

STATEMENT REGARDING THE USE OF OUTSIDE SERVICES TO PREPARE OR ADMINISTER CHEMOTHERAPY DRUGS

Adopted on March 3, 2004 by the American Society of Clinical Oncology*

Traditionally, outpatient chemotherapy has been administered in physician offices or hospital outpatient departments using drugs prepared by the physician's staff or the hospital pharmacy. More recently, some alternative arrangements are being proposed, typically by insurance companies and managed care organizations, which may require that their enrollees be subject to particular arrangements. Two such arrangements are (1) requiring cancer patients to receive their chemotherapy from an infusion center or home care agency that is operated by a person other than the patient's oncologist, and (2) requiring the oncologist to administer chemotherapy agents that were prepared outside the physician's office by an entity under contract with the third-party payer.

The American Society of Clinical Oncology is concerned that such arrangements may increase the potential for medication errors and other mishaps – with potential adverse effects on patient health, including toxic reactions and ineffective treatment. The purpose of this statement is to encourage oncologists to enter into such arrangements only if the arrangements provide adequate safeguards against such outcomes.

Many chemotherapy agents are extremely toxic drugs capable of causing death or serious injury to patients if prepared, handled, or administered improperly. Although deaths and injuries resulting from erroneous chemotherapy are believed to be relatively rare, serious medication errors can occur even in institutions that ostensibly have adequate systems to prevent mistakes. Oncologists who rely on entities not under their control to provide chemotherapy or chemotherapy drugs need to assure themselves that the risk of error has been minimized by those entities. Apart from the issue of medication errors, the toxic effects of chemotherapy drugs demand that their administration be supervised by physicians who are qualified to do so and furnished in a facility equipped to deal with the adverse effects of chemotherapy.

Referral to Outside Entities for Chemotherapy

An oncologist should refer patients to an outside entity, such as an infusion center or home care agency, for administration of chemotherapy only if the entity meets appropriate standards for administration of chemotherapy. These standards include the following criteria:

- ?? Administration of chemotherapy should be supervised by a physician who is qualified by training and/or experience to administer antineoplastic agents.
- ?? Chemotherapy should be administered by professional staff who are specifically trained in chemotherapy procedures. Licensure as a doctor of

medicine, doctor of osteopathy, registered nurse, or physician assistant, and certification as an oncology certified nurse, are highly desirable.

- ?? Physicians and nursing staff should have CPR training.
- ?? Medications for the treatment of anaphylaxis, including oxygen, should be immediately available.
- ?? An appropriately trained physician should be physically present in the facility when a drug or biological that is known to cause anaphylaxis is being administered.
- ?? The facility should have procedures to manage chemotherapy extravasation.
- ?? The facility should have review procedures to detect and prevent both over- and under-dosing of antineoplastic and supportive care drugs.

Use of Chemotherapy Drugs Prepared by an Outside Entity

If an oncologist administers chemotherapy drugs prepared by an outside entity, there may be a greater risk to patients than if the drugs are prepared within the oncologist's own office. There are a number of factors that may contribute to increased risk. Most important, the identity and dosage of the drug will not be known to the oncologist unless the outside entity has properly prepared and labeled the drug. In addition, there may be a question whether the drug was properly mixed; whether the drug is within the manufacturer's labeled expiration date; whether the drug has been properly handled before and after preparation; whether the drug or its container has become contaminated; or even, as in recently publicized cases, diluted; whether the drug may be the product of deliberate counterfeiting; whether the drug is available to the oncologist on a schedule that meets treatment needs; and whether the drug is being furnished to the oncologist soon enough after mixing to comply with the preparation instructions in the FDA-approved labeling or other applicable requirements.

To protect their patients, oncologists should administer drugs prepared by outside entities only if they are confident that the outside entities have adopted procedures that minimize the risk of error in complying with the oncologists' prescriptions and preparing the drugs. In addition, oncologists may wish to consider contractual provisions under which the outside entity warrants the proper preparation and furnishing of drugs and agrees to indemnify the oncologist for any losses resulting from the outside entity's errors.

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