

**LEVELS OF CARE FOR CANCER SYSTEMIC THERAPY
IN NOVA SCOTIA HOSPITALS**

2012 Revision



June 4, 2012

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Procurement Mechanism

The Levels of Care criteria are available from *Cancer Care Nova Scotia* upon request at (902) 473-2936 or 1-866-599-2267 or info@ccns.nshealth.ca

Feedback Mechanism

Feedback may be provided to the CCNS Quality Coordinator at (902) 473-2936 or 1-866-599-2267 or info@ccns.nshealth.ca

Approved *Cancer Care Nova Scotia* Levels of Care Steering Committee April 2005
 Endorsed DoH Health System Quality Committee November 30, 2005
 Revised May 2008
 Endorsed DoH Program Committee
 Approved *Cancer Care Nova Scotia*

Preamble

The *Cancer Care Nova Scotia (CCNS) Systemic Therapy Levels of Care* standards were approved in principle by the Nova Scotia Department of Health System Quality Committee on November 30, 2005. An Impact Assessment was conducted in early 2006 determine what additional resources would be required by DHAs to meet the standards.

The Impact Assessment identified where implementation would require additional resources. Where DHAs require additional resources, the request for these resources must be built into the annual business planning cycle. There is no guarantee from the Department of Health and Wellness (DHW) that additional resources will be provided.

Because DHAs require time to develop plans, the goal for implementation was April 1, 2008 in keeping with the DHW business planning cycle. However, in early 2008, questions were raised regarding specific aspects of the standards. As well, Cancer Care Ontario (CCO) had published similar standards, *Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment*¹, in 2007. It was decided to postpone the implementation date of April 1, 2008, identify a later implementation target date within the 2008-09 fiscal year and to reconvene the Systemic Therapy Working Group, which had developed the original standards, to review the initial standards in light of the CCO document and any other changes that had occurred in the Nova Scotia health system since 2005.

The Working Group met on May 29, 2008 and reviewed and revised the standards. The significant changes made are outlined in Appendix 4. The new target implementation date was April 1, 2009.

CCNS works with each DHA on an implementation plan based on identified gaps in each district and/or facility. As part of the implementation plan, CCNS and the DHA will agree to a time frame for when CCNS will expect a DHA to be complaint with the standards. Compliance with different parts of the standards may be phased in (e.g. the DHA will have appropriate space, equipment, and required policies and procedures in place by April 1, 2009 but training of staff will be phased in and will be expected to be completed by 2010.)

Districts are able to make operational decisions that demonstrate that they meet safety standards. This happens in all manner of clinical practice and is not unique to oncology or to the Levels of Care process. All districts have an internal quality process and this is certainly sufficient to address this need. DHA's are expected to continue to provide systemic therapy as safely as possibly based on the current resources and with their current knowledge of systemic therapy standards.

¹Cancer Care Ontario Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment 2007 <http://www.cancercare.on.ca/pdf/pebc12-10s.pdf> downloaded July 3, 2008

CCNS will monitor each DHA's progress towards implementation and will provide support as necessary. *CCNS* will also develop a process to confirm the Level for each cancer service in each facility.

As part of its mandate as a standard-setting and monitoring organization, *CCNS* will develop an evaluation framework for monitoring the overall effects of developing and implementing the Levels of Care as well as a process for monitoring adherence and congruence with the Levels of Care standards and criteria.

The process by which the Systemic Therapy Levels of Care criteria were developed is described in Appendix 5.

LEVELS OF CARE FOR SYSTEMIC THERAPY IN NOVA SCOTIA HOSPITALS

Systemic therapy for cancer includes many types of drugs used alone or in combination with other treatment modalities (e.g. surgery, radiotherapy). Chemotherapy drugs, a major component of cancer systemic therapy, are potentially hazardous to both patients and health care workers. Safety is of paramount importance in the use of systemic therapy for cancer treatment. For patients, most chemotherapy drugs are given at doses very close to toxic levels (i.e. narrow therapeutic window). Adverse reactions may be predictable or idiosyncratic, and must be appropriately managed when they occur. Tight controls must exist for the ordering and administration of these agents to avoid the potential for error. In addition, many drugs may cause serious adverse events during or shortly after administration.

Wherever chemotherapy is given, appropriate safeguards are required to optimize safety and minimize risks to both patients and health care providers. Safe delivery of systemic therapy can usually occur in locations as close to home as possible including community hospitals, regional hospitals, and tertiary hospitals as long as the appropriate safeguards are in place. The Systemic Therapy Levels of Care criteria have been developed to assist District Health Authorities (DHAs) and other providers of systemic therapy determine the types of services that can be safely provided in any given location and will apply to all facilities providing systemic therapy to patients (adult and pediatric) in Nova Scotia. These standards outline the minimum requirements to provide safe systemic therapy in community, regional and tertiary facilities in NS.

The fundamental principle behind these criteria is safety first. Guidelines on the safe administration of cancer chemotherapy, as published by the Institute for Safe Medication Practices (ISMP), have been applied to the development of these criteria. The Levels of Care criteria include ensuring that staff have developed and maintain the appropriate competencies.

The plan for Systemic Therapy Levels of Care separates hospital delivery-/ administration sites into four levels, based on the acuity and/or complexity of the therapy to be given, the physical facilities at the delivery site, the number of staff and training of that staff to deliver the medications and provide patient supportive care, and the credentialing of the medical staff and other health professionals monitoring the treatment. In addition, the management of oncologic emergencies is included in the Levels of Care criteria.

All cancer systemic therapy drugs and regimens have been assigned a level based on the toxicities and risks at the time of administration and are listed in the **Systemic Therapy Manual for Cancer Patients** with their assigned levels. Facilities can administer drugs that are classified at the same level or lower as the facility level. No institution is obliged to deliver every medication or regimen within the assigned level, if this is not felt to be safe.

No facility may deliver any medication or regimen rated at a higher level, without prior authorization from the DHA. If a facility wishes to administer a drug rated at a higher level

than the facility, the Oncology Practice Consultant and/or Systemic Therapy Program Manager should be consulted for a discussion of the specific circumstances and a recommendation to allow the facility to administer the drug for that specific patient. If the facility gains experience with any of these drugs over several cases, the Systemic Therapy Program Manager may grant authority to continue use of that drug for future cases without the need for a case-by-case request. The same case-by-case process is used for facilities administering a drug within their Level that they have not previously administered.

The primary guiding principle for assignment of any drug to a level is optimal patient safety. For some treatments, the safety may be inherent to risks associated with the specific drug, in other circumstances the risk may reflect a need for specific clinical supervision not necessarily available at the facility.

