

## Criteria for Facilities and Personnel for the Administration of Parenteral Systemic Antineoplastic Therapy

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From the American Society of Clinical Oncology, Alexandria, VA.

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These criteria will be reevaluated and revised as necessary biennially or at the discretion of the Chair of the American Society of Clinical Oncology (ASCO) Clinical Practice Committee.

Authors' disclosures of potential conflicts of interest are found at the end of this article.

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### A B S T R A C T

The following American Society of Clinical Oncology (ASCO) position statement represents an update to policy first adopted by the Board in 1997 (J Clin Oncol 15:3416-3417, 1997). The primary change to the statement is the addition of language to section 7, Standards for Antineoplastic Therapy, describing safeguards for preparing and administering chemotherapy drugs. As third-party payors consider and follow through with the establishment of new models for chemotherapy drug procurement, distribution, and delivery, ASCO provides guidance to oncologists to help them ensure the safety and integrity of the drugs they administer. Additionally, section 5, Office Operations, also suggests that oncologists consider measures protecting them from liability associated with drugs obtained from or prepared by outside entities.

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### INTRODUCTION

Modern antineoplastic therapy has improved both the quality of life and the chance for cure for millions of Americans afflicted with cancer. The treatment of patients with parenteral medications requires many safeguards to achieve the best possible outcome for the patient, with the least toxicity. Because of the toxicities of these agents, specialized training is necessary for those who prescribe, reconstitute, and administer them. In addition, specialized facilities and support services are required to manage the multiple side effects that may accompany use of these agents.

The purpose of this document is to set forth the minimum level of services necessary for the provision of systemic antineoplastic therapy. The criteria apply to a physician's office, infusion center, free-standing cancer center, and any other treatment site, except a hospital outpatient department. The terms "chemotherapy" and "antineoplastic therapy" as used in this document include all systemic parenteral antineoplastic therapy

(this does not include radiopharmaceuticals and photosensitizing agents).

### CRITERIA

#### 1. Physical Plant Requirements

A. The facility should comply with National Committee on Quality Assurance standards regarding the adequacy of waiting-room chairs per physician present and the adequacy of examining rooms per physician present.<sup>1</sup>

B. The facility should comply with the Federal Americans with Disabilities Act.<sup>2</sup>

C. The facility should have satisfactory treatment areas (eg, chairs, recliners, and/or beds, as appropriate to patient needs), and it should have treatment areas that can afford privacy when needed, yet maintain immediate nurse or physician access.

D. Chemotherapy and other hazardous drugs should be stored and prepared in adherence with federal requirements relating to occupational safety and health.<sup>3</sup>

#### 2. Staff Qualifications

A. Physicians who order, administer, and/or supervise the administration of

antineoplastic agents should be qualified to administer such agents. Qualification exists if the physician has acquired the specific cognitive and technical skills necessary to administer antineoplastic therapy, including management of its side effects. Such skills are best acquired in a formal training program of significant duration. However, such skills may also be acquired through a combination of training and experience. Experience should be obtained under the close supervision of a physician qualified to administer antineoplastic therapy.

B. If an antineoplastic agent is not personally administered by a qualified physician as described in paragraph A, it should be administered under the supervision of such a physician by professional staff who are specifically trained in antineoplastic administration procedures. Licensure as a registered nurse or physician assistant, and certification as an oncology-certified nurse are highly desirable. All staff should be in compliance with the respective US state's practice acts.

### **3. Laboratory Access**

Patients should have immediate access to a laboratory, either within the office or through another facility. This laboratory should be able to report the results of the patient's laboratory tests to the physician quickly enough to permit evaluation for chemotherapy on the same day. The laboratory should comply with state licensure and federal certification requirements.<sup>4</sup>

### **4. Office Emergency Procedures**

A. Physicians and nursing staff should have cardiopulmonary resuscitation training.

B. Medications for the treatment of anaphylaxis, including oxygen, should be immediately available.

C. An appropriately trained physician should be physically present in the facility when a drug or biologic therapy that is known to cause anaphylaxis is being administered.

### **5. Office Operations**

A. There should be appropriate physician supervision of all professional staff who provide patient care.

B. There should be documentation in patient records of all patient interactions, including evaluation and management services; dosage, route, and type of antineoplastic chemotherapy; and supportive-care treatments.

C. There should be professional review of laboratory, radiology, and other important reports before filing.

D. A physician should be continuously available by telephone for an emergency (24 hours a day, 7 days a week).

E. Oncologists may wish to consider contractual provisions under which any outside entity from whom drugs are purchased warrants the proper furnishing of drugs and agrees to indemnify the oncologist for any losses resulting from the outside entity's errors.

