Palo Alto VA Hospital
Address: 3801 Miranda Avenue (111-ONC), Palo Alto, CA 94304
Main number 650-493-5000
Operator 0

Admission/bed facilitator
Shelly 66969, pager 11773

Floors/rooms
Oncology clinic workroom 69383, 69382
AIC 65983, 68854
Clinic A 65863, 63919 (scheduler)
Clinic B 65844, 65862 (scheduler)
2A 65511, 65512
3C 64870
4C 65492
IICU 62200
MSICU 63833
Emergency Department 65470
ENT clinic 64046
Resident's Admission Pager 27113
Team A work room 66431, 64070, 65515
Team B work room 63805, 61106
Team C work room 66115, 61108, 69939
Team D work room 61104, 64078
Team E work room 69360, 69361, 69362
Defenders Lodge 61846 or 62819 or 61337
Fisher House 69914
CPRS Help 62777
IT Help Desk 64767

Labs
Blood bank 65522, 65842
Chemistry 65517
Cytology 64593
FNA team 66724, pager 13932
Hematology 65728 (also for bone marrow biopsies)
Pathology 63033, surgical path 65092
Path molecular markers – e-mail Kristin Jensen (kjensen1@stanford.edu) to request
Pathology Slides Drop-off E4-319

Pharmacy
Raj Joshi 64966, pager 11658
Inpatient 66489, 68536
Outpatient 61292
Heme-Onc VA Personnel
Millie Das, MD 66133, pager 14225, cell 650-776-6754
Maliha Agloria, MD 64348, pager 650-363-6625
Harlan Pinto, MD 64205, pager 13151, cell 650-380-3543
Charlotte Jacobs, MD 67890, pager 13345, cell 650-387-1995
Albert Lin, MD 69523, pager 415-607-1185 cell 669-204-2874
Allyson Spence, MD, PhD pager 13616, cell 650-575-8430
Manali Patel, MD pager 12159, cell 650-485-9462
Lakedia Banks, RNP (oncology) 65848 pager 11708
Patti Marton, RNP (oncology) 64169, pager
Connie Yabes-Sabolboro (inpatient chemo nurse) 64129, pager 11605, cell 415-652-9032
Mary Thomas, RN (hematology) 65509
Heather Cousins, MD (4C) 68820, pager 23556
Susan Price, MD (4C) 68620, pager 650-329-6453
Karen Chwick, LCSW (social work) 63967, pager 11826
Nikol Keeling 64948 Fax 650-849-1213
Travel office (travel pay) 65686
Decedent affairs 65432

Radiology
Reading room 65528
CT scheduling 65528
PET/CT scheduling 65520
MRI scheduling 65677
IR 68800
Xray 65959
Request for burning of radiology discs: hand-deliver discs to Paul or Mike in radiology (he will upload while you wait and return the discs to you)

Radiation Oncology
Radiation Oncology Clinic at Stanford 650-498-6339
Top 10 Keys to Being a Successful Fellow at the PAVA

1. Prepare for clinic by reading about your patients beforehand, especially new patients
2. Keep a running list/spreadsheet of the inpatients with pertinent labs/studies included, including a “to do” list for outpatient f/u
3. Assume responsibility for the oncologic management and follow-up of inpatients
4. Consider logistics when determining f/u and treatment plans for your patients, including need for transportation, housing, etc.
5. Learn to delegate appointment scheduling, logistics, to the appropriate team members (social work, AIC nurses, pharmacist, attendings, oncology NP/PA)
6. Cite at least 1 peer-reviewed article in your note, indicating that you are using evidence-based medicine in your w/u or treatment recommendation
7. Don’t fall behind on your notes (new consults need to be staffed and notes completed within 24 hrs)
8. Be on time and be a team player in clinic
9. Develop a checklist to prepare for scheduled procedures (IT chemo, BM biopsy) and chemotherapy (labs, TTE, hepatitis panel, staging studies, etc)
10. When in doubt, ask an attending for advice on how to handle a situation; we are here to help you
VA Tips (compiled by Dr. Daniel King, edited by Dr. Millie Das)

-General Info:
-Typical day is 8am to 5:30pm, 6 days per week.
-Fellows room (temporarily during construction, and housing the Hem, Onc, and ID fellow): Building 101, 2nd floor, room A2-200, the door code is 5-4-1 & Enter Key.
-How to set up your printer: Start button, Device Printers, add printer, add by IP, in room A2-200 the printer IP address is 10.168.77.120
-The EMR for chemo is different from Beacon, it is VCM. To learn how to use it, discuss with Raj (pharmacist) or Mary Thomas (RN)
-During the VA, in-patient consult month, on the day when you are assigned VA onc clinic in the AM, you are not required to attend the PM continuity clinic on that day for that month, e-mail that attending to let them know you are at the VA hospital that month and have clinic in the morning.
-When you send an email with patient info, include "secure: " as a prefix in the subject line to encrypt the message

-Websites to know and consider adding as bookmarks:
-Amion (www.amion.com, password: PAVA) with your personal pager
-Paging https://smartpage.stanford.edu/
-Drug s/e: use up-to-date or https://www.micromedexsolutions.com/home/dispatch/ssl/true
-Cancer staging: https://cancerstaging.org/references-tools/quickreferences/Pages/default.aspx
-Lane Medical Library (for article access): http://lane.stanford.edu/index.html

-Useful Contact Info:
Administrative assistant: Nikol Keeling 64948
NPs: Patti 64169 (off on Mon) & Lakedia 65848 (off on Thurs)
Chemo pharmacist: Raj Joshi 64966, p11658
Pathology: Kristin Jensen 60022
Inpatient Chemo Nurse Specialist: Connie YS 64129; (c) 650 621 0654
Social worker: Karen Chwick (c) 650-444-7082
Onc Clinic Main Desk (clinic B) 65844
Onc Clinic Offices 64169
Ambulatory Infusion Center (AIC) 65983
Rad-Onc Radiation Oncology pager 12764
Vocera (to call an intern/resident, say their full name): 650-485-5092
Stanford Pager Operator: 650-723-4000
IT helpdesk: 64767
-Consults
-Every patient who is an oncology clinic patient is an automatic referral; do not wait for consults on these patients; a note should be placed in the chart on the day of admission if patients are admitted from clinic, or at the latest the day following if patients are admitted through the emergency room.
-The primary teams will page you with consults and should order an Oncology Consult to which you assign your original consult note. If there is no order and you need one to assign your note to, you can ask them to do it, or do it yourself using Orders→Medicine Orders→Consults→Oncology Consult.
-Writing a new note, go to Notes→New Notes→type Oncology Consult (new consult) or Oncology Inpatient (follow-up notes)
-Remember to link your new inpatient note to the open Oncology Consult, which will then close the consult.
-You can determine who is the primary team intern/resident by clicking "Orders" and look at the top box that says A/D/T. The intern's pager will be listed there.
-To create your own consult list in CPRS, click Tools--> Options --> Lists --> Personal Lists--> then type in the patient's names and add. Then set your list as the default list.
-To sign your note, you first need a signature password, which can be assigned to you by IT (through VISTA) if you don't yet have that set up.
-Once your note is completed (signed), then right click and click "Identify Additional Cosigner" and select the attending.
-There are two NPs, Patti and Lakedia who can help to answer questions about oncology patients who are not in house during daytime hours (8AM-5PM). For example, an outpatient's lab come back and the lab calls you with a potassium is 6, or someone who is getting outpatient infusions calls with pain and nausea/vomiting. Sometimes, these calls are mistakenly directed to the rotating Oncology fellow. You should politely redirect these calls to the NPs (office extension 65848 or 64169). The oncology fellow during day-time hours is only responsible for in-patients or patients in the clinics or ER who may need admission. Per Millie Das, discuss with her if this becomes an issue.
-When an outpatient oncology gets admitted/discharged, notify the primary outpatient oncology attending via e-mail or phone.
-When patients are discharged, please order their follow-up appointments and labs.
-If you are consulting Radiation Oncology and it is urgent, contact the rad-onc fellow on-call (p12764).
-To schedule a follow-up appointment, it is usually easiest to drop by the Oncology out-patient desk and talk to one of the schedulers in person.
-To get consent prior to chemotherapy, Tools-->IMEDCONSENT
-Chemotherapy orders must be reviewed and signed by a member of the admitting house staff team; please also connect with Connie Y-S, the inpatient chemotherapy nurse, to ensure everyone is on the same page.
-Daily progress notes (7 days a week) need to be placed for all chemotherapy patients, any patient in the MSICU or ICU, or complicated oncology patients.
Patients on 4C/Rehab (usually undergoing radiation) must be seen on weekend days and a brief note should be written that the patient was seen and vitals were reviewed.

Rounds
Rounds happen at different times and days depending on your and your attending's schedule. Chat the day before with your attending to get a ballpark for what may work depending on both schedules.
-You usually get paged late morning or midafternoon with consults. See and staff them within 24 hrs.
-Karen Chwicz is the social worker, so you can reach out to her if something complex needs coordination or if you have questions for a consult plan logistically.

Clinics:
-While doing your VA Onc Consults rotation you will typically have VA clinic on Friday mornings. It is located on the first floor, near the lobby.
-You will typically have three follow-up patients (9:30, 10, 10:30) and one-two new patients (11:00, 12:00). Note that the fellowship's Onc journal club is at Stanford at 8am, which is why flu patients aren't scheduled until 9:30.
-You can see the scheduled patients in CPRS by clicking File-> Select New Patient --> "Clinics", then typing Oncology in the search box below, then finding 1) Oncology - Fellow and 2) Oncology - New Fellow, and selecting the date in question from the dropdown.
-For new patients/consults being seen in the clinic, remember to link your note to the open Oncology Consult, which will then close the consult.
-Please complete an encounter for each patient you see in clinic (the VA version of billing); visit code for follow up is usually "Detailed (99214)" and for a new patient is usually "Comprehensive (99205)"; your attending is the primary provider and be sure to include diagnoses codes.
-Chemotherapy is ordered in VCM and orders can be queued to your attending.
-Remember to place a "Return to clinic" order for every patient you seen in clinic, specifying the grid, date/time, and AIC appt for the patient's next appointment (ask an attending to show you how to do this if you have not done it before); also remember to order the labs that need to be completed for the future appointment (usually CBC with diff and onco panel).
-Patients receiving long chemotherapy need to be scheduled and seen as early as possible since AIC closes at 4 pm; the AIC is closed on weekends so there is no chemotherapy administration on Sat/Sun, unless patient is an inpatient.
-For patients receiving chemotherapy over the weekend, please notify both Connie Y-S and Raj Joshi prior to 2 pm on Friday.
-Do not overbook patients and speak to Lakedia or Patti if you are having trouble scheduling a patient for a follow up visit due to insufficient grid space.
-To get consent prior to chemotherapy, Tools->IMEDCONSENT

E-consults:
-This is a consult for a patient who is physically not in-house
-E-consults will appear on the CRPS "splash page" that opens when you open CPRS. Make sure you write down their last name and last 4 digits of SSN, because once you click on it to open it'll disappear and you can't look that person up again.

-These are rare on Onc (compared to Heme). You do a chart biopsy, write a brief note (the title of this note is Oncology E-consult), discuss it with your attending, and co-sign your attending and the referring provider.

-Bone marrow biopsies:
In rare cases, you will do a BMBx. Call Heme lab at extension 65728 to coordinate. Call early (or 1 day in advance), since BMBx don't happen after 2 pm any weekday, none on weekends. You must put orders in CPRS for all lab testing (i.e. flow and cytogenetics) on a marrow except for the basic histology path report, which is automatic. Ask your Heme co-fellow about details since she will have done many on Heme.

-CME tumor board
Usually on the 4th Monday of the month, the Multidisciplinary Tumor Board conference takes place. Carole Fong will send you an e-mail to request the case you have chosen to present. Please discuss with the VA inpatient hematology fellow and choose 1 interesting/educational inpatient case to present from either the VA inpatient oncology or hematology service. The presentation should be 40 min total, with plan to have both the VA hematology and oncology fellow to present in a combined presentation (20 min each). Choose a case that would be of interest to the medicine housestaff and try to incorporate board-type questions and avoid going into too much detail regarding chemotherapy regimens, etc. Please contact Dr. Das or Dr. Pinto for any questions.
HEALTH CARE SYSTEM MEMORANDUM No. 00PO-15-04

SUBJECT: CLEAN DESK POLICY

1. **SUMMARY:** Health Care System Memorandum (HCSM) No. 00PO-12-04, Clean Desk Policy, dated August 15, 2015, is rescinded. Minor changes have been made.

2. **PURPOSE:** To provide guidance for a clean desk policy at the VA Palo Alto Health Care System (VAPAHCS) and secure methods for conducting business while maintaining the ability to work effectively. This policy will present a positive image to our customers, present paper reduction opportunities, aid in accounting for documentation, and reduce the risk of potential privacy violations of sensitive information.

3. **POLICY:** It is the policy of VAPAHCS to provide guidance, identify risks/vulnerabilities, and employ reasonable measures in the various health care working environments to protect sensitive information from misuse, loss, unauthorized access, unintended modification and disclosure.

