control.

NOTE: The Laboratory Service should have skilled (Ph.D. level or equivalent) leadership in the Microbiology Section and be staffed adequately to ensure provision of necessary services.

6.07 EQUIPMENT AND SUPPORT

The healthcare facility should furnish whatever space, equipment, office supplies and other clerical services necessary for the effective operation of the section and the Infection Control Program. This includes:

- a. Appropriate data processing equipment (or access to such items);
- b. Supplies to fulfill the mission of the section and the Infection Control Program; and
- c. Adequate funds for the training and continuing education of the infectious diseases staff and infection control personnel.

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RESCISSIONS

The following material has been rescinded:

1. Manuals

M-2, Part IV, Chapter 7, dated October 23, 1990

CHAPTER 7. SICKLE CELL SCREENING AND COUNSELING PROGRAM

7.01 POLICY

a. Title 38 United States Code (U.S.C.) Sections 1751 through 1754, authorizes a Sickle Cell Anemia Program within the Department of Veterans Affairs (VA). The specific provisions of this authority state that:

(1) Screening, counseling and medical treatment are available to all eligible sickle cell anemia patients (see par. 7.05);

(2) Participation by the patient will be voluntary;

(3) An annual report shall be prepared on the administration of this program, including recommendations for additional legislation which may be deemed necessary.

b. The Chief Hematologist at the facility having a VA Sickle Cell Screening and Counseling Program has overall administrative responsibility for the program.

7.02 SCOPE

The objectives of the Sickle Cell Screening and Counseling Program are to:

a. Provide a Voluntary Screening Program for all patients who are recognizable as risks for hemoglobin (Hb) S and/or glucose-6-phosphate dehydrogenase (G-6-PD) deficiency who are admitted to the medical center, or who are eligible for treatment in the outpatient clinic.

b. Provide a Voluntary Educational Program on the basic medical and genetic aspects of the hemoglobinopathies and enzyme deficiency to all such patients and their spouses.

c. Educate physicians, registered nurses (R.N.s), and other VA personnel regarding sickle cell disorders and G-6-PD deficiency.

7.03 PATIENT SELECTION

a. Persons otherwise eligible for VA bed care or outpatient treatment are potential candidates for participation in the Sickle Cell Program (see 38 CFR (Code of Federal Regulations) Section 17.135.)

NOTE: Where applicable and medically indicated, spouses of patients may participate in the program but actual treatment is limited to eligible veterans.

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b. Preliminary screening of persons for identification of potential candidates will be performed in the admissions office.

c. A patient's racial background or ethnic origin will be ascertained and placed in lower right corner of item 1 of VA Form 10-10m, Medical Certificate and History.

d. For uniformity of data analysis, race or ethnic origin and codes for race contained in coding instructions in MP-6, Part XVI, Supplement No. 4.1, for the Patient Treatment File Program will be used. A rubber stamp or other suitable means similar to the following will be used for designating the appropriate race of the applicant:

Race or Ethnic Origin of Applicant

- (1) Hispanic White
- (2) Hispanic Black
- (3) American Indian or Alaskan Native
- (4) Black not of Hispanic Origin
- (5) Asian or Pacific Islander
- (6) White not of Hispanic Origin
- (7) Unknown

7.04 PATIENT CONSENT

a. Except for preliminary screening in the admission office, participation in the Sickle Cell Program by the applicant will be voluntary, and will not be a prerequisite for any other VA benefit.

b. An Standard Form (SF) 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, will be used to obtain the applicant's written consent.

(1) Item A 1 of SF 522 will include the statement "Participation in Sickle Cell Screening and Counseling Program."

(2) Item B 1 of SF 522 will include the statement "Necessary laboratory examination(s) for hemoglobinopathies."

(3) All other applicable items on SF 522 will be completed.

7.05 DRAWING BLOOD SAMPLES

Blood samples for testing will be obtained, if available, from the clinical laboratory using the residue of blood that has been obtained for routine blood counts or other ordered laboratory tests when possible.

7.06 LABORATORY METHODOLOGY

a. Hemoglobin Electrophoresis

(1) A number of accurate techniques are available for determining the hemoglobin type present.

(2) Testing should be done in a College of American Pathology (CAP) approved laboratory.

(3) To verify the presence of hemoglobin S, solubility tests should be performed. Techniques that can be applied for the confirmation of abnormal hemoglobins are:

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- (a) Citrate agar electrophoresis at pH 6.1, isoelectric focusing, and
- (b) Globin chain electrophoresis.