A Levels of Care standard for management of pediatric hematology/oncology patients has been developed by APPHON (the Atlantic Provinces Pediatric Hematology/Oncology Network). When systemic therapy is given to pediatric cancer patients, these criteria must also be considered in conjunction with the Systemic Therapy Levels of Care criteria.

Summary:

The Systemic Therapy Levels of Care criteria provide a model and a provincial standard for delivery of this hazardous treatment to cancer patients. With these criteria, District Health Authorities can plan their service delivery and monitor the quality of care through adherence to provincial standards. Other components also contribute to quality and safety of systemic therapy delivery, including:

- The provincial Cancer Systemic Therapy policies and procedures (developed provincially and adopted by each district)
- The provincial standard Physician Standing Orders for cancer systemic therapy
- The **Systemic Therapy Manual for Cancer Patients** (as a consistent information source, correlating drugs and regimens with Level of Care assignments and identifying occupational risk levels for each drug)- available online.
- The Medication Info Sheets and other provincial patient education resources.
- Staff qualifications are supported by education and certification programs available or under development in partnership with *Cancer Care Nova Scotia*.

A key principle in this package of programs and initiatives is consistent standards across the province, with accountabilities at the DHA level. *Cancer Care Nova Scotia* is mandated and committed to assist each district as standards are developed and implemented. It is expected that the full set of criteria will be implemented over time as resources and supporting programs or services become available within the province. Each district is expected to achieve the standards as soon as reasonably achievable.

Definitions for Systemic Therapy Levels of Care:

Every hospital where systemic therapy is provided in Nova Scotia will be assigned a Level in accordance with the criteria specified in this document and in discussion between CCNS and the DHA

Community/Home Level (not a Hospital) - Systemic therapy which may be self-administered (e.g. oral medications), or given in a community setting (e.g. physician's office) but does not require hospital services

Basic Level Hospital – Chemotherapy drugs/regimens and other systemic therapies with minimal risk associated with administration (non-vesicants/irritants, low risk of hypersensitivity) and that do not require complicated adverse effect management. Treatments must be administered within a health care institution (i.e. hospital). The presence of additional resources and expertise at a facility may permit selected Intermediate level drugs/regimens to be administered, on approval by CCNS in collaboration with the appropriate Cancer Site Team and the DHA.

Intermediate Level Hospital - Chemotherapy drugs/regimens with moderate risks associated with administration where more specialized nursing skills or volume of activity (to maintain competence) are needed. Agents at this level include:

- Vesicant agents (e.g. anthracycline agents, vinca alkaloids)
- Agents which require active hydration support (e.g. platinum salts)
- Agents with a high risk of hypersensitivity reactions or administration-related reactions (e.g. monoclonal antibodies, biologic agents, taxanes, irinotecan)

The presence of additional resources and expertise at a facility may permit selected Advanced level regimens to be administered, on approval with CCNS in collaboration with the appropriate Cancer Site Team and the DHA.

The development of satellite oncology clinics in Nova Scotia has resulted in an increased medical oncology presence in some facilities. When the medical oncologist is present, a facility normally classed as an Intermediate-level may be able to provide Advanced level drugs and regimens. Particularly, a facility may give first dose high risk drugs when the oncologist is present but not at other times. The medical oncologist must be aware that Advanced-level drugs are being given, and agree in advance to respond to any patient reaction.

Advanced Level Hospital - Regimens that should be given under the direct supervision of a medical oncologist, hematologist, gynecologic oncologist or urologist (as determined by the appropriate Cancer Site Team); regimens given concurrently with radiotherapy (Advanced level during portion of chemotherapy given concurrently with radiotherapy- other portions of treatment may be rated at a different level)

Specialized Level Hospital – Regimens that require specialized facility resources (e.g. BMT support, special laboratory support such as Methotrexate levels) or multidisciplinary specialist teams (e.g. acute leukemia service, stem cell transplant service, oral-maxillofacial cancer team, neuro-oncology team).

The Levels of Care criteria are divided into categories, which are defined below.

1. Health Professionals

The Levels of Care criteria describe health human resource expectations for each level. An emphasis is placed upon the training and competence of individual practitioners, with greater training expected for higher levels. Some basic skills and training are required for any chemotherapy ordering, preparation or administration.

It is hard to determine appropriate numbers of each health care professional proportionate to workload, especially when less than one FTE is required for any given category. Minimum numbers of health professionals for each level are provided. Any facility providing systemic therapy must have sufficient numbers of qualified staff to ensure sustainable service, for instance during vacation periods or absences due to illness. Some workload standards were developed for the satellite oncology clinics and these have been included in this document.

Within this document, there are specific health professional roles that are in bold and italics. The definition for these roles can be found in Appendix 2.

2. Physical Facilities

The general expectations for physical facilities are described in the Levels of Care criteria. A sample estimate for space, equipment and furnishings for a Basic Level or Intermediate Level facility is described in Appendix 1, as adopted from planning documentation used by outreach oncology affiliation agreements from some Cancer Care Ontario cancer centres. This information will be helpful for sites to identify areas of potential improvement.

3. Organizational Support

Systemic therapy is a high-risk enterprise within District Health Authorities, and it is often a shared responsibility between organizations. It is important for optimal patient safety that organizations operate according to provincial standards and are consistent with each other. While each DHA is accountable for the services provided within the district, provincial policies and programs are designed to enhance continuity of care. The Organizational Support section outlines the criteria DHAs should address so that chemotherapy can be provided safely and efficiently. *Cancer Care Nova Scotia* is mandated to work with each DHA to assist with training, and standards development and compliance, as appropriate.

In 2011, Accreditation Canada released standards for ambulatory chemotherapy¹ as one module for health care institution accreditation. It is expected that all facilities that offer chemotherapy administration will complete these standards as part of the overall facility accreditation process.

4. Supportive Care

Systemic therapy includes more than just the administration of cytotoxic chemotherapy. The drugs and regimens can cause toxic adverse reactions that must be managed appropriately.

¹ Ambulatory Systemic Cancer Therapy Services Standards, Accreditation Canada, 2011

Some predictable types of drug toxicity may be prevented with prophylactic supportive measures.

In addition to supportive care for physical symptoms, cancer patients have many other supportive care needs. A facility that chooses to provide systemic therapy to cancer patients must also address the supportive care needs of the patient. It is not enough to just administer chemotherapy safely. All cancer patients have supportive care needs, and it is expected that these needs will be addressed wherever patients receive treatment. Regardless of the facility where treatment is given, each patient should be assessed for supportive care needs and referred to the appropriate service locally or at a tertiary site to address the need(s).