4. **DEFINITIONS:**

a. **Sensitive Information:** Sensitive information is all Department of Veterans Affairs (VA) data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule, and information that can be withheld under the FOIA (Freedom of Information Act). Examples of VA sensitive information include the following: Individually Identifiable medical, benefits, and personnel information; financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information; information that is confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and other information which, if released,
Health Care System Memorandum No. 00PO-15-04
August 15, 2015

could result in violation of law or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs.

b. Secured Work Area: Work area that can be locked to prohibit entry and is accessible only to individuals with authorized access.

c. Unsecured Work Area: An open workstation or work area that cannot be properly secured to prevent unauthorized access.

d. Unattended: For the purposes of this policy, is defined in the context of an object or work area not being visible from where the individual is currently located and leaving opportunities for the object or work area to unauthorized exposure.

e. Incidental disclosure: Incidental use or disclosure of protected health information that occurs as a result of a use or disclosure permitted by the privacy regulation. They are not considered violations of the rule. The covered entity has met the reasonable safeguards and minimum necessary requirements. Examples of such incidental use or disclosures include using sign-in sheets in waiting rooms, maintaining beside patient charts, and engaging in confidential conversations that are overheard by others (despite reasonable measures to prevent such disclosures).

5. PROCEDURES:

a. Unsecured Common/Public Areas (Nurse’s Station, Registration Counter, Clinic Counter, Cubicle Offices without lockable doors, etc.):

   (1) Only sensitive information used to conduct business or health care activities should be visible on desktops or work areas, but should be protected when dealing with anyone without the “need-to-know”. When the sensitive information is not being used by staff, it should be protected by placing it facedown, covered, or secured in a manner to prevent incidental disclosure.

   (2) Be conscious of potential incidental disclosure of sensitive information during the course of daily business or health care activities. The area should be cleared of sensitive information when unattended and at the end of each working day, by locking the material in file cabinets or desk drawers behind the locked office door.

   (3) Discard printed paper-based materials using the locked confidential shredding bins. Do not use paper recycling containers to dispose of printed paper-based materials.

   (4) Do not use paper recycling containers, boxes, etc., as temporary storage of printed or sensitive materials under desks or computers, prior to discarding them in the locked confidential shredding bins.
b. Secured Areas (cubicles, shared or private office space with lockable doors):

(1) Double-locking is strongly recommended to protect sensitive information, this means locking desk drawers/filing cabinets and locking the office door when the office is unattended and at the end of each working day.

(2) Be conscious of potential incidental disclosure of sensitive information during the course of daily business or health care activities. The area should be cleared of sensitive information when unattended and at the end of each working day, by locking the file cabinets or desk drawers behind the locked office door.

(3) Discard printed paper-based materials regardless of its content using the locked confidential shredding bins. Do not use paper recycling containers to dispose of printed paper-based materials.

(4) Do not use paper recycling containers, boxes, etc., as temporary storage of printed or sensitive materials under desks or computers, prior to discarding them in the locked confidential shredding bins.

c. Health and Medical Records Filing/Storage Areas (Shared or Private work spaces with lockable doors):

(1) Should be limited to authorized personnel only for the purposes of conducting business or health care activities.

(2) As a temporary filing and storage area (clinic or treatment areas, record review areas, quality assurance areas, release of information, medical records section, radiology/nuclear medicine reading rooms, etc.), must be locked when unattended to ensure the security and prevent unauthorized access. Lock doors and desk drawers/filing cabinets when the office is unattended and at the end of each working day.

d. Other General Guidelines for Maintaining a Clean Desk:

(1) Do not leave keys in their locks or in places accessible to an unauthorized person.

(2) Sensitive materials including patient information (i.e., medical/health record), employee information (i.e., pay stubs, personnel actions, etc.) must not be stored in unsecured staff mail slots/boxes.

(3) Folders/ binders containing Personally Identifiable Information (PII)/Protected Health Information (PHI) are not to be stored in bookcases or cabinets/shelves that are not lockable.
There shall not be any storage of documents containing PII/PHI in rooms, office spaces, closets, etc., that are not designated as record storage areas. A contracted document storage facility must be utilized through arrangement with the Chief of Health Information Management Section.

Reduce waste in the work environment by creating, sustaining, and improving a clean, uncluttered work area.

VA identification (ID) badges, personal cell phones, and other personal items must be kept secured at all times when unattended.

Secure VA issued Information Technology (IT) assets, such as but not limited to encrypted laptops, Universal Serial Bus (USB) thumb drives, mobile phones, pagers, and other electronic devices.

Erase boards that contain sensitive information. Electronic boards must not display sensitive patient information.

Remove printed materials from fax machines, copiers, and/or printers immediately. Only authorized personnel are allowed to print extractions from the electronic record or to make copies from the paper chart.

Fax machines/printers in areas that do not have 24/7 attendance/surveillance and are not capable of restricting usage during off hours, must be kept in a locked area not easily accessible to those that do not have the need-to-know. Use the secure printing feature or remove paper trays during unattended hours to prevent automatic printing.

If possible, desks and furniture should be positioned so that sensitive material and computer monitor is not visible from public areas by individuals who do not have a legitimate need-to-know. If a computer monitor cannot be repositioned, a privacy screen must be in place.

Staff should challenge and/or question unauthorized or unfamiliar individual(s) entering their area, for identification. Individuals include other VA employees not assigned to their area.

Staff must ensure all storage (file cabinets/drawers/bookshelves) is cleared of sensitive information prior to vacating offices/work areas.

e. It is intended that employees will abide by this policy without compromising their ability to effectively perform their assigned duties. The policy is to be applied in the most effective means for the employee's work area. Non-compliance with the policy, and/or any suspected/potential privacy violations, should be reported to the supervisor and/or the facility Privacy Officer, and/or the Information Security Officer (ISO), within one hour of its discovery.
6. **RESPONSIBILITIES:**

   a. The Privacy Officer is responsible for assuring an appropriate clean desk policy is designed to improve the security and privacy of sensitive information, while allowing the means of conducting business. Other responsibilities include, but are not limited to the following:

      (1) Issuance of local policies and procedures consistent with national privacy policies, and appropriate to implement this clean desk policy, and monitoring compliance with such policies and procedures;

      (2) Providing guidance to VAPAHCS staff on privacy-related matters including the clean desk policy;

      (3) Assistance to supervisory staff and/or employees with barriers to compliance with the clean desk policy;

      (4) Investigating possible violations of the clean desk policy, and referring to the appropriate official/supervisor for corrective action; and

      (5) Timely reporting (must be within one hour) of all actual and/or suspected breaches of privacy to the Privacy and Security Events Tracking System (PSETS) as designated by the VA Privacy Program.

   b. The ISO responsibilities include, but are not limited to the following:

      (1) Application, monitoring, and implementing appropriate security controls to enforce the clean desk policy as it relates to information security;

      (2) Investigating possible information security related violations of the clean desk policy, and referring to the appropriate official/supervisor for corrective action; and

      (3) Timely reporting of all actual and/or suspected breaches of information security to the National Remedy System as designated by the VA Network Security Operations Center (VA-NSOC).

   c. Service Chiefs and Supervisors are responsible for monitoring areas under their supervision for compliance with the Clean Desk Policy, and reporting actual and/or suspected breaches of privacy to the Privacy Officer and/or ISO within one hour of knowing it, as appropriate.

   d. All VAPAHCS employees are responsible for:

      (1) Protecting the confidentiality of sensitive information utilized in their daily business activities by complying with all Federal laws and regulations, and VA, and VHA policies relating to privacy;
(2) Compliance with the clean desk policy and/or identifying specific barriers to compliance;

(3) Informing the supervisor, Privacy Officer, and/or ISO; as appropriate; of barriers to compliance with the clean desk policy; and

(4) Reporting all possible, suspected and actual breaches of privacy to the employee’s supervisor, Privacy Officer, and/or ISO within one hour of knowing it.

7. REFERENCES:
   a. VHA Handbook 1605.1, Privacy and Release of Information.
   b. VHA Handbook 1907.01, Health Information Management and Health Records.
   c. VHA Directive 1605, VHA Privacy Program.
   d. VA Directive 6502 Privacy Program.
   e. VHA Handbook 1605.2, Minimum Necessary Standard for Protecting Health Information.
   f. VA IT Directive 06-2, Safeguarding Confidential and Privacy Act-Protected Data at Alternative Work Locations.
   g. VA Handbook 6502.1, Privacy Violations Tracking System (PVTS).
   h. HIPAA, 45 CFR, Part 160 and 164.


9. RESPONSIBLE OFFICIAL: Privacy Officer.

Elizabeth Joyce Freeman
Director
1. **SUMMARY:** This Health Care System Memorandum rescinds Health Care System Memorandum No. 111-05-04. Some changes have been made.

2. **PURPOSE:** To provide high-quality care to cancer patients at this Health Care System by establishing weekly consultative and multidisciplinary cancer conferences. The conferences will present a format for review of diagnostic, staging and patient data for comprehensive patient treatment decisions, staff education and quality assurance.

3. **POLICY:** Multidisciplinary cancer conferences are conducted to provide consultative services to cancer patients. Physician representatives from all appropriate disciplines attend and participate in this activity. This interdisciplinary consultation is integral to the patient management process and patient outcomes. The cancer committee at VA Palo Alto Health Care System (VAPAHC) will follow and comply with the requirements outlined in the most current American College of Surgeon's Commission on Cancer, Cancer Program Standards 2004.

4. **PROCEDURES:**

The Cancer Care Committee at VAPAHCS assures that these conferences demonstrate the following:

   a. Physician representatives from surgery, medical oncology, radiation oncology, diagnostic radiology and pathology attend and participate in the cancer conferences.

   b. Attendance at cancer conferences should target at 80% for the five main disciplines list above.

   c. The Cancer Committee may modify the multidisciplinary attendance requirement for the conferences.

   d. Cancer Conferences are held weekly and monthly.

   e. The number of cases presented annually is 10% of the annual analytic caseload.
f. At least 75 percent of the cases discussed at cancer conferences are presented prospectively.

g. Documentation of these meetings meets the requirements of the American College of Surgeon's Commission on Cancer.

h. Cancer conferences may be hospital-wide, departmental, site focus meetings designated in advance as cancer conferences. The requirement for Tumor Board Conferences at VAPAHCS is met through these:

1. **Genitourinary CME Tumor Board Conference – monthly**
   
   (a) This tumor board conference discusses patients with genitourinary disease as well as cancer related cases.

   (b) Physicians schedule cases or presentation to the Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed for pathology and radiology review at least one week prior to the meeting.

   (c) The Cancer Conference coordinator notifies members of the Board of the selected patients by electronic mail and fax. Meeting notices are distributed throughout the facility.

   (d) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Surgery, Pathology, and Diagnostic Radiology. All care providers, Residents, Fellows, Medical Students are encouraged to attend. Continuing Medical Education (CME) credits are available for this conference.

   (e) The Genitourinary CME Tumor Board Conference meets monthly on the third Tuesday, in the Pathology Conference Room, Bldg 100, 4th Floor, PAD.

   (f) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in Computerized Patient Record System (CPRS) by the managing physician.

2. **Multidisciplinary CME Tumor Board Conference – monthly**

   (a) This conference discusses patients with various malignancies who present diagnostic problems.

   (b) Physicians schedule cases or presentation to the Multidisciplinary CME Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed for pathology and radiology review at least one week prior to the meeting.
(c) The tumor board coordinator notifies members of the Board of the selected patients by fax and electronic mail. Meeting notices are distributed throughout the facility.

(d) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Diagnostic Radiology, Radiation Oncology and General Surgery and Pathology. All other multidisciplinary staff, residents, fellows and medical students are encouraged to attend. CME credits are available for this conference.

(e) The Multidisciplinary CME Tumor Board Conference meets monthly on the fourth Monday in the Auditorium at PAD, Building 100, 1st Floor at noon.

(f) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

(3) **Otolaryngology – Ear, Neck & Throat (ENT) Tumor Board – weekly**

(a) Meetings are conducted at the ENT, Head & Neck Tumor Board Conference, Stanford, with VAPAHCS physicians in attendance. They are encouraged to present patients with malignancies who present diagnostic problems.

(b) The VAPAHCS ENT department is responsible for scheduling and coordinating the presentation of patients at this conference. Documentation, including attendance and cases presented, are forwarded to the Cancer Registry.

(c) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Surgery, Diagnostic Radiology, Radiation Oncology, and Pathology. All multidisciplinary staff, residents, fellows and medical students are encouraged to attend. CME credits are available for this conference.

(d) The ENT tumor board meets weekly on every Thursday at Stanford Cancer Center, Clinic B at 10am.

(e) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

(4) **Pulmonary - Thoracic CME Tumor Board Conference – monthly**

(a) This multidisciplinary case review conference discusses patients with pulmonary/chest diseases as well as cancer related cases.

(b) Physicians schedule cases or presentation to the CME Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed for pathology and radiology review at least one week prior to the meeting.
(c) The Pulmonary-Thoracic CME Tumor Board Conference meets monthly on the last Thursday of the month in the Diagnostic Radiology Center (DRC) Conference Room, Bldg 102, PAD at 4:00 PM.

