

**REQUIREMENTS FOR THE ADMINISTRATION OF CHEMOTHERAPY AND OTHER
ANTI-CANCER DRUGS**

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for the administration of chemotherapy and other anti-cancer drugs.

2. SUMMARY OF CONTENT: This is a new directive. This directive delineates responsibilities for VHA health care professionals regarding the use of chemotherapy and anti-cancer drugs in Veterans Affairs (VA) health care facilities. This directive sets mandatory processes that must be satisfied prior to administration of chemotherapy and other anti-cancer drugs. **NOTE:** *While this directive is focused on the administration of drug therapy for cancer care, the requirements outlined in this policy apply broadly when these drugs are administered for non-cancer uses.*

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Office of Patient Care Services, Specialty Care Services (10P11) is responsible for the contents of this directive. Questions may be referred to (202) 461-7120 or cancer@va.gov.

5. RESCISSIONS: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of June 2020. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health
for Policy and Services

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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REQUIREMENTS FOR ADMINISTRATION OF CHEMOTHERAPY AND OTHER ANTI-CANCER DRUGS

1. PURPOSE

This directive establishes Veterans Health Administration (VHA) health responsibilities including processes and facility requirements that must be satisfied prior to administration of chemotherapy and other anti-cancer drugs at Veterans Affairs (VA) health care facilities. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

Anti-Cancer drugs have frequent and sometimes severe, acute drug reactions, and present unique occupational health challenges. While this directive is focused on the administration of drug therapy for cancer care, the requirements outlined in this policy apply broadly when these drugs are administered for non-cancer uses.

3. DEFINITIONS

a. **Anti-cancer drugs.** For the purposes of this directive, anti-cancer drugs are used to treat malignancies or cancerous growth. Anti-cancer drugs include chemotherapy, biologics, immunotherapy, targeted agents, hormonal agents, and steroids. Many anti-cancer-drugs have a narrow therapeutic window. **NOTE:** *A narrow therapeutic window means that there is a small difference between an effective dose and toxic dose of an anti-cancer drug. Safe and effective use of anti-cancer drug products require careful dosage titration and patient monitoring. NOTE: Radiopharmaceuticals are another class of anti-cancer drug but are not covered by this directive.*

b. **Licensed Independent Practitioner.** For the purposes of this directive, a licensed independent practitioner is an individual permitted by and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted privileges.

c. **VA Medical Facility.** For the purposes of this directive, a medical facility is any property assigned to VHA that is under the charge and control of VA (and not under the charge and control of GSA) and includes Veterans Integrated Service Networks (VISNs), VHA Health Care Systems, Community-Based Outpatient Clinics (CBOCs), Readjustment Counseling Centers (Vet Centers), and VHA Research Centers of Excellence.

d. **VHA Health Care Providers.** For the purposes of this directive, a health care provider includes Medical Doctor (MD), Doctor of Osteopathy (DO), Nurse Practitioner (NP), Physician Assistant (PA), Clinical Nurse Specialist (CNS), Registered Nurses (RN), and Clinical Pharmacy Specialists (CPS). **NOTE:** *Not all health care providers are licensed independent practitioners.*

4. POLICY

It is VHA policy that chemotherapy and other anti-cancer drugs are uniformly administered in a safe manner that maximizes Veteran benefit, minimizes risk, and minimizes environment exposure to potentially hazardous materials for VHA health care professionals and VA medical facility staff.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Policy and Services.** The Deputy Under Secretary for Policy and Services is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Ensuring that each VISN Director has the sufficient resources to implement this directive in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **Chief Officer (or Designee), Office of Specialty Care Services.** The Chief Officer (or designee), Office of Specialty Care Services is responsible for:

(1) Conducting an Oncology Services Survey that includes staffing, procedures, and policy for administration of anti-cancer drugs at least every 5 years.

(2) Reviewing any reports of non-compliance provided by VISNs and provide advice and corrective action to VISNs and VA medical facilities as needed.

d. **Veterans Integrated Services Network (VISN) Director.** The VISN Director is responsible for:

(1) Ensuring facilities administering chemotherapy and other anti-cancer drugs follow the procedural requirements during the administration of chemotherapy and other anti-cancer drugs in accordance with Program Guidance located on the Oncology SharePoint: <https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/>. **NOTE:** *This is an internal website that is not available to the public.*

(2) Ensuring the facility requirements are satisfied prior to the administration of chemotherapy and other anti-cancer drugs in accordance with Program Guidance located on the Oncology SharePoint.