NOTE: The Reference Laboratory for the program is located at the VA Medical Center, Jackson, MS, and is available for questionable results and difficult problems.

b. Glucose-6-phosphate Dehydrogenase. The fluorescent spot test will be used to detect the presence or absence of G-6-PD deficiency. NOTE: The reference laboratory at the VA Medical Center, Jackson, MS, is available for questionable results.

7.07 REPORTING RESULTS ON SICKLE CELL DISEASE

a. Results of all tests are recorded on a laboratory form and filed in the patient's medical record.

b. The laboratory will maintain a log identifying each patient by name, Social Security Number, hospital location, and results. These data are used in the compilation of:

- (1) The annual report, and
- (2) Quality assurance.

c. All persons tested will be given VA Form 10-1450, Identification Card, that indicates the results of the tests.

7.08 EDUCATIONAL SESSIONS

a. The hematologist will determine the best technique for the method of conducting educational programs for patients, their spouses and facility personnel. One of the effective methods is to hold daily or tri-weekly sessions of all patients (screened or otherwise) conducted by the counselor, utilizing such modalities as brochures, film strips, movies and lantern slides with appropriate narration. A question and answer period can be instituted following the formal session.

NOTE: Training of counselors will be the responsibility of each participating hospital.

b. If possible, educational exhibits, with educational brochures, describing sickle cell disorders may be constructed and placed in the lobby of the medical facility making this information available for, and acting as a reminder for personnel and visitors.

NOTE: Availability of nearby sickle cell centers for non-VA beneficiaries can be disseminated through such exhibits.

7.09 STAFFING

a. In a hospital that is able to screen 1,000 new patients per year, one medical technician, grade GS 5-7, and one counselor, grade 7-9, can effectively handle the program. If a hospital were able to screen only half this amount, a single Full-time Employee Equivalent (FTEE) capable of both counseling and the

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laboratory support work would be required. NOTE: A prototype job description for a GS-7 Counselor is available from the Office of Human Resources Management, VA Central Office;

b. The position of counselor requires a practical understanding of the methods and techniques used in interviewing and counseling. NOTE: There are numerous centers and considerable resource materials available for training in counseling and the introduction of educational concepts. The counselor must have the ability to:

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(1) Communicate effectively with black veterans and their spouses and with persons from other population groups who may be tested with respect to the highly sensitive area of sickle cell disorders;

(2) Develop sufficient knowledge of the medical and genetic aspects of the significance and implications of these problems; and

(3) Adapt and create, with imagination and skill, teaching aids and information materials.

NOTE: A 1-week course or apprenticeship in counseling techniques is desirable before initiating the program.

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part IV, Chapter 8, dated October 23, 1990

CHAPTER 8. ALLERGEN THERAPY

8.01 POLICY

It is the Department of Veterans Affairs (VA) policy to provide allergen therapy to all eligible veteran patients, when medically indicated.

8.01 ALLERGEN EXTRACTS

a. Source. Allergen extracts for testing and therapy are supplied by a centralized VA Program in cooperation with the United States (U.S.) Army, Walter Reed Army Medical Center through the United States Army Centralized Allergen Extracts Laboratory (USACAEL).

b. Administration. The program is administered by the Program Director for Allergy, at VA Lakeside Medical Center, Chicago, IL, in consultation with the VA Allergy Advisory Group.

c. Requests. All requests for allergen diagnostic or treatment extracts must come to the Program Director for Allergy. Only VA centers serviced by a Board Certified Allergist (or equivalent credentials as determined by the Program Director for Allergy) will be eligible for this program. All requests will be in a standard format as set out by VA and USACAEL.

8.02 SELF-ADMINISTRATION OF IMMUNOTHERAPY (IT)

a. Under past policy, self-administration of allergenic material was permitted in exceptional cases.

b. New policy dictates that under no circumstances will these potent extracts from VA and/or USACAEL be self-administered by the veteran patient. All allergen testing and treatment must be given by trained personnel in a setting where there is access to adequate measures to treat an anaphylactic reaction.

c. The certified allergist prescribing IT is responsible to ensure that the personnel administering IT in a VA medical center, VA outpatient clinic, or other outside setting, are adequately versed in this type of therapy and the treatment of adverse reactions, which rarely occur.