(d) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Surgery, Diagnostic Radiology, Radiation Oncology and Pathology. All multidisciplinary staff, residents, fellows and medical students are encouraged to attend. CME credits are available for this conference.

(e) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

(5) Liver Tumor Board Conference - monthly

(a) This multidisciplinary case review conference discusses patients with liver diseases as well as cancer related cases.

(b) Physicians schedule cases or presentation to the Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed radiology review at least one week prior to the meeting.

(c) Meetings are attended by the medical staff in the following disciplines: Diagnostic Radiology and General Surgery. All multidisciplinary staff, residents, fellows and medical students are encouraged to attend.

(d) The Liver Tumor Board Conference meets monthly on the 2nd Monday of the month in the DRC Conference Room, PAD at 4:30 PM.

(e) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

5. RESPONSIBILITIES:

a. All Cancer Care Committee Members will be responsible for:

(1) Ensuring that educational and consultative cancer conferences are available to the medical staff and allied health professionals.

(2) Ensuring that educational and consultative cancer conferences cover all major sites and related issues.

(3) Ensuring that all Multidisciplinary Tumor Board Conference physicians are fully informed of this policy and that this policy is followed.
Health Care System Memorandum No. 111-08-06
May 12, 2008

(4) Monitoring and evaluating the cancer conference frequency, multidisciplinary attendance, total case presentation, and prospective case presentation on an annual basis.

b. The Cancer Program Coordinator and the Cancer Registrar will be responsible for:

(1) Coordinating the activities of the multidisciplinary cancer conferences (Tumor Board) and maintain the required documentation for those activities.

(2) Submitting a yearly cancer conference activities report to the Cancer Care Committee.

6. REFERENCE: American College of Surgeon Commission on Cancer, Cancer Program Standard 2004

7. RESCISSION DATE: May 31, 2011

8. RESPONSIBLE OFFICIAL: Chief, Medical Oncology

Elizabeth Joyce Freeman
Director
1. **SUMMARY:** Health Care System Memorandum (HCSM) No. 11-09-135, Oral Chemotherapy and Biotherapy for Cancer Therapy: Prescribing, Administration, Handling and Disposal, dated February 2009, is rescinded. Major changes have been made. The policy and procedure for parenteral chemotherapeutic and biotherapeutic drugs are described in HCSM No. 11-14-108, Ordering, Preparing and Administering Parenteral Chemotherapy and Biotherapy, dated June 23, 2014.

2. **PURPOSE:** To define the policy, procedure, and responsibilities in the use, preparation, prescription, administration, handling, and disposal of oral chemotherapy and biotherapy drugs for cancer therapy.

3. **POLICY:** To minimize risk and enhance positive outcomes, it is the policy of the Veteran Affairs Palo Alto Health Care System (VAPAHCs) that all staff will follow the standardized procedures outlined in this HCSM for ordering, preparing, administering, dispensing, and disposing of waste related to oral chemotherapy and biotherapy as defined by Occupational Safety and Health Administration (OSHA) and the Resource Conservative and Recovery Act (RCRA).

4. **PROCEDURES:**

   a. Oral chemotherapy must be handled in a manner which avoids skin contact, aerosolization of the drugs, and cross contamination with other medication or contamination of surfaces.

   b. Employees who are pregnant, breastfeeding, or who have a written statement from a physician which provides medical reasons why they should not be exposed to hazardous drugs will not prepare or handle these drugs.

   c. The term biotherapy will refer to both hazardous and non-hazardous biotherapy unless otherwise specified. Hormonal therapies for cancer are not covered in this policy.
d. The prescriber (physician, registered nurse practitioner [RNP], physician assistant [PA]), pharmacist, and nurse administering the drug will conduct independent dose calculation for drugs requiring calculations (i.e., drugs with recommended dosing of mg/m², mg/kg).

e. For non-cancer therapy, when administering chemotherapy and biotherapy, follow this policy’s administration procedures described in Attachment E.

f. A list of oral chemotherapy and biotherapy drugs are listed on Attachment A.

g. Informed Consent:

(1) Except in emergent situations, all patients must give informed consent for chemotherapy or biotherapy prior to start of treatment.

(2) The preferred method for obtaining signed informed consent for cancer indications is through the iMedConsent™ software program (IMED). If IMED is not available, the signature may be obtained on an approved paper form.

(3) The informed consent will specify the name of the drug(s) included in the treatment regimen. This serves as an educational tool when communicating to patients about the treatment plan.

(4) Research Protocols: Patients receiving chemotherapy or biotherapy as part of an Institutional Review Board (IRB)-approved research protocol must give informed consent and sign a study-specific consent form using VA form 10-1086 in addition to the iMedConsent form. A copy of the study-specific form must be sent to the Pharmacy Investigational Drug Service.

h. LOCATION: Oral chemotherapy or biotherapy may be administered in the outpatient, inpatient, and long-term care areas.

i. Orders:

(1) Authorized Prescribers:

(a) Providers with approved privileges (oncology, hematology, and urology) may order oral chemotherapy and/or biotherapy.

(b) Sub-specialty Fellows, RNPs, and PAs may write/renew orders in Veterans Health Information Systems and Technology Architecture (VistA) Chemo Manager or as handwritten orders, but the order needs to be co-signed by the attending sub-specialty physician.
(c) When orders are written in Computerized Patient Record System (CPRS) (i.e., not in VistA Chemo Manager [VCM]), subspecialty fellows and PAs must indicate the name of the supervising physician with whom the prescription was discussed with, by adding under order comments “Discussed with (Attending Physician’s name).”

(d) Other providers, from both the outpatient and inpatient settings, must consult from subspecialty providers to obtain chemotherapy or biotherapy.

(2) Physician’s Orders:

(a) No verbal orders are allowed for oral chemotherapy or biotherapy except to discontinue the order.

(b) Orders for oral chemotherapy/biotherapy will be made using VISTA VCM whenever possible.

(c) If the treatment regimen is not available in VCM or if VCM is not available, orders will be entered in CPRS.

(d) Any changes to existing orders (e.g., dose modification or schedule modification) must be documented in the electronic health record as progress notes or addendum.

(e) For drugs that are not on the formulary, physicians must complete a Prior Authorization Drug Request (PADR) in CPRS in accordance to HCSM No. 11-15-26, Medication Ordering, dated January 28, 2015. This request must be entered in CPRS as soon as the decision to use the medication is made to facilitate utilization review and procurement of medication.

(f) The prescriber will follow the standards for prescribing drugs that have special requirements for ordering (e.g., immune modulators or IMiDs).

(g) The prescriber is directed to review the Veterans Integrated Service Network (VISN) 21 Oncology Medication Safety Measures that outlines monitoring and refill guidelines at: https://vaww.r01.cdw.va.gov/sites/V21/CPMSite/Pages/Oncology.aspx.

j. Pharmacy Processing:

(1) Order Verification:

(a) Pharmacy procedure for order verification in CPRS and/or VCM must be followed.
(b) If the order set is available in VCM, but Pharmacy is unable to process the order, the printed version of VCM orders may be used in place of manually written orders. Procedures will be the same as those outlined in HCSM No. 11-14-108, Parenteral Chemotherapy and Biotherapy: Prescribing, Preparation, Administration, Handling, and Disposal.

(c) A pharmacist will only process appropriately signed orders (e.g., co-signed order by a specialty attending physician).

(d) Prior Authorization Drug Requests will be adjudicated in CPRS within 96 hours unless urgent (STAT). It is possible that some newer agents might take longer to procure due to specialty pharmacy dispensing (e.g., Ibrutinib, Pomalidomide etc.).

(2) Labeling and Dispensing;

(a) All medications are labeled with the generic names.

(b) Use clear and specific labeling instructions.

(c) Every attempt will be made to obtain and dispense medications in the most ready to use form.

(d) If the medicine is to be administered via a nasogastric tube, or if patients are unable to swallow tablets/capsules, appropriate formulations must be obtained from manufacturer, if available.

(e) Drugs dispensed by a specialty pharmacy must be brought to the hospital when the patient is admitted. Procedures for using patient’s own drug supply will be followed according to HCSM No. 119-11-13, Patient Medication Brought to the Health Care System, dated July 11, 2011.

k. Safe Handling of Hazardous Drugs: The following are safe handling practices related to oral hazardous drugs:

1. The minimum requirement for safe handling of oral agents is to wear gloves. Double gloving is recommended. Additional Personal Protective Equipment (PPE) (e.g., gown, mask) will be donned as deemed necessary.


l. Administration:
All Registered Nurses (RNs), Licensed Vocational Nurses (LVNs), or licensed providers may administer oral chemotherapy or biotherapy. The administering RN/LVN/Licensed Provider will:

(a) Be familiar with the basic drug information (indication, dose, side effects) through review of Micromedex or other resource;

(b) Contact the Clinical Pharmacist, Clinical Nurse Specialist or the ordering provider if there were any questions about the drug or therapy ordered. In-services to the staff will be provided based upon identified educational need; and

(c) Follow the oral chemotherapy and biotherapy administration, handling, and disposal procedures (See Attachment E).

m. PATIENT EDUCATION

(1) In addition to the education provided by the licensed providers, the Pharmacist dispensing the drug or the staff administering the drug or the Clinical Nurse Specialist who was consulted will provide additional patient education.

(2) The patient and/or caregiver will receive additional educational instruction that includes, but not limited to the following:

(a) Treatment goals;

(b) Drug name;

(c) Drug dose, including number of tablets needed to make a dose;

(d) When to start and stop treatment;

(e) Potential adverse effects;

(f) Adverse effects prevention and management;

(g) What to do when dose is missed;

(h) When and whom to call for questions, concerns, problems;

(i) Safe handling practices, including handling of hazardous drugs, such as chemotherapy;

(j) Storage;

(k) Disposal; and
(1) Proper hand washing before and after taking/administering the drug.

(3) Instruct patient about checking with local agency about disposal of unused chemotherapy tablets (See Attachment F).

(4) Written education materials about the oral chemotherapy or biotherapy will be provided to the patient.

n. Documentation:

(1) Follow appropriate documentation procedure for drug administration (e.g., Bar Code Medication Administration [BCMA], CPRS).

(2) Include patient/family education, as well as adverse effects experienced by patients and interventions to manage the adverse effects.

o. EMPLOYEE PROTECTION: PPE will be worn by all personnel handling chemotherapy and hazardous biotherapy drugs. Should a patient receive chemotherapy in an inpatient setting, a chemotherapy cart will be obtained from Sterile Processing Services (SPS) to ensure appropriate protective supplies are available.

p. ENVIRONMENTAL PROTECTION: Hazardous drug (HD) precautions will be followed until the drug is adequately metabolized and excreted (typically 48 hours after infusion complete). Chemotherapy and hazardous biotherapy waste will be disposed in accordance with HSCM No. 11-13-109, Pharmaceutical Waste and Disposal, dated February 15, 2013. Spill kits are to be kept in all areas where chemotherapy and hazardous biotherapy is handled (See Attachment H).

(1) Specific chemotherapy precautions, which begin on day one of therapy and end 48 hours after therapy is completed, will be communicated among the healthcare team where applicable.

(2) Caregivers, family members and visitors will be instructed regarding these precautions.

q. EMPLOYEE MEDICAL SURVEILLANCE: All staff who experience a documented exposure to chemotherapy or hazardous biotherapy agents is to have an evaluation by the Occupational Health Service (OHS) (See Attachment G). Medical surveillance may include history (medical and occupational) physical examination, and/or laboratory studies as appropriate for the exposure. Exposures may occur when there is 1) a breach in the use of appropriate PPE, 2) an accidental spill or splash, or 3) when the facility Industrial Hygienist identifies routine exposure above the Permissible Exposure Limit (PEL) for a particular hazardous drug.
5. **RESPONSIBILITIES:**

a. **CLINICAL SERVICE CHIEFS:**

   (1) Provide initial and on-going (annual) training of employees who order, administer, and/or handle chemotherapy or biotherapy agents.

   (2) Provide alternative duty to staff members who are pregnant or breastfeeding, or have written statement by a physician relating the reason why staff should not be exposed to hazardous drugs.

b. **PRESCRIBING/ADMINISTERING PROVIDERS:**

   (1) Notify Pharmacy of Prior Authorization Drug Requests, specialty pharmacy prescriptions, rarely used drugs or unusual requests in a timely manner so that the agent(s) can be procured. The request must be reviewed by the Oncology Pharmacist or designee for monitoring and assessment.

   (2) Adhere to the prescribing guidelines delineated in this policy.

c. **Associate Director of Patient Care Service/Nursing Services:** Ensure that nursing areas for chemotherapy and biotherapy administration receive chemotherapy PPE, and chemotherapy waste disposal equipment (to be obtained from EMS and Safety and Emergency Management Service); emergency kits (to be obtained from pharmacy), and up-to-date electronic access to references on chemotherapeutic agents that include side effects and other clinical considerations.

d. **Chief Nurse, Clinical Practice and Professional Development:** Ensure that nursing areas for chemotherapy and biotherapy administration receive an updated copy of Oncology Nursing Society Guidelines and Recommendations for Practice, as well as drug references, electronic or in print.

e. **Nurses:** Adhere to this policy on chemotherapy and biotherapy administration and safe handling and pharmaceutical waste management disposal practices.

f. **Clinical Nurse Specialists:**

   (1) Assess/evaluate patient and staff educational needs.