Distress has been recognized by Accreditation Canada as the 6th vital sign in cancer patients (pain is the 5th). Cancer Care Nova Scotia introduced formal screening for distress in newly diagnosed cancer patients in 2010. As of the writing of this document, screening for distress is occurring for some cancer patients in every district, but not all patients are being screened. Implementation of screening for distress continues to be rolled out. It is the expectation that all newly diagnosed cancer patients will be screened for distress. Patients should also be screened for distress at critical moments during their cancer journey, such as at the beginning and end of a treatment modality. Therefore, it is assumed that nurses involved in chemotherapy administration at any facility in Nova Scotia will be screening some, or all of their patients for distress and taking appropriate action based on the results of the screen.

While it is beyond the scope of the Systemic Therapy Levels of Care model to address the entirety of supportive care, supportive care needs most common for systemic therapy patients are identified in this document. These should be considered within the broader scope of all supportive care needs and issues. Supportive care is divided (for ease of assessment and service planning) into 4 major categories: informational needs; psychosocial/emotional needs; physical needs, and practical needs.

5. Management of Oncologic Emergencies

Oncologic emergencies are not specific to systemic therapy. Processes to manage oncologic emergencies, however, are mandatory for any institution providing systemic therapy to cancer patients. While some oncologic emergencies occur immediately during the administration of chemotherapy, others may be delayed reactions or are not related to chemotherapy at all. There must be effective communications between specialists and general practitioners as needed for management of oncologic emergencies when these occur in the patients' home communities. These processes are described briefly.

Cancer Systemic Therapy Levels of Care Criteria

Description	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Aspects of care which do not require hospital services • Self administration of oral systemic therapy; drugs acquired from retail pharmacy • Injectable cytotoxic chemotherapy should NOT be initiated in home settings (unless stipulated otherwise in the Systemic Treatment Manual or pediatric regimen) • Treatments in physicians' offices or at home
Basic Level Hospital	<ul style="list-style-type: none"> • Basic chemotherapy and other systemic therapies that do not require complicated adverse effect management. • Treatment could be delivered on prescheduled "chemotherapy clinic" days.
Intermediate Level Hospital	<ul style="list-style-type: none"> • Higher volume of visits, usually in Regional Hospital setting • Chemotherapy regimens that include agents for which more specialized nursing skills or sufficient volume of activity (to maintain competence) is needed. • Provides Basic Level systemic therapy also
Advanced Level Hospital	<ul style="list-style-type: none"> • Very high volume of visits, including ambulatory cancer centre, inpatient oncology beds and radiotherapy services on site (tertiary hospital) • Chemotherapy regimens that include agents for which additional specialized nursing skills or volume of activity are needed or that must be administered in dedicated oncology inpatient beds. • Provides Intermediate Level systemic therapy also
Specialized Level Hospital	<ul style="list-style-type: none"> • Regimens which require specialized facility resources (e.g. Bone Marrow Transplant/Stem Cell Transplant support, special laboratory support such as Methotrexate levels) or designated specialist teams (e.g. acute leukemia, stem cell transplant, oral-maxillofacial services, neuro-oncology team), which may include co-ordinated multidisciplinary care • May be specific to individual regimens and package of services required for delivery (e.g. local availability of other specialists, lab services, etc.) • Specialized programs for provincial or Maritime provinces, eg. acute leukemia, BMT

Physical Facility	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Parenteral cytotoxic chemotherapy drugs should NOT be administered in the community setting (i.e. treatment should not be initiated and managed completely outside the hospital setting)
Basic Level Hospital	<ul style="list-style-type: none"> • Space for chemotherapy administration which minimizes distractions during administration • Computer, fax and phone readily available • Presence of additional resources and expertise may be considered for allowance of selected Intermediate level regimens, as negotiated with CCNS • Access to oxygen • Appropriate parenteral administration equipment, including luer-lock syringes • IV equipment for simple ambulatory parenteral drug treatments • Personal protective equipment for staff who are handling systemic treatment or waste • Easy access to spill kits, supplies for decontamination • Pharmacy area for secure storage and preparation of systemic treatment drugs • Biological safety cabinet (Class IIB) externally vented and related equipment if chemotherapy is prepared on site • Rapid access to resuscitation and anaphylaxis equipment/drugs (e.g. crash cart, other emergency supplies, drugs, oxygen and suction) • Access to basic laboratory tests/results for monitoring chemotherapy
Intermediate Level Hospital	<p>Basic Level, plus:</p> <ul style="list-style-type: none"> • Dedicated chemotherapy treatment area adequate for volume of treatment visits • Presence of additional resources and expertise may be considered for allowance of selected Advanced level regimens, as negotiated with CCNS • Appropriate parenteral administration equipment, including specialized IV tubing for specific drugs • IV equipment for ambulatory or inpatient infusional drug treatments (e.g. Infusors); • Rapid access to supportive drugs for treatment of extravasation • On-site Emergency department • Ready access to Intensive care unit • The hospital should have access to diagnostic imaging/radiology and laboratory tests/pathology for monitoring of chemotherapy • Facilities & procedures in place to ensure that insertion of central venous access devices (e.g. Port-a-caths, Hickman, PIC lines etc) and central lines (and other medical devices, as necessary) occurs in a timely and coordinated fashion
Advanced Level Hospital	<p>Intermediate Level, plus:</p> <ul style="list-style-type: none"> • Inpatient oncology ward, or dedicated beds for cancer patients with oncology nurses and oncologists available • Appropriate parenteral administration equipment for Advanced Level regimens, including intrathecal and intraperitoneal equipment for specific drugs and regimens

	<ul style="list-style-type: none">• On-site pharmacy with externally vented biological safety cabinet and related equipment• On-site ICU• Radiation therapy services on site (for regimens that require radiotherapy concurrently with chemotherapy)• Specialized diagnostic imaging/radiology and laboratory tests/pathology for cancer drug selection and monitoring.
Specialized Level Hospital	Same as Advanced Level; <ul style="list-style-type: none">• Specialized ambulatory/inpatient treatment areas for bone marrow/peripheral stem cell transplantation, acute leukemia and other specialized services.