(3) Reviewing audit reports for compliance with this policy at least annually and reporting any non-compliance to the Chief Officer, Office of Specialty Care Services. **NOTE:** *The audit reports are submitted by the VA medical facility Directors.*

e. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Providing staffing, training, space, and resources needed to comply with the procedural requirements during the administration of chemotherapy and other anti-cancer drugs in accordance with Program Guidance located on the Oncology SharePoint: <https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/>. **NOTE:** *This is an internal website that is not available to the public.*

(2) Completing any Oncology Services Survey, including staffing, procedures, and policy for administration of anti-cancer drugs, within 60 days of issuance. **NOTE:** *The Oncology Services survey is completed every 5 years. The survey collects information about the types of services available for Veterans and facility capacities.*

(3) Conducting an annual audit of compliance with this directive, generating a report of the annual audit, and reporting any non-compliance with this directive to the VISN Director.

(4) Promoting a culture of safety in which employees feel free to report noncompliance with this directive through the chain of command based on local organizational charts. **NOTE:** *Reporting instances of noncompliance is a responsibility at all levels of the organization and is repeated in each of the responsibilities below.*

f. **VA Medical Facility Chief of Staff (or Designee).** The VA medical facility Chief of Staff (or designee) is responsible for:

(1) Assigning a physician or other licensed independent provider to be on site during the administration of chemotherapy and other anti-cancer drugs.

(2) Confirming that Oncology Providers follow the procedural requirements during the administration of chemotherapy and other anti-cancer drugs in accordance with Procedural Requirements for the Prescribing, Reviewing, and Dispensing of Anti-Cancer Drugs located in the Program Guidance folder located on the Oncology SharePoint: <https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

g. **Associate Director for Patient Care Services (or designee).** The Associate Director for Patient Care Services (ADPSC) or designee is responsible for:

(1) Ensuring the procedural requirements for the administration of chemotherapy and other anti-cancer drugs in accordance with Procedural Requirements for the Prescribing, Reviewing, and Dispensing of Anti-Cancer Drugs located in the Program Guidance folder located on the Oncology SharePoint: <https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

(2) Ensuring that nursing procedures are in place based on local need for handling and managing chemotherapy and other anti-cancer drugs, including management of immediate drug reactions and side effects and adverse events.

(3) Ensuring that nurses receive the appropriate training in accordance with Education, Training, Facility Best Practices/Recommendations for the Administration of Anti-Cancer Drugs which is located in the Program Guidance folder located on the Oncology SharePoint. **NOTE:** *Nurses must receive training that demonstrates knowledge and competency in the administration and handling of anti-cancer medications, regardless of indication.*

(4) Ensuring that nurses involved in the administration and handling of anti-cancer medications, regardless of indication, have access to appropriate personal protective equipment (PPE) and waste disposal equipment.

(5) Providing up-to-date electronic access to evidence-based nursing references.

(6) Reporting any instances of noncompliance of this directive through the chain of command based on local organizational charts.

h. **Oncology Providers and others prescribing anti-cancer drugs.** Prior to prescribing anti-cancer medications oncology providers are responsible for:

(1) Obtaining informed consent from the patient, including signature consent, in accordance with VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009. **NOTE:** *For more information about the applicability of Informed Consent see, Informed Consent located in the Program Guidance folder on the Oncology SharePoint: <https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** *This is an internal VA Web site that is not available to the public.**

(2) Document the treatment plan in accordance with instructions located in the Program Guidance folder on the Oncology SharePoint.

(3) Ordering Anti-cancer drugs based on established evidence and a published treatment regimen.

(4) Ensuring the procedural requirements are followed during the ordering and administration of chemotherapy and other anti-cancer drugs in accordance with Procedural Requirements for the Prescribing, Reviewing, and Dispensing of Anti-Cancer Drugs located in the Program Guidance folder on the Oncology SharePoint.

(5) Reporting any instances of noncompliance of this directive through the chain of command based on local organizational charts.

i. **Chief of Pharmacy or designee.** The Chief of Pharmacy or designee is responsible for:

(1) Following the pharmacy-related procedural requirements for the administration of chemotherapy and other anti-cancer drugs in accordance with Procedural Requirements for the Prescribing, Reviewing, and Dispensing of Anti-Cancer Drugs located in the Program Guidance folder on the Oncology SharePoint:

<https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** This is an internal VA Web site that is not available to the public.

(2) Instituting the pharmacy-related facility requirements for the administration of chemotherapy and other anti-cancer drugs in accordance with Education, Training, Facility Best Practices/Recommendations for the Administration of Anti-Cancer Drugs which is located in the Program Guidance folder on the Oncology SharePoint.

(3) Reporting any instances of noncompliance of this directive through the chain of command based on local organizational charts.

j. **Oncology Nurses**. Oncology Nurses are responsible for:

(1) Prior to and during the administration of anti-cancer medications, oncology nurses are responsible for following the procedural requirements for the administration of chemotherapy and other anti-cancer drugs in accordance with Procedural Requirements for the Prescribing, Reviewing, and Dispensing of Anti-Cancer Drugs located in the Program Guidance folder on the Oncology SharePoint:

<https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** This is an internal VA Web site that is not available to the public.