   (2) Conduct, facilitate/coordinate staff education.

g. **Chief, Pharmacy Service**

   (1) Ensure that pharmacy staff who dispense oral chemotherapy and biotherapy are educated on the about proper procedures.
(2) Ensure that adequate supplies of drugs are available.

(3) Ensure timely delivery of drugs both in the outpatient and inpatient settings.

(4) Provide dedicated equipment (counting trays, unit dose (UD) packaging material, etc.) for the packaging, handling, and distribution of oral chemotherapy agents.

h. Pharmacists:

(1) Communicate drug shortages to appropriate services.

(2) Adhere to this policy on oral chemotherapy and biotherapy distribution, safe storage, handling, and disposal procedures.

i. Occupational Health Service is responsible for providing medical examinations for evaluating the medical health of employees who are exposed to HDs, such as chemotherapy and hazardous biotherapy agents in accordance with OSHA regulation 29 Code of Federal Regulations (CFR) 1910.1450 subpart g.

j. Chief, Environmental Management Service: Train EMS Staff on the safe handling and disposal of chemotherapy and ensure that waste containers are always available.

k. Chief, SPS: Ensure that chemotherapy carts that contain PPE.

l. Chief, Safety and Emergency Management: Ensure that black hazardous waste containers are always available.

m. The Facility Industrial Hygienist (FIH) is responsible for choosing the proper PPE for eyes, face, head and extremities, protective clothing and respiratory devices. Explicitly, the FIH will work with the supervisors to establish a Job Hazard Analysis (JHA) to determine the risk associated with each specific procedure. Based on the JHA the FIH will determine the proper PPE that will be used when hazards of process or environment, chemical hazards, radiological hazards or mechanical irritants are encountered in a manner capable of causing injury or impairment of any part of the body through absorption, inhalation or physical contact.

n. The FIH is responsible for measuring employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level, established ceiling limit, or in the absence of an action level, the Permissible Exposure Limit (PEL). For uses of OSHA regulated substances, the employer shall assure that
employees' exposures to such substances do not exceed the PELs specified in 29 CFR part 1910, subpart Z.

6. REFERENCES:


   e. HCSM No. 119-11-13, Patient Medication Brought to the Health Care System, dated July 11, 2011.


8. **RESPONSIBLE OFFICIAL**: Chief of Staff.

Elizabeth Joyce Freeman
Director

Attachments (8)
Attachment A:

List of Oral Chemotherapy and Biotherapy

Oral chemotherapy and biotherapy prescription must be ordered by sub-specialty physicians

*OTF (Oncology Task Force): Initial fill is 30 days with no refill; subsequent dose of 30 days’ supply has 2 refills

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand Name</th>
<th>Strength</th>
<th>NF(NDR)/ OTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altretamine</td>
<td>Hexalen</td>
<td>50mg</td>
<td>yes</td>
</tr>
<tr>
<td>Anagrelide</td>
<td>Agrylin</td>
<td>0.5mg, 1mg</td>
<td>yes</td>
</tr>
<tr>
<td>Axitinib</td>
<td>Inlyta</td>
<td>1mg, 5mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>Imuran</td>
<td>50mg</td>
<td></td>
</tr>
<tr>
<td>Bexarotene</td>
<td>Tarqretin</td>
<td>75mg</td>
<td>yes</td>
</tr>
<tr>
<td>Busulfan</td>
<td>Myleran</td>
<td>2mg</td>
<td></td>
</tr>
<tr>
<td>Capecitabine</td>
<td>Xeloda</td>
<td>500mg/150mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Chlorambucil</td>
<td>Leukeran</td>
<td>2mg</td>
<td></td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>Cytoscan</td>
<td>25mg, 50mg</td>
<td></td>
</tr>
<tr>
<td>Dasatinib</td>
<td>Sprycel</td>
<td>20, 50, 70, 80, 100, 140</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Erlotinib</td>
<td>Tarceva</td>
<td>25mg, 100mg, 150mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Estramustine</td>
<td>Emyct</td>
<td>140mg</td>
<td></td>
</tr>
<tr>
<td>Etoposide</td>
<td>Vepsid</td>
<td>50mg</td>
<td></td>
</tr>
<tr>
<td>Everolimus</td>
<td>Afinitor</td>
<td>2mg, 3mg, 5mg</td>
<td>Yes</td>
</tr>
<tr>
<td>Gefitinib</td>
<td>Iressa</td>
<td>250mg</td>
<td>Yes</td>
</tr>
<tr>
<td>Hydroxyurea</td>
<td>Hydrea</td>
<td>500mg</td>
<td>OTF, can be 90 days</td>
</tr>
<tr>
<td>Ibrutinib</td>
<td>Imbruvica</td>
<td>140mg OTF</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Imatinib</td>
<td>Gleevac</td>
<td>100, 400mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Lapatinib</td>
<td>Tykerb</td>
<td>250mg OTF</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Lenalidomide</td>
<td>Revlimid</td>
<td>2.5, 5, 10, 15, 20, 25mg</td>
<td>Yes REMS</td>
</tr>
<tr>
<td>Lomustine</td>
<td>CeeNu</td>
<td>10, 40, 100mg</td>
<td></td>
</tr>
<tr>
<td>Melphalan</td>
<td>Alkeran</td>
<td>2mg</td>
<td></td>
</tr>
<tr>
<td>Mercaptopurine</td>
<td>Purinethol</td>
<td>50mg</td>
<td></td>
</tr>
<tr>
<td>Methotrexate**</td>
<td></td>
<td>25mg</td>
<td></td>
</tr>
<tr>
<td>Mitotane</td>
<td>Lysodren</td>
<td>500mg</td>
<td></td>
</tr>
<tr>
<td>Nilotinib</td>
<td>Tasigna</td>
<td>150mg, 200mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Pazopanib</td>
<td>Votrient</td>
<td>200mg OTF</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Procarbazine</td>
<td>Matulane</td>
<td>50mg</td>
<td></td>
</tr>
<tr>
<td>Pomalidomide</td>
<td>Pomalyist</td>
<td>1mg, 2mg, 3mg, 4mg</td>
<td>Yes REMS</td>
</tr>
<tr>
<td>Regorafenib</td>
<td>Stivarga</td>
<td>40mg OTF</td>
<td></td>
</tr>
<tr>
<td>Ruxolitinib</td>
<td>Jakafi</td>
<td>5, 10, 15, 20, 25mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Sorafenib</td>
<td>Nexavar</td>
<td>200mg OTF</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Sunitinib</td>
<td>Sutent</td>
<td>12.5, 25, 50mg</td>
<td>Yes OTF</td>
</tr>
<tr>
<td>Tacrolimus</td>
<td>Prograf</td>
<td>2.5mg</td>
<td></td>
</tr>
<tr>
<td>Temozolomide</td>
<td>Temodar</td>
<td>5, 20, 100, 140, 180, 250mg</td>
<td>Yes</td>
</tr>
<tr>
<td>Testolactone</td>
<td>Teslac</td>
<td>250mg</td>
<td></td>
</tr>
</tbody>
</table>
**Methotrexate - May also be prescribed for non-cancer indication.**

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Brand Name</th>
<th>Doses</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thalidomide</td>
<td>Thalomid</td>
<td>50, 100, 150, 200mg</td>
<td>Yes REMS</td>
</tr>
<tr>
<td>Toremifene</td>
<td>Fareston</td>
<td>60mg</td>
<td>Yes</td>
</tr>
<tr>
<td>Vemurafenib</td>
<td>Zelboraf</td>
<td>240mg</td>
<td>Yes OTF</td>
</tr>
</tbody>
</table>
VAPAHCS has agreed to implement VCM as the primary means of ordering/order processing chemotherapy and biotherapy for treating malignant and clonal disease. It affords a standardized means for establishing chemotherapy treatment plans, and electronic order entry for these drugs. In addition, VCM provides a flow sheet for a review of a patient’s history of chemotherapy treatment and toxicity. Furthermore, it provides drug inventory management for pharmacy service.

Treatment plans developed within VCM are based on the best available evidence, including treatment guidelines and post marketing experiences whenever possible. High-quality Phase II studies may be used when Phase III data are not available. All treatment plans will be developed by members of the VCM administrative team and will be vetted by each member before releasing them for general use.

Chemo/biotherapy ordered for treating malignant/clonal disease will be ordered via VCM whenever possible. Orders may be initiated by any provider authorized to do so as delineated in this HCSM; orders not initiated by an attending physician will be “queued” for attending physician signature. Patient’s code status and goal of therapy will be documented on the order form.

Signed orders will be reviewed by a designated pharmacist, and if no discrepancy is identified, they will be processed in VistA. The attending physician will be notified of any identified discrepancies so the order can be corrected; it will then be processed by pharmacy (“written” status).

For patients receiving chemotherapy or biotherapy in the inpatient setting, the admitting medicine resident or medicine attending physician will co-sign the chemotherapy treatment plan note (generated by VCM and automatically transferred into CPRS) to document acknowledgement of the treatment planned during the hospital admission. Treatment administration documentation will be done on Bar Code Medication Administration.

Should part of a therapy be delayed or postponed due to clinical circumstances, the rescheduling of the orders will be written as a nursing text order in CPRS; this order should be printed and attached to the nursing copy of the VCM orders to ensure the new schedule is followed.

Training of staff regarding VCM use and upgrades will be conducted on an on-going basis by the VCM administrative team for their respective service.
Attachment C:

Contingency Plan For Oral Chemotherapy And Biotherapy Prescription

1. If the order set is available in VCM, but Pharmacy is unable to process the order, the printed version of VCM orders may be used. In this case, printed form (which reads “DO NOT EXECUTE” on left side of the VCM order) will be signed by ordering physician and attending physician. In addition, in the inpatient area, the managing will also sign the printed order.

2. If VCM is unavailable to use, then orders can be written in CPRS. The procedure is similar to the standard prescription process in CPRS. Subspecialty Fellows, Nurse Practitioners, and Physician Assistants:

   a. Can write prescriptions in CPRS

   b. Must indicate the name of the supervising physician whom the prescription was discussed with, by adding under comments, “Discussed with (Attending Physician’s name),” in CPRS order.

3. If VCM or CPRS is unavailable, orders can be written in VA-FORM 10-1058 for Inpatient or VA 10-2577F (blank VA prescription form) for Outpatient.

   a. VA FORM 10-2577 (VA Prescription Blank) is set of 100 prescriptions (equal to 1 pad) with serial numbers. This can be obtained from pharmacy. Each pad is assigned to the physician by obtaining necessary signature, issue date, signature of person issuing. These prescriptions are not transferrable or borrowed by anyone else. Only one chemotherapy or biotherapy drug is written on the prescription. Unused forms must be returned to Pharmacy, when VCM or CPRS becomes available.

   b. VA FORM 10-1058 is available on 2A (ward) and AIC. There are two Pages: the first page should be filled with diagnosis, treatment indication, height, weight, BSA, necessary lab data and any IV fluids. The second page is for chemotherapy or biotherapy agents with pre-medications (e.g., ondansetron, Benadryl etc.). Physician can order more than one chemotherapy drug on this page. These forms must be signed by Fellows and/or attending physicians, and managing physicians.
Attachment D:

Oral Chemotherapy And Biotherapy Pharmacy Processing

A. ORDER VERIFICATION. The Pharmacist will:

1. Review approval of Prior Authorization Drug Requests in a timely manner for drug regimen in CPRS.

2. Review the order for completeness and appropriateness (e.g., dosage, route, schedule, quantity).

3. Ensure that prescribed doses, treatment intervals and administration details are appropriate to the patient’s demographics, tumor type, hematological and biochemical profile, organ function and chosen treatment protocol.

4. Perform all necessary calculations (e.g., BSA, CrCL, ANC, AUC) for appropriate dosing.

5. Verify that the maximum and cumulative drug doses (e.g., lifetime cumulative dose) have not been exceeded.

6. Check that additional supportive drugs relevant to the treatment protocol have been prescribed and are appropriate for the protocol, the length of the course and the patients (e.g., antiemetics, colony stimulating factors, antidiarrheals, syringes, alcohol pads, sharps container).

7. Consult ordering physician for discrepancies prior to processing the order.

B. DISPENSING

1. For Inpatients, obtain unit dose packaging from the manufacturer whenever possible.
   a. If unable to obtain in unit dose, pharmacy shall utilize packager machine to package the drug in the unit dose area.
   b. Oral chemotherapy or biotherapy agents will not be packaged using automated packaging or counting machines.
   c. Inpatient pharmacy will package any medications dispensed by specialty pharmacy (e.g., pomalidomide etc.) that patient brings from outpatient when he or she is admitted into the hospital.

2. For Outpatients, use dedicated pharmacy equipment (counting trays, spatulas) will for oral chemotherapy and biotherapy agents.
a. Clean the equipment with 70% Isopropyl Alcohol after each use.

b. Provide a medication fact sheet with all outpatient prescription.

c. Instruct patients to bring their own specialty pharmacy prescription (e.g., Lenalidamide, Pomalidomide) when being admitted in the hospital.

d. Add appropriate storage requirement, disposal information, and/or cautionary and advisory labels, as appropriate.