Medical Staff	
Role descriptions in bold and italics are defined in Appendix 2.	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Family physicians in community/private practice provide supportive care in collaboration with oncology specialist • Community specialists (e.g. surgeons, internists) may provide office procedures for cancer patients within scope of service • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Basic Level Hospital	<ul style="list-style-type: none"> • All cancer chemotherapy should be ordered only by or in documented consultation with an Oncologist familiar with the delivery of systemic therapy <ul style="list-style-type: none"> ○ The chemotherapy may be ordered by or in consultation with a clinical associate or nurse practitioner from the consultant Oncologist's practice, if these alternate prescribers are practicing under Oncologist supervision and with a collaborative practice agreement that allows chemotherapy prescribing • At least one Community Physician (with identified and reliable back up for coverage) to be on site or readily available (within 20 minutes) during chemotherapy administration, for medical management of urgent or emergent reactions during chemotherapy administration • A physician or nurse practitioner in the community is identified for each patient who has clear responsibility for general medical care and symptom management during the course of systemic therapy. • Participation in designated education programs as required • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Intermediate Level Hospital	<ul style="list-style-type: none"> • All cancer chemotherapy should be ordered only by or in documented consultation with an Oncologist familiar with the delivery of systemic therapy <ul style="list-style-type: none"> ○ The chemotherapy may be ordered by or in consultation with a clinical associate or nurse practitioner from the consultant Oncologist's practice, if these alternate prescribers are practicing under Oncologist supervision and with a collaborative practice agreement that allows chemotherapy prescribing • If chemotherapy is ordered without consultation by an oncologist (not recommended), this must be done by a Community Specialist with appropriate privileges in the district • At least one physician available on site during chemotherapy administration, for medical management of urgent or emergent reactions during chemotherapy administration (may be responsible for chemotherapy treatment unit) • At least one Community Physician, Community Specialist or nurse practitioner (with prescribing privileges within the DHA (with identified and reliable back-up for coverage) who has clear responsibility for general medical care and symptom management for each patient during the course of systemic therapy. • Access to medical/surgical staff for insertion of central venous access devices • Participation in multidisciplinary oncology rounds as available • Participation in designated education programs as required

	<ul style="list-style-type: none"> • Participation in <i>CCNS</i> Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Advanced Level Hospital	<ul style="list-style-type: none"> • Medical <i>Oncologists</i> and Radiation <i>Oncologists</i> on staff & available around the clock; may have Hematologists and/or Surgical <i>Oncologists</i> on staff & available around the clock • At least one physician available on site during chemotherapy administration, for medical management of urgent or emergent reactions during chemotherapy administration • The consultant oncologist has clear responsibility for general medical care and symptom management for each patient during active systemic therapy.. • Chemotherapy may ordered by a clinical associate or nurse practitioner from the consultant <i>Oncologist</i>'s practice, if these alternate prescribers are practicing under <i>Oncologist</i> supervision and with a collaborative practice agreement that allows chemotherapy prescribing • Access to medical/surgical staff for insertion of central venous access devices • Regular participation in multidisciplinary rounds and continuing education for oncology • Participation in designated education programs as required
Specialized Level Hospital	<ul style="list-style-type: none"> • Same as Advanced Level • Oncologists have developed specific sub-specialized practices

Registered Nurses	
Role descriptions in bold and italics are defined in Appendix 2.	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Community or home care nursing (including Long Term Care) in collaboration with oncology specialists • Supportive care measures during active treatment phase • Basic knowledge of cancer care • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Basic Level Hospital	<ul style="list-style-type: none"> • At least two Registered <i>Nurses with Chemotherapy Certification</i> <ul style="list-style-type: none"> ○ During administration of chemotherapy, the nurse will not be assigned to other responsibilities <ul style="list-style-type: none"> • If only one Registered <i>Nurse with Chemotherapy Certification</i> is available, there must be sufficient professional staff available for appropriate double-checking of chemotherapy as per the Chemotherapy Administration policy and procedure². • Participation in designated education programs as required • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Intermediate Level Hospital	<ul style="list-style-type: none"> • At least two dedicated Registered <i>Nurses with Chemotherapy Certification</i> working in chemotherapy unit at all patient care times <ul style="list-style-type: none"> ○ During administration of chemotherapy, the nurse will not be assigned to other responsibilities ○ there must be sufficient professional staff available for appropriate double-checking of chemotherapy as per the Chemotherapy Administration policy and procedure • Adequate number of patient treatment visits¹ to maintain competence in managing vesicant administration, hypersensitivity reactions, venous access through central venous catheters (e.g. Port-a-Caths, Hickman catheters) • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged • Participation in designated education programs as required • Designation as <i>Oncology Nurse (CON(C))</i> is encouraged
Advanced Level Hospital	<ul style="list-style-type: none"> • Adequate numbers³ of Registered <i>Nurses with Chemotherapy Certification</i> to support all chemotherapy order verification and drug administration needs including ability to access central venous catheters (e.g. Port-a-Caths, Hickman catheters) • Adequate numbers of <i>Oncology Nurse(s)</i> and Clinical Nurse Specialists/Nurse Educators to provide full nursing service for inpatients & outpatients⁴

² Policy and Procedures: Administration of Cancer Chemotherapy, CCNS Systemic Therapy Program, 2011

³ In planning for the Satellite Oncology Clinics, the following workload standard for RNs **delivering chemotherapy** was developed: 1200 visits/FTE RN plus 20% replacement. (*Cancer Care Nova Scotia* Satellite Oncology Clinics Development Report January 2007 p. 12)

⁴ In planning for the Satellite Oncology Clinics, the following workload standard for RNs in ambulatory medical oncology clinics (care coordination, management of toxicities, symptoms and side effects but **does not include** chemotherapy administration) was 1.0 FTE RN to 1.0 FTE Medical Oncologist plus 20% for replacement. (*Cancer Care Nova Scotia* Satellite Oncology Clinics Development Report January 2007 p. 12)

	<ul style="list-style-type: none">• Provide support to nurses and other health professionals providing Basic and Intermediate Levels of Systemic Therapy (as needed)• Regular participation in continuing education for oncology• Participation in designated education programs as required• Designation as Oncology Nurse (CON(C)) is encouraged
Specialized Level Hospital	Same as Advanced Level; <ul style="list-style-type: none">• Clinical Nurse Specialists/Nurse Educators to support nursing staff in sub-specialized areas

Pharmacy

Role descriptions in bold and italics are defined in Appendix 2.

After June 2009, all parenteral chemotherapy will be prepared by a health professional (preferably a pharmacy technician) who has successfully completed the Chemotherapy Preparation Course offered through the Nova Scotia Community College and CCNS (or equivalent).

Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Retail pharmacists- dispense systemic and supportive care drugs, as directed in standing orders or other prescription, verification of oral chemotherapy orders, patient counselling on medications • Basic knowledge of cancer care • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Basic/Intermediate	<p>It is preferred that chemotherapy be provided in facilities with on-site pharmacists.</p> <p>It is preferred that chemotherapy be prepared by pharmacy technicians.</p> <p>The minimum requirements within the District Health Authority for chemotherapy order verification and preparation at the Basic and Intermediate levels are:</p> <ul style="list-style-type: none"> • At least one Hospital Pharmacist with Oncology Training¹ • At least one other hospital pharmacist with Basic Oncology Pharmacy Training (for back-up)¹ • All chemotherapy orders verified by a DHA oncology pharmacist, preferably on-site. If verification must be done off-site (i.e. when there is no pharmacist available on-site), this may be done by an alternate method, such as verification of faxed orders. • There will be timely access to DHA oncology pharmacist(s) (preferably a Hospital Pharmacist with Oncology Training) for all staff and physicians involved in chemotherapy ordering, preparation and administration. <ul style="list-style-type: none"> ○ Access to the pharmacist could be via face-to-face, phone, fax, email or web/video conferencing. • All chemotherapy will be prepared by staff who have successfully completed the Chemotherapy Preparation Course, as noted above • Each chemo dose will be double checked by a second pharmacy staff member²

¹ In planning for the Satellite Oncology Clinics, the following workload standard for pharmacists and pharmacy technicians involved with chemotherapy is:

- Clinical pharmacist 5000 chemotherapy doses/FTE
- Distribution pharmacist 8700 chemotherapy doses/FTE
- Distribution technician 8700 chemotherapy doses/FTE

² “All chemotherapy and pediatric/neonatal IV admixtures are double-checked by a pharmacist (even if initially prepared by a pharmacist and documented (with initials) before dispensing the products)” Core Distinguishing Characteristic #185. Institute for Safe Medication Practices Canada. Hospital Medication Safety Self-Assessment™. Toronto, ON: Institute for

	<ul style="list-style-type: none"> • or other health professional before dispensing to the administering nurse according to procedures approved by the DHA. There must be sufficient professional³ staff available for appropriate double-checking of chemotherapy as per the Chemotherapy Preparation Policy and Procedure. • At least two staff (for coverage) who have successfully completed the Chemotherapy Preparation Course as noted above, if chemotherapy is prepared on site¹ • If there is no pharmacy staff on site, consider chemotherapy preparation by DHA pharmacy service off-site and transportation to the administration facility <ul style="list-style-type: none"> ○ If chemotherapy preparation occurs off-site, transportation of prepared chemotherapy must comply with all Transportation of Dangerous Goods Act requirements. • Pharmacy staff are responsible for ordering, stocking and inventory maintenance of required medications and supplies • Participation in designated education programs as required • Participation in CCNS Interprofessional Core Curriculum for cancer care (ICC) and other oncology-related continuing education is encouraged
Advanced Level Hospital	<ul style="list-style-type: none"> • Adequate numbers of Oncology Pharmacists, Hospital Pharmacists with Oncology Training and pharmacy technicians (who have successfully completed the Chemotherapy Preparation Course) to support all chemotherapy order verification and drug preparation needs^{1,2} • At least one Oncology Pharmacist and adequate Hospital Pharmacists with Oncology Training to provide full clinical service for inpatients & outpatients¹ • Provide support to pharmacists and other health professionals providing Basic and Intermediate Levels of Systemic Therapy as needed • Regular participation in continuing education for oncology • Participation in other designated education programs as required
Specialized Level Hospital	<p>Same as Advanced Level, plus;</p> <ul style="list-style-type: none"> • At least one Oncology Pharmacist to provide full clinical service for appropriate sub-specialty areas

Safe Medication Practices Canada, 2001 In some centres, a trained and certified technician may be authorized to double check chemotherapy admixtures.

³ For this document, pharmacy technicians will be included as “health professionals”

Other Human Resources (Including Supportive Care)	
Role descriptions in bold and italics are defined in Appendix 2.	
Basic/Intermediate	<ul style="list-style-type: none"> • Adequate clerical support personnel for patient scheduling¹ • Adequate health records personnel support to supply & maintain health records in a timely fashion for ambulatory patient care (and inpatient care when necessary) • There is a <i>Cancer Patient Navigator</i> in each district
Advanced Level Hospital	<p>Same as Basic and Intermediate Levels, plus:</p> <ul style="list-style-type: none"> • Multidisciplinary Psychosocial Oncology Team, including members with advanced training to address complex, cancer patient needs
Specialized Level Hospital	<p>Same as Advanced Level, plus:</p> <ul style="list-style-type: none"> • Multidisciplinary team for comprehensive psychosocial support services unique to specialty populations (e.g. pediatrics, ASCT/BMT patients, head & neck cancer patients, brain tumour patients and families, etc.)

¹ In planning for the Satellite Oncology Clinics, the following workload standard for clerks for **booking and registration** is 5000 visits/FTE plus 0.2FTE for replacement. This **does not include** other ward clerk duties (chart preparation, test booking, phone management). (*Cancer Care Nova Scotia Satellite Oncology Clinics Development Report January 2007* p. 13)

Supportive Care	
Role descriptions in bold and italics are defined in Appendix 2.	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Reinforcement of patient education initiated in hospital/clinic setting • Basic supportive care (reassurance, monitoring for distress) and referral as necessary for additional support
Basic/Intermediate	<ul style="list-style-type: none"> • Patients are screened for distress at the start of each course of systemic therapy treatment,. <ul style="list-style-type: none"> • All patients receiving systemic therapy should have access to supportive care professionals and services based on their needs- either locally, within the district, or, if appropriate, from the tertiary site. This includes: Access to psychosocial/spiritual support services within the district, which may include social work, psychology, psychiatry, psychosocial counselors, chaplains and others. Health care professionals (including pastoral care) and volunteers trained in Palliative Care may assist with supportive care needs • Access to rehabilitative health professionals such as dietitians, occupational therapists, physiotherapists and others • Access to palliative care services within the district • Where specific services are not available within the district, arrangements are made so that patients can access necessary services from other districts. • Cancer patients should be referred to the local Cancer Patient Navigator for supportive care needs, as appropriate. • Psychosocial and other supportive care services offered to patients according to guidelines (where these exist) by the Supportive Care Cancer Site Team. <p><u>Information Needs:</u></p> <ul style="list-style-type: none"> • Initiation of patient education if new treatment, or reinforcement if education provided elsewhere • Use of all approved cancer patient information material, including Living Well with Cancer and Medication Info Sheets, as appropriate • Access to experts for referral of difficult questions (e.g. Medical Oncologists, Hematologists, Oncology Nurses, Oncology Pharmacists, psychosocial oncology experts) <p><u>Psychological/Emotional Needs:</u></p> <ul style="list-style-type: none"> • General psychological and emotional support integrated into routine patient care; • Involvement of other supportive care professionals (see above) as appropriate and available • Patients referred to peer and family support groups for lay psychosocial support, as necessary and available • Referral to advanced level services as necessary for psychosocial and rehabilitative care <p><u>Practical Needs:</u></p> <ul style="list-style-type: none"> • Social work involvement to assist in resolution of practical/financial difficulties; dietitian referral for nutritional problems; occupational

	<p>therapy/physiotherapy for specific rehabilitation problems; access to palliative care team, pharmacist assistance with medication acquisition, insurance coverage, medication counseling</p> <ul style="list-style-type: none"> • Coordination of integrated care plan by primary oncology team to access services close to home or at tertiary centre, as appropriate <p><u>Physical Needs:</u></p> <ul style="list-style-type: none"> • General medical care for common symptom management • Communication with and involvement of family physician for regular management of medical care/follow up in collaboration with oncology specialists
Advanced Level Hospital	<p>Same as Basic and Intermediate Levels, plus:</p> <ul style="list-style-type: none"> • Psychosocial Oncology Team for referrals of complicated psychologic or emotional support
Specialized Level Hospital	<p>Same as Advanced Level plus:</p> <ul style="list-style-type: none"> • Resources developed to meet the specific needs of patients receiving these services.