### **6. Administrative Support**

A. There should be adequate staff to fulfill the following functions: (1) compliance with the procedures of managed-care organizations and other insurers; (2) completion and distribution of medical reports; (3) patient scheduling, office management, and telephone follow-up; (4) ordering, stocking, and maintaining inventory of drugs and supplies.

B. There should be appropriate equipment and staff to receive emergency medical reports.

C. There should be sufficient, appropriately trained staff to provide education to patients regarding their disease and proposed antineoplastic treatment.

### **7. Standards for Antineoplastic Therapy**

A. The administration of chemotherapy should comply with federal and state requirements regarding occupational safety and health.<sup>3</sup>

B. Procedures to manage chemotherapy extravasations should be established.

C. There should be review procedures to detect and prevent both overdosing and underdosing of antineoplastic and supportive-care drugs.

D. Procedures to ensure that antineoplastic and supportive-care drugs are properly labeled for identity and dosage should be established.

E. Procedures to ensure that antineoplastic and supportive-care drugs are mixed properly should be established.

F. The date of administration of an antineoplastic or supportive-care drug should fall within the date of expiration on the manufacturer's label.

G. Procedures to ensure that antineoplastic and supportive-care drugs are properly handled before and after preparation should be established.

H. Procedures to ensure that antineoplastic and supportive-care drugs and their containers are not contaminated or diluted should be established.

I. Antineoplastic and supportive-care drugs should be available on a schedule that meets treatment needs.

J. Antineoplastic and supportive-care drugs should be furnished soon enough after mixing to comply with the US Food and Drug Administration's preparation instructions.<sup>5</sup>

### **8. Policies and Procedures for Support Services**

A. Materials for patient education regarding diagnosis, treatment, and drugs administered should be available.

B. Referral procedures for psychosocial services should be available.

C. Referral procedures for nutritional counseling should be available.

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### **Authors' Disclosures of Potential Conflicts of Interest**

The authors indicated no potential conflicts of interest.

REFERENCES

1. Standards for Accreditation of Managed Care Organizations are issued by the National Committee for Quality Assurance and updated on a yearly basis. Copies of the standards (Item No. 10351-100-04) may be obtained for \$85.00 by contacting the Publications Department of NCOA at 2000 L Street, Suite 500, Washington, DC, 20036. To order by telephone, call 888-275-7585. Orders are also taken online at [www.ncqa.org/publications](http://www.ncqa.org/publications).

2. The Americans with Disabilities Act of 1990 (Public Law 101-336) is codified in the United States Code at 42 U.S.C. 12101-12213. Many libraries have a copy of the United States Code. In addition, copies of the law (Stock No. 869-010-00096-1), may be obtained for \$2.00 from the US Government Printing Office, ATTN: Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250-7954. Credit card orders may be placed by calling 202-512-1800 (fax 202-512-

2250). The US Code is also available online at [www.gpoaccess.gov/uscode](http://www.gpoaccess.gov/uscode).

3. Occupational health and safety standards issued by the Occupational Safety and Health Administration (OSHA) of the US Department of Labor are codified in the Code of Federal Regulations at 29 C.F.R. Part 1910. University and county law libraries have copies of the Code of Federal Regulations. The two volumes of the Code of Federal Regulations that contain the OSHA standards (Parts 1900 to 1910 and Part 1910) (Stock No. 869-048-00104-2 and 869-044-00105-5) may be purchased for \$58.00 and \$42.00 from the US Government Printing Office as described in ref 2. The Code of Federal Regulations is also available online at [www.gpoaccess.gov/cfr](http://www.gpoaccess.gov/cfr). The OSHA Technical Manual includes Chapter 21, "Controlling Occupational Exposure to Hazardous Drugs." The OSHA Technical Manual is available online at [www.osha-slc.gov/dts/otm/otm\\_toc.html](http://www.osha-slc.gov/dts/otm/otm_toc.html).

4. The Clinical Laboratory Improvements Act (CLIA) is codified in the United States Code at 42

U.S.C.A. 263a. Many libraries have a copy of the United States Code. Regulations issued by the Centers for Medicare & Medicaid Services to implement CLIA are codified in the Code of Federal Regulations at 42 C.F.R. Part 493. University and county law libraries have copies of the Code of Federal Regulations. The volume of the Code of Federal Regulations that contains the CLIA regulations (Title 42, Part 430 to End) (Stock No. 869-048-00168-9) may be purchased for \$61.00 from the US Government Printing Office as described in ref 2. The Code of Federal Regulations is also available online at [www.gpoaccess.gov/cfr](http://www.gpoaccess.gov/cfr).

5. The Food and Drug Administration (FDA) approved preparation instructions can be found on the package insert that comes with each drug. Package inserts can also be obtained by contacting the FDA in writing at Food and Drug Administration, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, or in compendia such as the Physicians' Desk Reference.