C. LABELING.

1. The Pharmacist will label the medication and should have following information:
   (a) Patient’s full name
   (b) Drug name
   (c) Drug dose
   (d) Quantity
   (e) Route and frequency of administration
   (f) Duration — number of days with start and stop date
   (g) Any auxiliary labels (water, food, sunlight etc.)
   (h) Physician’s Name/Pharmacy Name

2. If the prescription requires taking different strengths of tablets to complete the dose, the label must include the number of tablets for each strength and the total dose to be taken.

3. Place a cytotoxic warning sticker “Cytotoxic, Handle With Care” on all dispensed containers of cytotoxic drugs, including the outside bag.
Attachment E:

Oral Chemotherapy And Biotherapy Administration Procedures

A. PRE-ADMINISTRATION: Prior to administering oral chemotherapy or biotherapy, the licensed provider must:

1. Should the patient voice a lack of willingness to receive the prescribed treatment, the prescriber will be contacted.

2. For cancer therapy, verify signature consent

3. Verify the patient's identification using two identifiers

4. Identify the patient's educational needs and understanding of the treatment. Additional education will be provided if needed.

5. Perform appropriate drug verification procedure with other licensed personnel. Any discrepancy will be addressed before the drug is administered.

6. Calculate drug doses for drugs requiring calculations (i.e., mg/m², mg/kg) with each new order (including order renewal) of oral chemotherapy and biotherapy.

7. All other chemotherapy or biotherapy drugs (i.e., fixed dose drugs), conduct a double check. During the double check process, the staff who is administering the drug will read the label on the drug, while the other licensed staff will verify by comparing the information on the label with the order (e.g., BCMA, CPRS, VCM) in the presence of the patient.

8. The information that is verified in the double check includes, but is not limited to the following:

   a. Patient's full name and a second patient identifier
   b. Drug name
   c. Drug dose
   d. Quantity to be administered
   e. Route and frequency of administration
   f. Duration of therapy - number of days of treatment

9. Safe Handling:

   a. Observe safe handling of oral chemotherapy drugs, which are hazardous drugs at all times. Chemotherapy precautions begin on the first day of treatment and ends 48 hours after therapy is completed.
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November 30, 2015

b. Ensure that chemotherapy precautions are communicated to staff caring for the inpatients receiving chemotherapy (e.g., in some areas, signage above the head of the bed; handoff).

c. In areas where chemotherapy is not regularly administered, obtain chemotherapy carts from Total Supply Support (TSS). The chemotherapy cart contains the appropriate PPE necessary, and must be available from the start until the end of chemotherapy precautions. Upon completion of chemotherapy precautions, the chemotherapy cart must be returned to TSS.

d. Some oral biotherapy drugs are not considered hazardous. Chemotherapy precautions are, therefore, not required.

B. ADMINISTRATION

1. Don double chemotherapy gloves for safe handling of oral drugs. Additional PPE will be donned as deemed necessary.

2. Follow verification procedure. Refer to A. 5.

3. Place all materials used for preparation and administration, including gloves, medication cup, and medication packaging in the re-sealable plastic chemotherapy zip lock bag prior to disposal into the appropriate hazardous waste container.

C. POST ADMINISTRATION:


2. Communicate therapy through handoff and appropriate drug administration documentation (e.g., CPRS, BCMA).
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Attachment F:

Disposal On Unused Hazardous Drugs

Instruct patients to contact their Local Enforcement Agency for information on disposal of unused chemotherapy drugs.

Local Enforcement Agency Phone Numbers:

Santa Clara
(408)-299-7300

San Mateo
(650)-363-4718

Alameda
(800)-606-6606

Contra Costa
(800)-750-4096

San Joaquin
(209)-468-3066

Santa Cruz
(831)-454-2022

Stanislaus
(209) 525-4123

Calaveras
(209) 532-1413

Tuolumne
(800) 870-9378
ATTACHMENT G: Employee Protection And Surveillance

1. PPE: PPE is to be used in the preparation, administration, handling and disposal of hazardous drugs (such as chemotherapy and some biotherapy agents) and related items. Personal protective equipment will not be worn outside the patient's room except when transporting the drug (e.g., wearing gloves to handle Hazardous Drug (HD) container from the medicine room to the patient room). PPE includes:

   a. Gloves. Disposable, powder-free, latex-free, tested with hazardous drugs (e.g., CHEMO-BLOC) will be used for any type of handling of HDs.

   b. Gloves must be removed and properly disposed immediately after use, when a tear or drug spill occurs, or when in direct contact with hazardous drugs. Do not re-use gloves once removed.

   c. Gowns. Gowns must be disposable, lint-free, low permeability fabric, with solid front, long sleeves, and knit or elastic cuffs. Follow hazardous waste guidelines when disposing gowns used for any type of handling of HDs.

   d. Eye and facial protection. A plastic face shield will be worn in situations when there is a risk for splashing to the eye, mouth, or nose, such as during a bladder instillation of HDs.

   e. Respiratory protection. A fit tested NIOSH-approved (N95 or greater) mask is necessary when drug aerosols are present (e.g., administration of aerosolized HDs or during HD spill clean-up).

2. Chemotherapy Supply Carts. In areas where chemotherapy is seldom administered, obtain a chemotherapy supply cart (yellow cart) from SPS that contains all the chemotherapy PPE as well as disposal containers. This is to be used during the chemotherapy precautions period (at the start of treatment until 48 hours following completion of treatment).

   a. Once chemotherapy precautions are completed, return the chemotherapy cart to SPS for cleaning and re-stocking. Chemotherapy carts are available in PAD, MPD, and LMD. (PAD Operating Room has its own chemotherapy cart.)

3. Acute Exposure (Patient and/or Personnel):

   a. Skin Exposure

      i. Immediately remove contaminated PPE and clothing.

      ii. Wash affected body areas continuously with water and soap. There is no current recommendation for specific length of time affected areas should be cleansed.

   b. Eye Exposure
i. Immediately rinse eye/s with water, saline eye wash, or sterile NS attached to IV tubing for at least 15 minutes.

c. Obtain medical attention immediately

   i. If a patient is involved, notify his/her provider.

   ii. If an employee is involved, notify supervisor and the employee should report to either the Occupational Health or on off-tours, the Emergency Department.

d. Document patient exposure in the medical record and employee exposure on accident form (ASSISTS).

e. Refer to Material Safety Data Sheets (MSDS) – available electronically on VAPAWEB

4. Occupational Health Service: Staff from Occupational Health Service will:

   a. Provide medical surveillance and evaluation for employees who have a suspected or documented acute or routine exposure to chemotherapy or hazardous biotherapy drugs.

   i. Medical evaluation will include history (medical & occupational), physical examination, and laboratory studies indicated by the type and severity of the exposure (e.g., CBC with differential, urine microscopy or urine dipstick for blood with or without reticulocyte count, liver transaminases, alkaline phosphatase).

   ii. Medical surveillance will include baseline and follow-up evaluations as indicated by the HD type and duration of documented exposure.
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Attachment H: Environmental Protection

1. Spill Kits: Spill kits will be available in patient care areas where chemo/hazardous biotherapy is administered and in Pharmacy; kits will contain personnel protective equipment including eye protection, masks, latex-free gloves, spill mats/towels, detergent, and chemotherapy waste disposal bags.

2. Spills outside the Pharmacy Biological Safety Cabinet: Spills must be cleaned up immediately in accordance with the Chemotherapy Spill Management Guidelines (see below).

3. Spills within the Pharmacy Biological Safety Cabinet:
   a. Spills into the intake perforations may require that the work surface be removed, according to the manufacturer's directions, in order to thoroughly clean the drain pan.
   b. Do not use the hood if the HEPA filter is contaminated.
   c. Place a "DO NOT USE – CHEMO CONTAMINATED" label on the unit.
   d. Change the filter according to the manufacturer's instructions, wearing protective gloves, goggles, respirator mask and gown.
   e. Place contaminated filter in a plastic chemotherapy waste disposal bag.

4. Disposal: Chemotherapy and biotherapy agents will be disposed in accordance with the HCSM No. 11-13-109, Pharmaceutical Waste and Disposal. Refer also to the Pharmaceutical Waste Stream, located in the VAPAHCS Pharmacy Service website for the list of federally regulated RCRA hazardous waste.

5. Chemotherapy Spill Management Guidelines:
   a. Staff who discovers/identifies the spill
      - Close off area to traffic until spill is completely managed
      - Seek assistance from chemotherapy-trained RN
      - Call EMS for assistance
   b. Chemotherapy Trained RN
      - Close off area to traffic until spill is completely managed
      - Contain spill immediately placing two chucks in "V" position
      - Obtain chemotherapy spill kit; follow directions
      - Display sign near spill area
c. Environmental Management Service employee

- Clean spill area three times with new detergent solution
- Clean the carpet as appropriate
- Discard mop & other materials used for cleaning spill area appropriately in accordance with the Hazardous Waste Policy.
- Note: On off shifts, this cleaning is completed by the staff who initiated the spill cleanup process
HEALTH CARE SYSTEM MEMORANDUM No. 11-15-41

SUBJECT: INFORMED CONSENT POLICY AND PROCEDURES

1. SUMMARY: This Health Care System Memorandum (HCSM) supersedes HCSM No. 11-11-41, dated May 10, 2011. Minor changes have been made. Every patient applying for and/or receiving treatment at a VA facility has the right to informed participation in decisions involving care. VA regulations require that all "diagnostic and therapeutic endeavors will be undertaken only with the prior, informed voluntary consent of the patient."

2. PURPOSE: This directive describes the criteria for informed consent and the process essential to promote "informed" decision-making by the patient. It also defines the obligations and duties of the health care staff to assure that the patient is given sufficient information so that he or she can make an informed decision concerning the available treatment options. An example of procedures for which informed consent is required is included as Attachment B.

3. POLICY: It is the Veterans Health Administration (VHA) policy that patients have the right to accept or refuse any medical treatment or procedure recommended to them. Except as otherwise provided in this memorandum, all treatments and procedures require the prior, voluntary informed consent of the patient, or if the patient lacks decision-making capacity, the patient's authorized surrogate. The preferred method for obtaining signed informed consent is through the iMedConsent application. Authorization for release/disclosure of information cannot be included in an informed consent document.

4. PROCEDURES:
   a. SCOPE: The scope of informed consent may be limited to a one-time, single treatment or procedure, or may encompass consent for routine care of a particular problem or condition (such as asthma), or for a series of treatments (such as dialysis). When the proposed treatment plan involves multiple or recurrent treatments and procedures, it is generally not necessary to repeat the informed consent discussion. There are, however, two circumstances where the informed consent discussion must be repeated and a new consent must be obtained:

      (1) If there is a significant deviation from the treatment plan to which the patient originally consented, or

      (2) If there is a change in the patient's condition or diagnosis that should reasonably be expected to alter the original informed consent.
b. DECISION-MAKING CAPACITY:

(1) In order to obtain informed consent, the practitioner must first determine whether the patient has decision-making capacity. Patients are presumed to have decision-making capacity unless an appropriate clinical evaluation determines that the patient lacks decision-making capacity, or the patient is a minor, or the patient has been ruled incompetent by a court of law. For patients who have decision-making capacity, the practitioner must undertake the informed consent process with the patient as described in Paragraph 4(c) INFORMED CONSENT PROCESS. For patients who lack decision-making capacity, practitioners must comply with Paragraph 4 (c) as well as Paragraph 4 (d), PATIENTS WHO LACK DECISION-MAKING CAPACITY.

(2) The practitioner must perform (or obtain) and document a clinical assessment of decision-making capacity for any patient suspected of lacking decision-making capacity.

(3) If the practitioner determines that the patient is likely to regain decision-making capacity, the practitioner must wait until the patient’s decision-making capacity returns, and then undertake the informed consent process with the patient, provided that delaying the recommended treatment or procedure would not adversely affect the patient’s condition. If the practitioner determines that the patient is unlikely to regain decision-making capacity within a reasonable period of time, an authorized surrogate must be sought.

(4) When the determination of lack of decision-making capacity is based on a diagnosis of mental illness, a psychiatrist or licensed psychologist must be consulted in order to ensure that the underlying cause of the lack of decision-making capacity is adequately addressed. However, even in this instance, the practitioner who will perform the treatment or procedure remains responsible for the final determination of decision-making capacity with respect to informed consent for that treatment or procedure.

(5) If the patient is considered a minor under State law in the jurisdiction where the VHA facility is located, that patient is deemed to lack decision-making capacity for giving informed consent except as otherwise provided by law. Consent must be obtained from the patient’s parent or legal guardian.

(6) Patients who have been judicially determined to be incompetent are incapable of giving consent as a matter of law. Such persons are deemed to lack decision-making capacity for the purpose of giving informed consent. If a practitioner believes that a patient who is legally incompetent does in fact have the capacity to make a particular health care decision, the practitioner must discuss this with the legal guardian and seek advice from the local ethics program and/or Regional Counsel.

c. INFORMED CONSENT PROCESS: For patients who have decision-making capacity, the informed consent process involves the following outlined procedures. The same process applies to surrogates who make decisions for patients who lack decision-making capacity, except as noted in subparagraph 4 (e) 5.