Organizational Support	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Maintenance of open communications with district health care facilities and health care professionals involved in that patient's care
Basic and Intermediate	<ul style="list-style-type: none"> • Guidance by District Cancer Committee • Institutions at each Level will offer service up to the assigned Level (e.g. Intermediate Level facilities can provide Basic and Intermediate level services). • Accredited by Accreditation Canada, including the Ambulatory Systemic Cancer Therapy Services Standards. • Training of personnel supported by DHA (provision of adequate time and resources to acquire requisite training and maintenance of competence as per CCNS guidelines). • DHA will ensure adequate physical facilities and certified staffing for the level. • Compliance with provincial Policies and Procedures on Cancer Systemic Therapy and synchronization of local policies and procedures with provincial systemic therapy policies and procedures. • Each facility where chemotherapy is provided has a protocol outlining its chemotherapy emergency response plan. • Facilities & procedures in place to ensure that insertion of central venous access devices (e.g. Port-a-caths, Hickman, PIC lines etc) and central lines (and other medical devices, as necessary) occurs in a timely and coordinated fashion. • Co-ordination of district hospital formulary with provincial oncology formulary. • Adoption of provincial standing orders for cancer systemic therapy regimens appropriate to treatment level(s). • DHA has non-formulary approval processes in place to access non-formulary drugs and Special Access Program drugs that can be given at that Level of Care. • DHA supports staff in participating in provincial Cancer Site Team activities. • All cancer chemotherapy is ordered by, or in consultation with, an oncologist (or a clinical associate/nurse practitioner under supervision by an oncologist). • CCNS disease, symptom management and drug guidelines are available to all appropriate DHA staff and physicians. • Policies & procedures in place to address development, adoption and/or collaboration of patient education materials. • Policies and procedures in place to ensure communication with and involvement of family physician for regular medical care/follow up in collaboration with oncology specialists. • DHA/CCNS will audit sites for compliance with criteria for assigned Level of Care.
Advanced Level Hospital	<p>As with Basic and Intermediate, plus:</p> <ul style="list-style-type: none"> • Provide expertise to provincial Cancer Site Teams for developing standard systemic therapy regimens and protocols. • Receive provincial referrals for Advanced Level care patients;

	facilitate referrals to local communities for Basic Level and Intermediate Level care patients. <ul style="list-style-type: none"> • Assist in training of health care professionals across province.
Specialized	Same as Advanced

Oncology Formulary²

Role descriptions in bold and italics are defined in Appendix 2.

- Drugs used for the systemic therapy of cancer are listed in a single formulary² found in the provincial **Systemic Therapy Manual for Cancer Patients**. The maintenance of the formulary is the responsibility of the CCNS Systemic Therapy Program. Formulary inclusions and exclusions will be determined by the provincial Cancer Systemic Therapy Advisory Committee.
- The Formulary lists drugs/regimens by Levels of Care, and includes clinical indication restrictions where appropriate. Drugs/regimens should only be delivered in hospitals with a Level of Care rating the same as or greater than that assigned to the drug/regimen.
 - In consultation with the CCNS Systemic Therapy Program Manager and/or Oncology Practice Consultant, a recommendation may be made to a district to allow a hospital to administer a drug with a level higher than the hospital on a case-by-case basis
- As new drugs/regimens become available, the appropriate provincial Cancer Site Team will identify which Level facilities can administer the drug. The “Level of Care” is assigned based on the level of risk during or immediately following administration (not upon drug costs or adverse events that may occur hours or days after the administration visit), or the level of specialist supervision required during administration. See classification below.
- Drugs used alone or in combination are listed as disease-specific regimens. The Level assigned to a regimen is usually related to the drug with the most stringent single agent level. Some regimens are given a higher listing due to the specialty nature of the cancer disease under treatment or the need for concurrent treatment (e.g. radiotherapy).
- In addition to identifying the Level of Care and Indication-specific restrictions, the **Systemic Therapy Manual for Cancer Patients** also identifies Occupational Health risk levels for each drug³.
- Non-formulary drugs and Special Access Program drugs may be available (appropriate to the assigned Level of Care) on approval by district non-formulary approval mechanism in collaboration with CCNS Systemic Therapy Program
- Selected drugs may be available at a lower level facility if appropriate criteria are met (e.g. staff hematologist) on approval by CCNS in collaboration with the appropriate Cancer Site Team and the DHA.
- Some drugs may be restricted to one level for the initial course(s) of treatment, but may be provided at a lower level if the patient has tolerated earlier doses

Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Certain parenteral drugs may be administered in physicians' offices (eg. prostate cancer hormones) • Chemotherapy drugs for retail dispensing should only be ordered on oral preprinted standing orders for specific regimens. • Drug costs are covered by the patient's prescription insurer (private or public) or paid out of pocket for uninsured patients
Basic Level Hospital	<ul style="list-style-type: none"> • Drugs with minimal risk associated with administration (e.g. non-vesicants/irritants, low risk of hypersensitivity) • Basic Level regimens do not require close monitoring by specialists
Intermediate Level Hospital	Basic Level, plus: <ul style="list-style-type: none"> • Drugs with moderate risk associated with administration (eg. hypersensitivity or tissue necrosis on extravasation) • Monitoring by <i>Nurses with Chemotherapy Certification</i> (as directed

² Provincial Cancer Drug Formulary, CCNS Nov 2011

³ Hazard Risk Levels For Cancer Systemic Therapy Drugs, CCNS Dec 2011

	on standard Pre Printed Orders (PPOs) and Community Physicians or Community Specialists
Advanced Level Hospital	Intermediate Level, plus: <ul style="list-style-type: none"> • All other systemic therapy drugs and regimens excepting sub-specialty regimens • Monitoring by Oncology Nurses and Nurses with Chemotherapy Certification; Oncology Pharmacists; and Oncologists,
Specialized Level Hospital	Same as Advanced Level; <ul style="list-style-type: none"> • Systemic drugs or regimens specific to sub-specialty practices • Regimens or drug dosages which require specialized laboratory support (e.g. Methotrexate levels with high-dose Methotrexate regimens)