(2) Responsible for patient and family education related to anti-cancer therapy as well as evaluating and intervening related to response to education.

(3) Responsible for the safe administration and management of chemotherapy and other anti-cancer therapy, prevention and management of adverse effects of therapy.

(1) Responsible for using the appropriate PPE to minimize exposure to and environmental contamination related chemotherapy and other anti-cancer therapy that are considered hazardous.

(2) Reporting any instances of noncompliance of this directive through the chain of command based on local organizational charts.

k. **VA Facility Hazardous Chemical Management Program Coordinator**. The VA facility hazardous chemical management Program Coordinator is responsible for providing support regarding the safe handling and disposal of hazardous anti-cancer medications in accordance VHA Directive 7705 Management of Hazardous Chemicals, dated August 14, 2015. **NOTE:** This directive does not create new responsibilities for hazardous chemicals and waste management. Policy requirements for these topics are found in VHA Directive 7701 Comprehensive Occupational Safety and Health Program, dated May 5, 2017, and VHA Directive 1850.06 Waste Management Program, dated May 19, 2017.

6. TRAINING

There are no formal training requirements associated with this directive. **NOTE:** For educational and training expectations of VHA health care professionals in oncology

services see *Requirements for the Administration of Chemotherapy and Anti-Cancer Drugs* located in the Program Guidance folder on the Oncology SharePoint: <https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** This is an internal website that is not available to the public.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. 38 U.S.C. 7301(b).
- b. 21 CFR 320.33.
- c. VHA Directive 1108.06 Inpatient Pharmacy Services, dated February 8, 2017.
- d. VHA Directive 1108,07 Pharmacy General Requirements, dated March 10, 2017.
- e. VHA Directive 1108.12 Management and Monitoring of Pharmaceutical Compounded Sterile Preparations, dated November 5, 2018.
- f. VHA Directive 1412, Department of Veterans Affairs Cancer Registry System, dated, May 29, 2019.
- g. VHA Directive 1850.06 Waste Management Program, dated May 19, 2017.
- h. VHA Directive 7701 Comprehensive Occupational Safety and Health Program, dated May 5, 2017.
- i. VHA Directive 7705 Management of Hazardous Chemicals, dated August 14, 2015.
- j. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.
- k. VHA Handbook 1108.11(1) Clinical Pharmacy Services, dated July 1, 2015.

ADDITIONAL RESOURCES

For more Information about the administration of anti-cancer drugs, see *Requirements for the Administration of Chemotherapy and Anti-Cancer Drugs* located in the Program Guidance folder on the Oncology SharePoint:

<https://vaww.infoshare.va.gov/sites/specialtycare/Oncology/Documents>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

a. Commission on Cancer Care. *Cancer Program Standards: Ensuring Patient-Centered Care* (2016):
https://www.facs.org/~media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx. **NOTE:** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

b. Goldspiel, B., Hoffman, J.M., Griffith, N.L., Goodin, S., DeChristoforo, R., Montello, C.M., Chase, J.L., Bartel, S., and Patel, J.T. *ASHP guidelines on preventing medication errors with chemotherapy and biotherapy*. *Am J Health-Syst Pharm* 2015;72: e 6-35: <https://www.ncbi.nlm.nih.gov/pubmed/25825193>.

c. Goodin S, Griffith N, Chen B, Chuk, K., Daouphars, M., Doreau, C., Patel, R., Schwartz, R., Tames, M.J., Terkola, R., Vadnais, B., Wright, D., Meier, K., *Safe Handling of Oral Chemotherapeutic Agents in Clinical Practice: Recommendations from an International Pharmacy Panel*. *J Oncology Practice* 2011; 7:7-12:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3014516/>.

d. Neuss, M.N., Gilmore, T.R., Belderson, K.M., Billett, A.L., Conti-Kalchik, T., Harvey, B.E., Hendricks, C., LeFebvre, K., Mangu, P.B., McNiff, K., Olsen, M., Schulmeister, L., Von Gehr, A., Polovich, M. *Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology*. *J Oncol Pract*. 2016 12: 1262-127:
<https://reference.medscape.com/medline/abstract/27868581>. **NOTE:** *This Web site is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

e. United States Pharmacopeia (USP), <http://www.usp.org/>. **NOTE:** *This Web site is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

f. 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. *Oncology Nursing Forum*. Vol. 44, No. 1, January 2017. Doi: 10.1200/jop.2016.017905:
https://www.researchgate.net/publication/310627398_2016_Updated_American_Societ

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[y of Clinical OncologyOncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for Pediatric Oncology.](#) **NOTE:** *This Web site is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*