(1) Informing the Patient: During the informed consent process, the practitioner must:
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(a) Provide information that a patient in similar circumstances would reasonably want to know.

(b) Describe the recommended treatment or procedure in language that is understandable to the patient. An interpreter must be provided, if necessary, to achieve this purpose.

(c) Give a clear and concise explanation of the patient's condition(s) or diagnosis(es) that relate to the recommended treatment or procedure.

(d) Describe the name, nature and details of the recommended treatment or procedure and the indications for that course of action including the likelihood of success of the recommended treatment or procedure for that particular patient.

(e) Describe expected benefits and known risks associated with the recommended treatment or procedure, including problems that might occur during recuperation. Risks of minor seriousness do not have to be described unless they commonly occur. Risks that are extremely unlikely do not have to be described, unless the patient requests that information, or unless such risks may result in death or permanent disability.

(f) Describe reasonable alternative treatments and procedures. The practitioner must explain why the recommended treatment is thought to be more beneficial to the patient than the alternatives. Expected benefits and known risks associated with the alternative treatments and procedures must also be described. Reasonable alternatives discussed must include: the option of no treatment or procedure, and the expected benefits; and known risks of that option. Reasonable alternatives discussed must also include potential emergency responses to known complications of the treatment or procedure that the patient may wish to forgo (e.g., blood transfusion for bleeding during an operation, hysterectomy for complications of an obstetrical procedure, open-heart surgery for complications of an angioplasty).

(g) Identify by name and profession the practitioner who has primary responsibility for the patient's care. The names and professions of any other individuals responsible for authorizing or performing the treatment or procedure under consideration must also be disclosed.

(h) Advise the patient if another practitioner will be substituted for any of those named. If the need for a substitution is known prior to initiating a treatment or procedure that requires signature consent, the patient must be informed of the change and this discussion and the patient's assent must be documented in the medical record.

(i) Advise the patient if the recommended treatment is novel or unorthodox.

(j) Where relevant, advise the patient of the patient's responsibilities when undertaking the treatment or procedure (e.g., taking medications at home, changing own bandages, etc.).
(k) Obtain specific consent for any aspect of the recommended treatment or procedure that involves research in accordance with M-3, Part I, Chapter 9, or superseding regulation and policy.

(l) Ensure that the patient indicates understanding of all the information provided. For example, the practitioner may ask the patient to describe the recommended treatment or procedure in the patient’s own words.

(m) Encourage the patient to ask questions.

(2) Promoting Voluntary Decision-Making: The practitioner must promote the patient’s voluntary decision-making during the informed consent process. The practitioner must convey that the patient is free to choose among any recommended treatments and procedures, including no treatment, or to revoke a prior consent, without prejudice to the patient’s access to future health care or other benefits.

(3) Documenting the Informed Consent Process: Prior to undertaking any treatment or procedure, the practitioner must obtain informed consent and document the informed consent process in the medical record except when documenting for consents in special situations.

(a) Treatments and Procedures that Do Not Require Signature Consent:

(1) Treatments and procedures that are low risk and are within broadly accepted standards of medical practice (e.g., administration of most drugs or for the performance of minor procedures such as routine X-rays) do not require signature consent. However, the informed consent process must be documented in the medical record. In accordance with VHA policy on documentation of patient records, documentation must be sufficient to serve as a basis to plan patient care, support diagnoses, and warrant treatment (see M-1, Pt. I, Ch. 5).

(2) HIV Consents: Signature consent for HIV testing and pre-and post-test counseling is not required. Specific oral informed consent is required and is to be documented in a progress note.

(b) Treatments and Procedures that Require Signature Consent: Prior to undertaking certain treatments and procedures, the practitioner must document the informed consent process in detail and obtain the patient’s signature in the iMedConsent application. If iMedConsent is not available the signature may be obtained on an approved paper form.

(1) The patient’s signature consent must be obtained for treatments and procedures that:

(a) Involve the use of sedation;

(b) Involve the use of anesthesia or narcotic analgesia;

(c) Can be reasonably expected to produce significant discomfort to the patient;
(d) Can be reasonably considered to have a significant risk of complication or morbidity;

(e) Require injections of any substance into a joint space or body cavity, including any non-vascular space;

(f) Are listed in Appendix B.

(2) Documentation of the informed consent process for treatments and procedures that require signature consent must include all of the following items:

(a) The practitioner's assessment of whether the patient has decision-making capacity.

(b) The name(s) of all the practitioner(s) immediately responsible for the performance, and if applicable, the supervision of the treatment or procedure, such as the resident physician and the attending physician.

(c) A brief description of the recommended treatment or procedure.

(d) A statement that relevant aspects of the treatment, or procedure, including indications, benefits, risks, and alternatives, including no treatment, have been discussed with the patient in language that the patient could understand; and that the patient indicated comprehension of the discussion.

(e) A statement that the patient had an opportunity to ask questions.

(f) A statement that the patient gave consent voluntarily.

(g) The date and time the discussion took place and whether the patient consented to the treatment or procedure.

(h) The written or valid electronic signature of the practitioner writing the note (including the practitioner's legibly written name).

(c) A properly executed VA authorized consent form is valid for a period of 12 months from the date signed. If during this 12 month period there is a significant change in the patient's condition that would reasonably be expected to alter the diagnosis or therapeutic decision, the consent is automatically rescinded and the informed consent process must be repeated for subsequent treatment. Rescission of consent must be documented in the patient's medical record. The practitioner who obtained consent must certify or verify the patient's rescission.

(d) The witness signature is not required for consents by patients who have decision making capacity or their surrogates.

(1) Consents obtained by telephone require a witness signature if the conversation is not audio-taped.
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(2) Consents signed with an “X” or other non-signature markings require two witnesses.

(e) The signed consent form is filed in the patient’s medical record. The patient must be offered a copy of the completed consent form, which may be printed from iMedConsent or VistA Imaging.

(f) When the Patient Chooses an Alternative Treatment, Including No Treatment, or Revokes Consent:

1. The patient may choose among recommended or alternative treatments and procedures, including no treatment. Or, the patient may revoke a prior consent, even if that decision may increase the risk of serious illness or death, without prejudice to the patient’s access to future health care or other benefits.

2. If the patient chooses an alternative treatment or procedure, including no treatment, that increases the risk of illness or death, or revokes a prior consent, the progress note must document the patient’s reason(s), if known, and the expected outcome.

3. If the patient’s choice of treatment or procedure poses a potential hazard to others (e.g., declining treatment for tuberculosis), the practitioner must notify the Chief of Staff, or designee, and consult with the Bioethics Committee and/or Regional Counsel.

d. PATIENTS WHO LACK DECISION-MAKING CAPACITY: If the patient is judged to lack decision-making capacity (see Appendix A for definition), the following procedures apply (in addition to the procedures in Paragraph 4 (c)):

1. Identifying a Health Care Agent or Authorized Surrogate:

(a) When a Health Care Agent is Authorized and Available. When a patient lacks decision-making capacity, the practitioner must make a reasonable inquiry as to the availability and authority of an advance directive naming a Health Care Agent (see Appendix A for definition). A Health Care Agent has the highest priority as a surrogate.

(b) When no Health Care Agent is Authorized and Available. The practitioner, with the assistance of other staff, must make a reasonable inquiry as to the availability of other possible surrogates according to the order of priority listed below. If a surrogate is identified, an attempt to contact that person by telephone must be made within 24 hours of the determination that the patient lacks decision-making capacity. If a particular surrogate is unavailable or unwilling to serve as surrogate, the next surrogate in the established priority order must be sought. A surrogate must be sought even if the recommended treatment or procedure does not require signature consent.

(c) Priority of Surrogates: The surrogate is authorized to give informed consent on behalf of the patient in the following order of priority:

1. Health Care Agent (see Appendix A for definition);
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(2) Legal guardian or special guardian (see Appendix A for definition);

(3) Next-of-kin. The next-of-kin is a relative, 18 years of age or older, in the following order of priority: spouse, child, parent, sibling, grandparent, grandchild (see Appendix A for definition); and

(4) Close friend (see Appendix A definition);

(d) Disagreement Between Surrogates at same Priority Level: Where there are multiple surrogates at the same priority level in the hierarchy and they do not agree about the recommended treatment or procedure, the practitioner must make reasonable efforts to reach a consensus. If consensus cannot be reached, the practitioner must choose the surrogate who is best able to speak for the patient, and document the reasons for choosing that individual. In cases where the choice is unclear, the practitioner must consult with the Bioethics committee and/or Regional Counsel.

(e) Documentation of the Process in Identifying an Authorized Surrogate: The practitioner must document the process and outcome of efforts to identify a surrogate.

e. PATIENTS WHO HAVE A SURROGATE. If it is determined that the patient lacks decision-making capacity and has a surrogate, that surrogate generally assumes the same authority and responsibilities as the patient in the informed consent process.

(1) The requirements for obtaining informed consent are described above in Paragraph 4 (c) 1 through 3, except as noted below.

(2) Disclosures otherwise required by this policy to be made to the patient must be made to the patient’s surrogate to the extent permitted by law (see M-1, Part I, Chapter 9, or superseding regulation and policy).

(3) Even though the patient lacks decision-making capacity, the practitioner must explain to the patient the treatment or procedure to which the surrogate has consented, if feasible.

(4) The surrogate’s decision must be based on substituted judgment or, if the patient’s values and wishes are unknown, on the patient’s best interests (see Appendix A for definitions). If the practitioner considers the surrogate to be clearly acting contrary to the patient’s values and wishes or the patient’s best interests, the practitioner must notify the Chief of Staff, or designee, and consult with the Bioethics committee and/or Regional Counsel before implementing the surrogate’s decision.

(5) The requirements for documenting the informed consent process are described in subparagraph 4c (3a) through subparagraph 4c (3f); however, documentation for patients who lack decision-making capacity, but have a surrogate must also include the surrogate’s name, relationship to the patient, authority to act as surrogate (whether Durable Power of Attorney for Healthcare (DPAHC), legal guardian, next-of-kin, or close friend), and how the consent was obtained (in person, by telephone, by mail, or by facsimile (fax).
f. PATIENTS WHO HAVE NO SURROGATE: If none of the surrogates listed in subparagraph 4d (1c) (i.e., a health care agent, legal guardian or special guardian, next-of-kin, or close friend) is available, the practitioner may either contact Regional Counsel for assistance in obtaining a guardian for health care decisions, or the practitioner may follow the procedures in this paragraph that set out an alternative process for decision-making on behalf of patients who have no surrogate.

(1) Treatments and Procedures that Do Not Require Signature Consent. Medically appropriate treatments and procedures that do not require signature consent may be performed in accordance with the following procedures, provided the procedures are low-risk and are within broadly accepted standards of medical practice.

(a) The decision to provide a treatment or procedure must be based on substituted judgment or, if the patient's specific values and wishes are unknown, on the patient's best interests (see Appendix A for definitions). If there is doubt regarding whether a treatment or procedure is consistent with the patient's values and wishes or the patient's best interests, the practitioner must consult with the Bioethics Committee and/or Regional Counsel.

(b) Even if the patient lacks decision-making capacity, the practitioner must, where reasonable, attempt to explain the nature and purpose of the proposed treatment or procedure to the patient. The practitioner must indicate, in the medical record, whether it was possible to communicate with the patient and if the patient appeared to understand the explanation.

(c) The practitioner must sign and date a progress note in the medical record that describes the treatment or procedure and its indications.

(d) Treatment must not be provided indefinitely without periodic review by the primary treatment team and by an advocate for the patient. The primary treatment team must review the treatment plan to ensure that clinical objectives are being met. Someone outside the primary treatment team who can serve as the patient's advocate must review the treatment plan at least every 6 months to ensure it is in the patient's best interests.

(2) Treatments and Procedures that Require Signature Consent: For medically appropriate treatments and procedures that require signature consent, but do not involve the withholding and/or withdrawal of life-sustaining treatment, the following procedures apply (see subparagraph 4c (3b) 1a through subparagraph 4c (3b) g for an explanation of procedures requiring signature consent). NOTE: Procedures for withholding or withdrawal of life-sustaining treatment for patients who have no surrogate are described in subparagraph 4f (3).

(a) The attending practitioner must sign and date a progress note in the medical record that describes the treatment or procedure and its indications; and

(b) The chief of service, or designee, must provide a signed and dated concurrence, in the patient's medical record, with the decision to perform the treatment or procedure, and the treatment's or procedure's indications.
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NOTE: In addition to the preceding, the provisions in subparagraph 4f (3a) through subparagraph 4f (3d) also apply to treatments and procedures that require signature consent.

(3) Withholding and/or Withdrawal of Life-sustaining Treatment: VA patients have the right to have unwanted life-sustaining treatment withheld and/or withdrawn even if this action results in death. In order to ensure a decision consistent with the patient's best interests, there is a special process that must be followed when considering the withholding and/or withdrawal of life-sustaining treatment for a patient who lacks decision-making capacity and has no surrogate. Implementation of decisions to withhold and/or withdraw life-sustaining treatments must follow the guidelines set out in VHA Handbook 1004.3, and VHA Handbook 1004.2. In addition, all the following procedures must be followed and documented in the medical record:

(a) The attending practitioner participates in the discussion of the withholding and/or withdrawal of life-sustaining treatment with the treatment team, and recommends life-sustaining treatment be withheld and/or withdrawn in a signed and dated progress note in the medical record.

