

ACHC ACCREDITATION STANDARDS

Customized for Oncology

Section 11: Oncology Specialty Accreditation

For a pharmacy to earn accreditation with a distinction in oncology, the provider should have ACHC Specialty Pharmacy Accreditation. This additional accreditation recognition encompasses: delivery of medications for the treatment of cancer-specific conditions; the ability to identify the toxic nature of these medications; and collaboration between the physician, pharmacist, and client/patient to optimize the client's/patient's plan of care, cost containment, and client/patient outcomes.

Standard DRX11-A: The governing body/owner forms a Professional Advisory Committee (PAC) with representation from organizations comprising professionals with expertise in the care and treatment of oncology clients/patients. The PAC meets at least once a year, with the first meeting taking place prior to accreditation being awarded. If the specialty pharmacy is part of a larger organization, this entity must also be represented on the PAC.

Interpretation: The membership of the PAC includes, but is not limited to:

- A physician board-certified in oncology
- A pharmacist with certification in oncology or at least two years experience with directly treating oncology clients/patients
- Registered Nurse (RN)
- Parent company representative, if applicable
- Compliance officer
- Accounting representative

Responsibilities of the PAC include, but are not limited to:

- Reviewing the organization's policies and procedures for accepting and monitoring client/patient medication profiles and developing and managing the plan of care
- Approving new policies and procedures and forms regarding medications offered
- Reviewing the educational material given to client/patients and family members
- Reviewing clinical records
- Reviewing client/patient complaints
- Monitoring organizational and clinical ethical issues, and their resolutions
- Monitoring client/patient medications costs and cost containment effectiveness
- Developing an annual strategic plan for dispensing chemotherapy medication
- Sharing Information with stakeholders and using it in the development of action plans to benefit the clients/patients and staff the organization serves

Evidence: Observation

Evidence: Response to Interview

Services applicable: ONC

Standard DRX11-B: Written policies and procedures are established and implemented for defining the protocol for chemotherapy drugs, where applicable.

Interpretation: Written policies and procedures are established and implemented detailing the review process for each medication order.

Components of the policies and procedures include but are not limited to:

- Dosing weight based on a recent height and weight according to protocol
- Body Surface Area (BSA) available and based on recent height and weight
- Doses calculated correctly and double checked
- Companion diagnostics available and reviewed where applicable

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: ONC

Standard DRX11-C: The organization will inform clients/patients of the cost of their medications and provide information about financial assistance programs for obtaining the medication needed for their treatment.

Interpretation: The organization will provide the client/patient information regarding the cost of medications, and will document the clients'/patients' understanding of their financial obligations and assistance programs. Client/patient education includes, but is not limited to:

- How multiple payors will be billed for the medication provided

- Client/patient assistance programs to offset drug costs
- Co-pay assistance foundations and programs that pertain to their specific therapy and personal financial situation
- Manufacturer assistance programs
- Evidence of pre-authorization approval for their specific medication
- The organization will have the ability to communicate with Pharmacy Benefit Management (PBM) organizations and payor groups to ensure all costs are disclosed to any stakeholders monitoring the overall medication cost of the client's/patient's treatment

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: ONC

Standard DRX11-D: The organization has an accounting system that can track all of its client's/patients' medications and costs.

Interpretation: The accounting system is capable of tracking and providing the following information:

- The total cost of the therapy including medications received through a client/patient assistance program and/or paid for by a third-party payor
- A detailed report of these costs for the client/patient
- The cost of the medications when the organization uses multiple methods for billing (e.g., when 340B pricing and inventory is used)

Evidence: Accounting System

Services applicable: ONC

Standard DRX11-E: Written policies and procedures are established and implemented by the organization in regard to the monitoring of medications using the most cost-effective means.

Interpretation: Written policies and procedures include, but are not limited to:

- Collaboration between physician and pharmacist to ensure that medications are ordered in the most cost-effective manner for the client/patient
- Managing dispensing to the client/patient small quantities of drugs with frequently adjusted doses in order to reduce waste
- Routinely reviewing client/patient medication records at least every 30 days for therapeutic medications that may not be necessary for treatment, and communicating the findings to the prescriber
- Using evidence-based modification strategies based on laboratory values and/or client/patient response, to minimize the risk of toxicity development

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Client/Patient Records

Services applicable: ONC

Standard DRX11-F: Written policies and procedures are established and implemented in regard to guidelines for personnel and organizational safety related to exposure to hazardous material, as set forth by OSHA.

Interpretation: Written policies and procedures include types of safety training as well as the frequency of training. The safety training activities include, but are not limited to:

- Specific training in oncology standards of practice
- Appropriate infection control precautions
- Specific regulations that apply to preparing and dispensing chemotherapy medications
- Safe methods of handling and compounding chemotherapy medications
- Medication error prevention including retraining requirements and thresholds of errors

There is documentation of all personnel training that is specific to the practice of oncology medicine.

Evidence: Written Policies and Procedures
Evidence: Personnel Files

Services applicable: ONC

Standard DRX11-G: Written policies and procedures are established and implemented in regard to additional training required

of personnel who care for cancer clients/patients.