Oncologic Emergencies	
<ul style="list-style-type: none"> • Oncologic emergencies, including those associated with systemic therapy, will usually occur when patients are at home; basic management of emergencies must be available in all facility levels • Emergency Department staff trained as appropriate for oncologic emergencies- <ul style="list-style-type: none"> ○ Contact oncologist as needed (strongly encouraged) ○ Participation in ICC Oncologic Emergencies module is recommended • CCNS Symptom Management guidelines (as available) will be followed • If patient has febrile neutropenia, empiric antibiotics at nearest Emergency Department according to guidelines; will require admission (unless otherwise instructed by oncologist) • DHA obligated to ensure appropriate staff are educated and prepared to provide care during an oncologic emergency (Participation in ICC Oncologic Emergencies module is recommended) • Emergency surgery and intensive care services, as appropriate for district 	
Community/Home Level (not hospital)	<ul style="list-style-type: none"> • Basic knowledge of oncologic emergencies and appropriate treatment • Know how and when to contact oncology specialists and/or Cancer Centres • Participation in ICC Oncologic Emergencies module is strongly encouraged
Basic and Intermediate Level facilities	<ul style="list-style-type: none"> • The facility has policies and processes in place for timely and appropriate emergency response to chemotherapy emergencies and acute reactions during the administration of chemotherapy. This includes: <ul style="list-style-type: none"> ○ Chemotherapy RNs know how to assess and respond to emergencies and acute reactions ○ Identified physicians available to respond appropriately ○ Ready access to emergency equipment, supplies and drugs in the chemotherapy suite ○ Access to emergency room (on-site access required for Intermediate Level facilities) ○ Access to ICU ○ Facility has standing orders (or equivalent) to address chemotherapy emergencies and acute reactions <p>It is recommended that each facility have a protocol outlining its chemotherapy emergency response plan and that prior to initiating the first chemotherapy dose of the day, the RN reviews the emergency response plan to make sure that all elements are in place (e.g. is the Emergency Room closed due to HR shortages? Is the identified MD aware that chemotherapy is being administered and available to respond if necessary?)</p>
Advanced and Subspecialized Level Facilities	<p>Policies and procedures for immediate and delayed reactions to chemotherapy are in place, communicated to all necessary staff and physicians and regularly reviewed</p>

Appendix 1**Levels of Care Assignments for Nova Scotia Hospitals**

(As At June 2012)

South Shore Health (DHA 1)

South Shore Regional Hospital (Bridgewater)- INTERMEDIATE Level⁴
 Fishermen's Memorial Hospital (Linenburg)- Not Currently Active
 Queens General Hospital (Liverpool)- Not Currently Active

South West Nova District Health Authority (DHA 2)

Yarmouth Regional Hospital (Yarmouth)- INTERMEDIATE Level⁴
 Roseway Hospital (Shelburne)- Not Currently Active
 Digby General Hospital (Digby)- Not Currently Active

Annapolis Valley Health (DHA 3)

Valley Regional Hospital (Kentville)- INTERMEDIATE Level⁴
 Soldiers' Memorial Hospital (Middleton)- Not Currently Active

Colchester East Hants Health Authority (DHA 4)

Colchester Regional Hospital (Truro)- INTERMEDIATE Level^{4,5}
 Lillian Fraser Memorial Hospital (Tatamagouche)- Not Currently Active

Cumberland Health Authority (DHA 5)

Cumberland Regional Hospital (Amherst)- BASIC Level⁴
 North Cumberland Memorial Hospital (Pugwash)- Not Currently Active
 All Saints Springhill Hospital (Springhill)- Not Currently Active

Pictou County Health (DHA 6)

Aberdeen Hospital (New Glasgow)- INTERMEDIATE Level⁴
 Sutherland Harris Memorial Hospital (Pictou)- Not Currently Active

Guysborough-Antigonish-Strait Health Authority (DHA 7)

St. Martha's Regional Hospital (Antigonish)- INTERMEDIATE Level⁴
 Strait-Richmond Hospital (Port Hawksbury)- INTERMEDIATE Level⁴
 Guysborough Memorial Hospital (Guysborough)- Not Currently Active
 Saint Mary's Hospital (Sherbrooke)- Not Currently Active
 Eastern Memorial Hospital (Canso)- Not Currently Active
 St. Anne Community & Nursing Care Centre (Arichat)- Not Currently Active

Cape Breton District Health Authority (DHA 8)

Cape Breton Regional Hospital (Sydney)- ADVANCED Level
 Inverness Consolidated Memorial Hospital (Inverness)- INTERMEDIATE* Level⁴

⁴ Drugs not previously given at this facility will be approved on a case-by-case basis, pending appropriate nurse education and competency assessment; may be used for subsequent patients by nurses previously trained on the new drug(s)

⁵ Intermediate Level for patients under direct supervision of on-site hematologist or with identified physician coverage, preferably a local community physician

Victoria County Hospital (Baddeck)- BASIC Level⁶
 Sacred Heart Hospital (Cheticamp)- BASIC Level⁶
 Buchanan Memorial Hospital (Neil's Harbour)- BASIC Level⁶
 Northside General Hospital (North Sydney))- BASIC Level⁶
 New Waterford Consolidated Hospital (New Waterford))- BASIC Level⁶
 Glace Bay Hospital (Glace Bay))- BASIC Level⁶

Capital Health (DHA 9)

Queen Elizabeth II Hospital (Halifax)- ADVANCED/SUB-SPECIALTY Level⁷
 Dartmouth General Hospital (Dartmouth)- Not Currently Active
 Cobequid Community Centre (Sackville)- Not Currently Active
 Hants Community Hospital (Windsor)- BASIC Level (Not Currently Active)
 Twin Oaks Memorial Hospital (Musquodobid Harbour)- Not Currently Active
 Musquodobid Valley Memorial Hospital (Musquodobid Valley)- Not Currently Active
 Eastern Shore Memorial Hospital (Sheet Harbour)- Not Currently Active

Other

IWK Hospital (Halifax)- SUB-SPECIALTY Level⁸

⁶ Drugs not previously given at this facility or drugs rated as Intermediate or higher will be approved on a case-by-case basis, pending appropriate nurse education and competency assessment

⁷ Some Units are designated Sub-Specialty based upon types of patients under treatment (e.g. Bone Marrow Transplant unit, OMF unit)

⁸ Pediatric Sub-Specialty Level

Appendix 2- Guidelines for Systemic Therapy Treatment Facilities

To assist districts in establishing systemic treatment facilities and programs for cancer patients, the following guidelines may provide more specific direction. These guidelines are not inclusive of all practices, but serve as a minimal standard for facility planning. For more information, consider the Ambulatory Systemic Cancer Therapy Services Standards⁹ from Accreditation Canada.