(b) A multi-disciplinary committee appointed by the facility Director must consider the procedural and ethical validity of the recommendation to withhold and/or withdraw life-sustaining treatment(s). NOTE: An existing local ethics committee, a subcommittee of the local ethics program, or an independent group may serve this function. The committee functions as the patient's advocate and may not include members of the primary treatment team. The committee must use the substituted judgment standard (where possible) or the best interests standard (see Appendix A for definitions). To the extent feasible, the committee must seek input from representatives of the patient's cultural, ethnic, or religious group. The committee must then submit a written report to the Chief of Staff that describes its findings and recommendation(s).

(c) The Chief of Staff, or designee, must approve or disapprove the committee's recommendation to withhold and/or withdraw life-sustaining treatment. The committee's recommendation(s) and the Chief of Staff's decision must be documented in the medical record.

(d) The facility Director must review the decision and may either concur, not concur, or request review by Regional Counsel. The final decision must be documented in the medical record. The withholding and/or withdrawal of life-sustaining treatment may only be undertaken with the concurrence of the facility Director.

(4) Surrogate Consent by Mail, Fax, Telephone, or E-mail: Ideally, the informed consent discussion and signature consent (where required) will be conducted in person; however, face-to-face discussions are not always possible. This subparagraph outlines the procedures to follow when it is impractical to obtain a surrogate's consent in person.

(a) Consent by Mail or Fax: When informed consent is sought by mail or fax, the practitioner must enclose a letter addressed to the surrogate with a VA authorized consent form. The letter must provide the same information that generally would be supplied to the surrogate in a face-to-face discussion and must be signed by the practitioner. A copy of the letter must be filed in the patient's medical record. A fax copy of a completed consent form
signed by the surrogate is adequate to proceed with treatment. Reasonable efforts must be made to ensure that the original form that the surrogate signed is returned and filed in the patient's medical record.

(b) Consent by Telephone. When consent is sought by telephone, the conversation must either be audio-taped or witnessed by a second VA employee.

(1) The practitioner must:

(a) Call the proposed surrogate and identify and verify the parties on the line. NOTE: This responsibility may be delegated.

(b) Ask the surrogate for permission to audio-tape the conversation or inform the surrogate that a second VA employee must witness the conversation. NOTE: This responsibility may be delegated.

(c) Determine that the individual has the authority and is willing and available to act as surrogate and make health care decisions on behalf of the patient who lacks decision-making capacity.

(d) Proceed with the informed consent discussion. NOTE: This responsibility may not be delegated.

(2) Document the process.

(a) Audiotapes. If the discussion is audio-taped, a typed transcript of the entire discussion with the date and time of the call must be filed in the patient's medical record.

(i) The transcriptionist must sign the document to certify that the transcript is an accurate verbatim account of the audio-taped conversation. The audiotape must be clearly labeled with the:

- Patient's name;
- Social Security Number;
- Name of treatment, or procedure, for which consent was obtained;
- Name of surrogate and relationship to patient;
- Date and time of conversation;
- Name of the VHA medical facility; and
- Name of the practitioner who obtained the consent.

(ii) Audiotapes must be kept under locked storage by the medical records custodian until replaced by a signed consent form or disposed of in accordance with VHA
(b) If the discussion is not audio-taped, the practitioner must document compliance with the informed consent process in the medical record as described in Paragraph 4c (1) through Paragraph 4c (3). If a second practitioner, or other VA employee, witnesses the conversation, both the practitioner and the second employee must sign a report of contact, or progress note that details the conversation.

(c) CONSENT BY E-MAIL. Signature consent by E-mail is not permitted.

(g. CONSENT IN SPECIAL SITUATIONS:

(1) Medical Emergencies:

(a) In medical emergencies the patient’s consent is implied by law. The practitioner may provide necessary medical care in emergency situations without the patient or surrogate’s express consent when all of the following conditions are met:

(1) Immediate medical care is necessary to preserve life or avert serious impairment of the health of the patient or others; and

(2) The patient is unable to consent; and

(3) The patient has no surrogate or the practitioner determines that waiting to obtain consent from the patient’s surrogate would increase the hazard to the life or health of the patient or others.

(b) In a medical emergency, reasonable attempts to contact the patient’s surrogate must be made as promptly as possible, before or after treatment is begun, to explain the nature of the treatment or procedure, the indications, and the expected outcome. The patient’s previously stated wishes must be followed to the extent that they are known. If these wishes are contained in a written advance directive, the practitioner must ensure that the advance directive is valid and applies to the current situation.

(c) When the patient’s consent is not obtained due to the emergency exception:

(1) The practitioner must date and sign a progress note in the medical record documenting the:

• Patient’s inability to provide consent;

• Imminent danger to the health of the patient, or others;

• Decision to undertake a particular treatment or procedure, and its rationale; and

• Attempts that were made to identify and contact a surrogate.
(d) Whenever treatment is provided in a medical emergency without the patient’s or surrogate’s express consent, the Chief of Staff or equivalent must sign and date the VA authorized consent form. This signature may be obtained after the clinical intervention, when necessary. If the Chief of Staff or equivalent is the treating practitioner, a second practitioner must sign the consent form.

(2) Unusual or Extremely Hazardous Treatments and Procedures: No patient will undergo any treatment or procedure considered to be unusual or extremely hazardous, such as psychosurgery, except under extraordinary circumstances, subject to the following:

   (a) Before treatment is initiated, the patient (or surrogate) must be given adequate opportunity to consult with independent specialists, legal counsel, or other interested parties of the patient’s (or surrogate’s) choosing. The patient’s (or surrogate’s) signature on a VA authorized consent form must be witnessed by someone who is not affiliated with the VA health care facility (e.g., spouse).

   (b) If a surrogate makes the health care decision, a multi-disciplinary committee, appointed by the facility Director, must review the surrogate’s decision before treatment is initiated to ensure that the decision to treat is consistent with the patient’s wishes (or best interests, if the patient’s wishes are not known). The committee functions as the patient’s advocate and may not include members of the primary treatment team. The committee must submit its findings and recommendations in a written report to the facility Director. The Director may authorize treatment consistent with the surrogate’s decision, or authorize the practitioner to seek a legal guardian or special guardian to make the health care decision.

   (c) If there is no available surrogate, the practitioner must follow procedures similar to those outlined in subparagraph 4f, PATIENTS WHO HAVE NO SURROGATE for the withholding and/or withdrawal of life-sustaining treatment, or request that a guardian be appointed to make health care decisions for the patient. NOTE: Contact Regional Counsel for assistance.

NOTE: The practitioner must document compliance with all these procedures in the patient’s medical record.

(3) Forced Administration of Psychotropic Medication: NOTE: Administration of psychotropic medication to an involuntarily committed patient against the patient’s (or surrogate’s) wishes must meet Constitutional due process requirements.

   (a) The patient (or surrogate) must be allowed to consult with independent specialists, legal counsel or other interested parties of their choice concerning treatment with psychotropic medication.

   (b) Any recommendation to administer or continue psychotropic medication against the patient’s (or surrogate’s) wishes must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. That committee must include a psychiatrist or a physician who has psychopharmacotherapy privileges. The committee functions as the patient’s advocate and may not include members of the primary treatment team. The facility
Director must concur with the committee’s recommendation to administer psychotropic medications contrary to the patient’s (or surrogate’s) wishes.

   (c) Continued therapy with psychotropic medication must be formally reviewed by the prescribing practitioner every 30 days and the results of the review documented in the patient’s medical record.

   (d) The patient, surrogate, or a representative on the patient’s behalf may appeal the psychotropic medication treatment decision to a court of appropriate jurisdiction. The patient and surrogate, if applicable, must be informed of the right to appeal the decision.

   (e) The practitioner must document compliance with these procedures in the medical record.

   h. RELEASE OF EVIDENTIARY INFORMATION AND/OR MATERIAL(S): Information and/or other evidentiary material(s) that could be used for legal prosecutions include those collected during the diagnosis and treatment of a patient who is suspected of criminal wrongdoing or who is the victim of a suspected crime. The practitioner must ensure that proper informed consent for treatments and procedures is obtained from the patient (or surrogate, if applicable) and appropriately documented in the medical record. If there is concern that the surrogate is acting contrary to the patient’s prior wishes or best interests because of involvement in suspected abuse or neglect, refer to subparagraph 4(e) 4. Specific conditions must be met before such information may be disclosed without the patient’s (or surrogate’s) consent (see M-1, Part I, Chapter 9). Evidentiary material must be collected, retained, and safeguarded according to local VA medical facility policy.

   i. RESEARCH: Participation in any human subjects research sponsored by VA, as well as any human subjects research conducted on VA premises, must meet requirements of current VHA policy (see M-3, Part I, Chapter 9, or superseding regulation and policy).

   j. TESTING FOR HIV:

   (1) Testing for HIV: This requires the prior informed oral consent of the patient (or surrogate) according to the procedures described in Paragraph 4c, INFORMED CONSENT PROCESS and Paragraph 4e, PATIENTS WHO HAVE A SURROGATE.

   k. CONSENT FOR TREATMENTS OR PROCEDURES DELIVERED VIA TELEMEDICINE AND TELEHEALTH: Informed consent is required for all clinical treatments and procedures, including those delivered via telemedicine and/or telehealth. For the purpose of informed consent, telemedicine and/or telehealth are considered to be part of the treatment or procedure, used to deliver health care services.

   (1) All elements of the informed consent process apply to treatments or procedures delivered by telemedicine and/or telehealth.

   (a) Specifically, practitioners need to provide information about telemedicine and/or telehealth that a patient would reasonably want to know, including:
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(1) The likely differences between receiving care delivered using telemedicine and/or telehealth technologies and face-to-face care.

(2) The benefits and risks of using telemedicine and/or telehealth in the patient's situation, the likely benefits and risks associated with the alternatives to using telemedicine and/or telehealth to deliver the treatment or procedure in the patient’s situation.

(3) Whether the use of telemedicine and/or telehealth to deliver the treatment or procedure would be generally considered novel or unorthodox.

(b) Practitioners need to tell patients that they are free to choose among treatments or procedures that use telemedicine and/or telehealth and those that do not use telemedicine and/or telehealth, and that a prior consent for telemedicine and/or telehealth can be revoked without prejudicing the patient's access to future care or other benefits.

(2) Documenting the Informed Consent Process: Prior to undertaking any treatment or procedure using telemedicine and/or telehealth, the practitioner must obtain an informed consent and document the informed consent process in the medical record as described in subparagraph 4c(3), "Documenting the Informed Consent Process".

(a) When the treatment or procedure that will be delivered via telemedicine and/or telehealth is low-risk and within commonly accepted standards of practice, a signature consent is not required.

(b) Treatments or procedures that meet one or more of the criteria listed in subparagraph 4c 3(b), "Treatment and Procedures that Require Signature Consent", or are listed in Appendix B, require signature consent, whether provided via telemedicine and/or telehealth or in a face-to-face consultation. The degree of risk associated with some procedures may increase when telemedicine and/or telehealth is used. If the method used to deliver the care, i.e., telemedicine and/or telehealth, can be reasonably expected to produce significant discomfort to the patient or can reasonably be considered to have a significant risk of complication or morbidity, then the patient or surrogate must sign an authorized VA consent form. In addition, signature consent is required for the use of home telehealth.

5. RESPONSIBILITIES:

a. All practitioners are responsible for ensuring that the informed consent processes outlined in this health care system memorandum are followed.

6. REFERENCES:

a. VA, VHA Handbook 1004.05, "IMEDCONSENT."

b. Title 38 U.S.C. § 7332, "Confidentiality of certain medical records."

c. Title 38 U.S.C. § 7333, "Nondiscrimination against alcohol and drug abusers and persons infected with the human immunodeficiency virus."
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d. Title 38 CFR § 16, “Protection of Human Subjects.”

e. VA, VHA Handbook 1004.05, Advance Health Care Planning (Advance Directive).


h. VHA Handbook 1004.3, "Do Not Resuscitate (DNR) Protocols Within the Department of Veterans Affairs (VA)."

i. Veterans Health Administration. VHA Six for 2006 (http://vaww.va.gov/6for2006/).

j. The Joint Commission, Comprehensive Accreditation Manuals, CAHM, CAMBHC, CAMHC, CAMLTC (2010).