Interpretation: Written policies and procedures describe the specific training required for personnel who will be caring for cancer clients/patients.

This training includes, but is not limited to:

- Sensitivity towards the cancer clients/patients and consideration of their altered condition that includes sensitivity to hot and cold, altered taste and smell, etc.
- Ongoing education on analytical tools available that provide client/patient-specific data for use in the clinical decision-making process

Training is documented.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Personnel Files

Services applicable: ONC

Standard DRX11-H: Written policies and procedures are established and implemented in regard to handling and dispensing oncology medications.

Interpretation: Written policies and procedures include safe methods of handling, labeling, storing, transporting, and dispensing medication. The organization follows local, state, and federal guidelines.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: ONC

Standard DRX11-I: Written policies and procedures are established and implemented for the disposal of hazardous materials and waste.

Interpretation: Written policies and procedures include safe methods for the disposal of hazardous materials and wastes. The organization follows local, state, and federal guidelines. There is documented training for the special care given to handling and disposing of cancer medications.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Personnel Files

Services applicable: ONC

Standard DRX11-J: The organization monitors the use of physician-ordered medications for chemotherapy treatment.

Interpretation: There is documentation in the client/patient record that specifically addresses management of the medication the physician ordered for the chemotherapy treatment. Documentation includes detailed monitoring of any changes in medication that is specific to the cancer treatment. The client/patient record includes, but is not limited to:

- Medication reconciliation among all providers
- Adverse reactions to chemotherapy
- Cumulative dose record for drugs that have a lifetime maximum (e.g., Anthracyclines)
- Client/patient history of drug resistance due to neutralizing immune antibody formation
- Drugs with Risk, Evaluation, and Mitigation Strategies (REMS) requirements
- Primary and comorbid diagnoses
- Documentation of the stages of cancer present
- Medication failure history
- Relevant labs including but not limited to:
 - Renal and liver panels
 - Complete Blood Count (CBC)
 - Radiology
 - Surgery
 - Imaging
 - Genetic testing results
- Drug administration:
 - Cycles completed

- Next cycle scheduled (e.g., cycle 2 of 6 scheduled June 6, 2015)
- Total cycles ordered
- Coordination of medication deliveries in relationship to other treatments
- Allergies
- History and physical
- Supportive care drug orders (hydration, pre-medication, toxicity, and symptoms)
- Goal of therapy (e.g., curative vs. palliative)
 - Client/patient performance status using published methodology (e.g., Karnofsky, Zubrod, Lansky, or ECOG score)

Evidence: Client/Patient Records

Services applicable: ONC

Standard DRX11-K: Written policies and procedures are established and implemented in regard to the education given to the client/patient on the protocols for use of the medication prescribed for their treatment.

Interpretation: Written policies and procedures include, but are not limited to:

- Protocol for investigational drugs
- Protocol for the specific dose range for each drug in a multiple drug protocol

Education is performed and documented in the client/patient record.

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: ONC

Standard DRX11-L: Written policies and procedures are established and implemented by the organization in regard to the documentation and communication of medication errors including documentation of all healthcare providers involved in the client's/patient's care and that medication errors have been reported.

Interpretation: Written policies and procedures define the process to document medication errors. Policies and procedures include, but are not limited to:

- Use of appropriate error reporting documents
- Notification to management
- Completion of a root cause analysis
- Provision of education to personnel to help prevent future occurrences
- When to report medication errors through national programs such as Medwatch

Evidence: Written Policies and Procedures

Evidence: Medication Error Reports

Services applicable: ONC

Standard DRX11-M: Communication with other healthcare providers related to the provision of oncology medications is documented.

Interpretation: There is documentation of communication with other healthcare providers involved in the client's/patient's care.

Documentation includes, but is not limited to:

- Client/patient adherence to medications ordered
- Specific monitoring plan for chemotherapy
- Therapy endpoints for medication management
- Investigational drug eligibility, if applicable
- Protocol management authority; if a physician orders medication per the organization's protocol, the physician acknowledges in writing that he or she understands the organization's protocol for proper medication management
- Client/patient-specific education on the prescribed medications
- Client/patient education on storage of chemotherapy medications
- Client/patient medication errors

Evidence: Client/Patient Records

Evidence: Response to Interview

Standard DRX11-N: Each client/patient receiving chemotherapy must have personnel available who perform client/patient advocate duties to help him or her with any medication needs and concerns.

Interpretation: Personnel will be trained in specific care given to oncology clients/patients and will be responsible for the following at minimum:

- Help the clients/patients understand information about their financial needs
- Answer any therapy-related questions, or direct them to the clinical pharmacist
- Help the clients/patients stay in compliance with the prescribed therapy by completing, at minimum, a 30-day follow-up on the client's/patient's plan of care

There will be documentation in the client/patient record of the assignment of a client/patient advocate. The client/patient advocate will document all communications with the client/patient including an introduction letter and/or a phone introduction.

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: ONC