8. RESPONSIBLE OFFICIAL: Chief of Staff.

Elizabeth Joyce Freeman
Director

Attachments (2)
DEFINITIONS

a. **Best Interests.** The standard to be used by surrogate decision makers to guide health care decisions when the patient’s specific values and wishes are unknown. The surrogate, together with the health care team, uses this standard to determine the optimal outcomes for patients and the interventions most likely to produce them. In making that determination the surrogate must also take into account the patient’s cultural, ethnic, and religious perspectives, if known.

b. **Close Friend.** Any person 18 years or older who has shown care and concern for the patient’s welfare and is familiar with the patient’s activities, health and religious beliefs, and values. The close friend must present a signed, written statement (to be filed in the medical record) describing (with specific examples) that person’s relationship to and familiarity with the patient. Social Work Service, or other staff, must verify, in a signed and dated progress note, that this requirement has been met.

c. **Coercion.** Influencing, or attempting to influence, the patient’s (or surrogate’s) choice of treatment by use of threat(s), inducement(s), or misleading information.

d. **Competency.** In relation to decision-making capacity, competency is a legal determination, made by a court of law, that a patient has the requisite capacities to make a medical decision. This is in contrast to the term “decision-making capacity” which is a clinical determination made by the practitioner.

e. **Decision-Making Capacity.** Decision-making capacity for health care decisions has four major components: understanding, appreciating, formulating, and communicating. The first two components represent the patient’s ability to understand and appreciate the nature and expected consequences of each health care decision. This includes understanding the known benefits and risks of the recommended treatment options, as well as any reasonable alternative options including no treatment. The latter two components represent the ability to formulate a judgment and communicate a clear decision concerning health care. As used in this Handbook, “capacity” is a clinical determination made by the practitioner, in contrast to the term “competency,” which is a legal determination made by a court of law.

f. **Health Care Agent.** The individual named in a Durable Power of Attorney for Health Care (DPAHC) document executed by the patient prior to losing decision-making capacity. This individual acts on the patient’s behalf to make health care decisions, including the use of life-sustaining treatment when the patient is unable to make such decisions (see VHA Handbook 1004.2, and Department of veterans Affairs (VA) Form 10-0137, VA Advance Directive: Living Will and Durable Power of Attorney for Health Care (DPAHC)).

g. **Legal Guardian or Special Guardian.** A person appointed by a court of appropriate jurisdiction to make health care decisions for an individual who has been judicially determined to be incompetent. The appointment may be of limited duration. Under VHA policy, legal guardians and special guardians have the same authority to make health care decisions as any surrogate authorized under this policy. **NOTE:** Financial or other types of limited guardianship do not always include the authority to make health care decisions.
h. **Next-of-Kin.** A relative (18 years of age or older) of the patient who may act as surrogate in the following order of priority, as specified in Title 38 Code of Federal Regulations (CFR) 17.32: spouse, child, parent, sibling, grandparent, grandchild.

i. **Practitioner.** Any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure. For the purpose of this Handbook, the term practitioner includes medical and dental residents, regardless of whether they have been granted clinical privileges.

Practitioners permitted to obtain informed consent: The category of practitioners who can obtain informed consent has been broadened to include health professionals (e.g., Nurse Practitioners, Physician Assistants) **who have consent and performance of the procedure included in their scope of practice.**

j. **Risks.** The possible undesirable outcomes of a treatment or procedure including side effects, complications, serious social or psychological harms, or other adverse outcomes.

k. **Signature Consent.** The patient’s (or surrogate’s) signature in the iMedConsent application or on a VA authorized consent form.

l. **Substituted Judgment.** The standard to be used by surrogate decision makers who have specific knowledge of the patient’s values and wishes pertaining to health care choices. This standard requires that the surrogate decide based on what the patient would have wanted if he or she were capable of expressing those preferences. That decision may not necessarily coincide with what the surrogate and health care team otherwise would consider optimal for the patient.

m. **Surrogate Decision Maker ("surrogate").** An individual, committee, or decision-making process authorized under VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity.

n. **Telemedicine and/or Telehealth.** Electronic communications and information technology used to provide and support health care when distance separates the participants. Telemedicine and/or telehealth includes the remote monitoring of physiological data and video visits. Telemedicine and/or telehealth does not include the use of the telephone for direct audio consultation between practitioners and patients or surrogates.

o. **VA Authorized Consent Form.** A published, numbered, official VA Form such as OF 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, or a comparable form approved by the local VHA facility, including approved electronic consent forms.

p. **iMedConsent.** A software package that supports electronic access, completion, signing, and storage of such documents as informed consent forms and advance directives.
APPENDIX B

TREATMENTS OR PROCEDURES REQUIRING THE PATIENT’S SIGNATURE CONSENT

1. Any procedure classified as a surgical operation

2. Anesthesia (epidural, spinal, endotracheal) or sedation

3. All endoscopic procedures

4. Transfusion of blood or blood components

5. Radiographic procedures requiring injection of contrast media in high-risk patients (e.g., those with prior allergic reactions, renal failure or other risk factors)

6. Examples of invasive procedures requiring informed consent:

   Acupuncture
   Angiograms
   Arthrocentesis
   Aversive conditioning
   Biopsy (including skin biopsy)
   Bone marrow aspiration or biopsy
   Bronchogram
   Bronchoscopy
   Cardiac Catheterization
   Cardiopulmonary exercise testing
   Cardioversion (electrical, non-emergent)
   Cardiac pacing, transvenous electrode insertion
   Centrally delivered TPN (total parenteral nutrition)
   Central venous access device insertion (e.g., PIC, PA, Hickman)
   Chemotherapy (for cancer)
   Cholangiogram
   Computerized axial tomography
   Colonoscopy
   Cystoscopy
   Dental extraction and other oral surgeries
   Patient interviews with IV administration of hypnotics
   Electrocautery
   Electroconvulsive therapy*
   ERCD - Endoscopic Retrograde Cholangioduodenoscopy
   Esophagoscopy
   Excision, removal or destruction of a lesion
   Foreign body removal
Genetic testing
Gastroscopy
Dialysis (a single written consent required for ongoing treatment)
Human immunodeficiency virus (HIV) antibody testing*
Injection into joint
Intercostal catheter insertion
Laparoscopy
Laryngoscopy
Laser therapy
Laser brain tissue ablation
Lumbar puncture
Myelogram (myelography)
Paracentesis (abdominal tap)
Pericardiocentesis
Peritoneal catheter insertion
Peritoneal dialysis (prior to first dialysis)
Photochemotherapy with psorales or other topical agents
Pneumothorax, induced
Pyelogram, retrograde/intravenous
Psychosurgery
Sigmoidoscopy
Sterilization, hysterectomy*
Subdural block
Surgery (of any type even cauterizations and suturing)
Thoracentesis
Thoracotomy, chest tube, for open drainage
Tracheotomy
Transhepatic cholangiogram
Transjugular intrahepatic portal stent (TIPS)
Ultrasound therapy (e.g., lithotripsy)
Ureteroscopy
Venograms

* Procedures regulated by specific statutes that expand ordinary informed consent requirements.
HEALTH CARE SYSTEM MEMORANDUM No. 111-08-06

SUBJ: CANCER PROGRAM, MULTIDISCIPLINARY TUMOR BOARD CONFERENCES

1. SUMMARY: This Health Care System Memorandum rescinds Health Care System Memorandum No. 111-05-04. Some changes have been made.

2. PURPOSE: To provide high-quality care to cancer patients at this Health Care System by establishing weekly consultative and multidisciplinary cancer conferences. The conferences will present a format for review of diagnostic, staging and patient data for comprehensive patient treatment decisions, staff education and quality assurance.

3. POLICY: Multidisciplinary cancer conferences are conducted to provide consultative services to cancer patients. Physician representatives from all appropriate disciplines attend and participate in this activity. This interdisciplinary consultation is integral to the patient management process and patient outcomes. The cancer committee at VA Palo Alto Health Care System (VAPAHCS) will follow and comply with the requirements outlined in the most current American College of Surgeon’s Commission on Cancer, Cancer Program Standards 2004.

4. PROCEDURES:

The Cancer Care Committee at VAPAHCS assures that these conferences demonstrate the following:

a. Physician representatives from surgery, medical oncology, radiation oncology, diagnostic radiology and pathology attend and participate in the cancer conferences.

b. Attendance at cancer conferences should target at 80% for the five main disciplines list above.

c. The Cancer Committee may modify the multidisciplinary attendance requirement for the conferences.

d. Cancer Conferences are held weekly and monthly.

e. The number of cases presented annually is 10% of the annual analytic caseload.
Health Care System Memorandum No. 111-08-06
May 12, 2008

f. At least 75 percent of the cases discussed at cancer conferences are presented prospectively.

g. Documentation of these meetings meets the requirements of the American College of Surgeon's Commission on Cancer.

h. Cancer conferences may be hospital-wide, departmental, site focus meetings designated in advance as cancer conferences. The requirement for Tumor Board Conferences at VAPAHCs is met through these:

(1) **Genitourinary CME Tumor Board Conference – monthly**

(a) This tumor board conference discusses patients with genitourinary disease as well as cancer related cases.

(b) Physicians schedule cases or presentation to the Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed for pathology and radiology review at least one week prior to the meeting.

(c) The Cancer Conference coordinator notifies members of the Board of the selected patients by electronic mail and fax. Meeting notices are distributed throughout the facility.

(d) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Surgery, Pathology, and Diagnostic Radiology. All care providers, Residents, Fellows, Medical Students are encouraged to attend. Continuing Medical Education (CME) credits are available for this conference.

(e) The Genitourinary CME Tumor Board Conference meets monthly on the third Tuesday, in the Pathology Conference Room, Bldg 100, 4th Floor, PAD.

(f) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in Computerized Patient Record System (CPRS) by the managing physician.

(2) **Multidisciplinary CME Tumor Board Conference – monthly**

(a) This conference discusses patients with various malignancies who present diagnostic problems.

(b) Physicians schedule cases or presentation to the Multidisciplinary CME Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed for pathology and radiology review at least one week prior to the meeting.
(c) The tumor board coordinator notifies members of the Board of the selected patients by fax and electronic mail. Meeting notices are distributed throughout the facility.

(d) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Diagnostic Radiology, Radiation Oncology and General Surgery and Pathology. All other multidisciplinary staff, residents, fellows and medical students are encouraged to attend. CME credits are available for this conference.

(e) The Multidisciplinary CME Tumor Board Conference meets monthly on the fourth Monday in the Auditorium at PAD, Building 100, 1st Floor at noon.

(f) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

(3) Otolaryngology – Ear, Neck & Throat (ENT) Tumor Board – weekly

(a) Meetings are conducted at the ENT, Head & Neck Tumor Board Conference, Stanford, with VAPAHCS physicians in attendance. They are encouraged to present patients with malignancies who present diagnostic problems.

(b) The VAPAHCS ENT department is responsible for scheduling and coordinating the presentation of patients at this conference. Documentation, including attendance and cases presented, are forwarded to the Cancer Registry.

(c) Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Surgery, Diagnostic Radiology, Radiation Oncology, and Pathology. All multidisciplinary staff, residents, fellows and medical students are encouraged to attend. CME credits are available for this conference.

(d) The ENT tumor board meets weekly on every Thursday at Stanford Cancer Center, Clinic B at 10am.

(e) The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

(4) Pulmonary - Thoracic CME Tumor Board Conference – monthly

(a) This multidisciplinary case review conference discusses patients with pulmonary/chest diseases as well as cancer related cases.

(b) Physicians schedule cases or presentation to the CME Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed for pathology and radiology review at least one week prior to the meeting.
The Pulmonary-Thoracic CME Tumor Board Conference meets monthly on the last Thursday of the month in the Diagnostic Radiology Center (DRC) Conference Room, Bldg 102, PAD at 4:00 PM.

Meetings are attended by the medical staff in the following disciplines: Medical Oncology, Surgery, Diagnostic Radiology, Radiation Oncology and Pathology. All multidisciplinary staff, residents, fellows and medical students are encouraged to attend. CME credits are available for this conference.

The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

Liver Tumor Board Conference - monthly

This multidisciplinary case review conference discusses patients with liver diseases as well as cancer related cases.

Physicians schedule cases or presentation to the Tumor Board Conference by calling or emailing the cancer registrar and by advising the registrar of the name, diagnosis and reports needed radiology review at least one week prior to the meeting.

Meetings are attended by the medical staff in the following disciplines: Diagnostic Radiology and General Surgery. All multidisciplinary staff, residents, fellows and medical students are encouraged to attend.

The Liver Tumor Board Conference meets monthly on the 2nd Monday of the month in the DRC Conference Room, PAD at 4:30 PM.

The plan of care and recommendations from the discussion are documented in the Tumor Board Progress note in CPRS by the managing physician.

RESPONSIBILITIES:

All Cancer Care Committee Members will be responsible for:

1. Ensuring that educational and consultative cancer conferences are available to the medical staff and allied health professionals.

2. Ensuring that educational and consultative cancer conferences cover all major sites and related issues.

3. Ensuring that all Multidisciplinary Tumor Board Conference physicians are fully informed of this policy and that this policy is followed.
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May 12, 2008

(4) Monitoring and evaluating the cancer conference frequency, multidisciplinary attendance, total case presentation, and prospective case presentation on an annual basis.

b. The Cancer Program Coordinator and the Cancer Registrar will be responsible for:

(1) Coordinating the activities of the multidisciplinary cancer conferences (Tumor Board) and maintain the required documentation for there activities.

(2) Submitting a yearly cancer conference activities report to the Cancer Care Committee.

6. REFERENCE: American College of Surgeon Commission on Cancer, Cancer Program Standard 2004

7. RESCISSION DATE: May 31, 2011

8. RESPONSIBLE OFFICIAL: Chief, Medical Oncology

Elizabeth Joyce Freeman
Director