Physical Facility:

1. The ambulatory treatment facility should have adequate treatment areas, appropriate to patient needs.

- Treatment space- for every 80-100 chemotherapy administrations per annum:
 - Treatment chair (may substitute a stretcher for larger patient volume treatment space)
 - Bedside table
 - IV pole
 - Side chair
 - Oxygen and suction available in each treatment unit
- Clinic space (proportionate to number of patient visits, number of clinicians)
 - At least one examination room (approx 120 square feet), with exam table, desk/table, chair, sink with counter and storage
- Waiting area (minimum 50 square feet)

2. The ambulatory treatment areas should afford privacy when needed, yet allow for immediate access by physician(s) or nurse(s)

- Privacy curtain to enclose each treatment chair/stretcher area
- Access to private room for patient counseling, as available
- Wheelchair accessible patient washroom within reasonable distance

3. The ambulatory treatment area should have sufficient medical equipment, which includes (but is not limited to):

- BP cuff
- Thermometer
- Pulse oximeter
- Plastic-backed pads
- Medications for treatment of anaphylaxis
- IV devices, IV system (needleless or closed system preferred)
- Powderless latex or non-latex gloves
- Fluid-safe lab coats, safety gowns
- Spill kit (for clean ups)
- Emergency drugs for crash cart
- Sink and eye wash station
- Sharps disposal system
- Waste disposal system for cytotoxic drugs, contaminated equipment
- Heating cupboard
- Upright scale for height and weight
- Access to telephone and fax machine
- Blankets and towels

⁹ Ambulatory Systemic Cancer Therapy Services Standards, Accreditation Canada, 2011

4. The chemotherapy drugs should be prepared in a separate pharmacy area, wherever possible employing the pharmacy service

- Area preferably adjacent or as close as possible to treatment area, low traffic area
- Class II biological safety cabinet, externally vented
- Designated storage for cytotoxic agents, separate from other drugs
- Storage for associated supplies and equipment (e.g. IV bags, syringes, etc.)
- Counters for dose checking and assembly
- Sink and eye wash station
- Sharps disposal system
- Waste disposal system for cytotoxic drugs, contaminated equipment
- Compliant with safe handling guidelines by CSHP and other professional organizations
- Workstation for order verification (may be separate from preparation area)
- Access to telephone and fax machine

5. The ambulatory treatment area should have ready access to hospital support facilities, as appropriate.

- Crash cart
- Clean and dirty supplies rooms
- Housekeeping closet
- Wheelchair storage, wheelchair(s) with IV pole
- Patient education materials wall rack
- Addressograph equipment (if used in hospital)
- Clerical office or counter
- Computer terminal and printer
- Administration/dictation space in close proximity to exam room

6. Access to inpatient beds if admission is required. If chemotherapy is to be given in the inpatient unit, proper facilities, equipment and trained staff must be available.

Administrative Support:

1. There should be adequate administrative staff and facilities to support the volume of patient visits

- Clerical staff and space for patient scheduling, clinic management
- Health records support appropriate to patient volumes
- Telephone follow-up, patient education by appropriate personnel
- Ordering, stocking and inventory maintenance of required medications and supplies
- Supply of appropriate provincial Physician Standing Order forms for chemotherapy regimens administered within the facility

2. There should be administrative space available for clinical staff

- Office with desk and chair
- Filing cabinet
- Telephone, fax machine

Medical Support:

1. There will be medical resources available for the management of medical emergencies during patient visit

- Crash cart readily accessible, and staff trained in cardiopulmonary resuscitation
- Ready access to Emergency Department and/or Intensive Care Unit (Intermediate Level and higher-higher risk medications given)
- Procedures in place for management of immediate adverse outcomes from systemic therapy (e.g. extravasations, hypersensitivity reactions, acute cholinergic reactions, etc.)

2. There should be on-call access to a physician around the clock for patient emergencies.
3. There should be ready access to laboratory facilities, with timely result reporting to facilitate chemotherapy treatment.
4. Chemotherapy ordering should comply with the provincial policies and procedures on ordering chemotherapy.

Appendix 3 Definitions of Health Professional Roles

These definitions are adapted from CCNS Systemic Therapy Policies and Procedures for Ordering Cancer Chemotherapy (2004) and apply to health professional role descriptions that are outlined in bold and italics in the Levels of Care document.

1. *Oncologist*: A physician with specialized training in the management of cancer. Specialization may be formal or informal, and may be subcategorized within other specialty disciplines (e.g. gynecology, pediatrics, hematology, urology, thoracic surgery, etc.) or specific to cancer (e.g. medical oncology, radiation oncology). A physician designated as an *Oncologist* will be granted privileges for the full practice of cancer care within the scope of their specialty practice area and/or time limitation for cancer care.
2. *Pediatric Oncologist*: A pediatrician with specialized training in the management of childhood cancer.
3. *Community Physician*: A community physician, with accredited prescribing privileges in the local treatment facility, designated to supervise a cancer patient through local cancer chemotherapy treatments. For the treatment of children with cancer this physician is preferably a *pediatrician*, if available, but may be a family physician who commits to gaining additional education, information and support in the care of the child. This physician has privileges to order cancer chemotherapy, which has been recommended on consultation by an *Oncologist*, a *Pediatric Oncologist*, or a *Community Specialist*. For treatments given at the local treatment facility, this physician might be referred to as the 'most responsible physician'.
4. *Community Specialist*: A community specialist physician, with accredited prescribing privileges in the local treatment facility, designated to assess and diagnose cancer patients, and to initiate a cancer chemotherapy program within a defined scope of practice, as defined by the District Health Authority in consultation with *Cancer Care Nova Scotia*. For treatments given at the local treatment facility, this physician might be referred to as the 'most responsible physician'.
5. *Oncology Nurse*: A [registered] nurse who is experienced and skilled in the care of cancer patients and their families.
6. *Registered Nurse with Chemotherapy Certification*: The administration of cancer chemotherapy is a shared competency and requires that a Registered Nurse complete a specified training program. The oncology nurse with chemotherapy certification will hold a current certificate from the training program, and will be responsible for maintenance of certification, as defined by the health district (in collaboration with *Cancer Care Nova Scotia*). *For privileges to administer chemotherapy to a pediatric oncology patient, this nurse will also have pediatric experience or work closely with a pediatric nurse (in this case certification may also be in collaboration with the IWK Health Centre/APPHON).*
7. *Oncology Pharmacist*: A pharmacist trained and assigned to a clinical practice in the District cancer care program. An oncology pharmacist is certified through a training

program offered in consultation with *Cancer Care Nova Scotia* or an equivalent pediatric program.

8. *Hospital Pharmacist with Oncology Training*: A hospital pharmacist, with oncology-specific training, competency assessment and practice privileges in the local treatment facility, designated to verify cancer chemotherapy treatment orders within a scope of practice, defined by the District Health Authority in consultation with *Cancer Care Nova Scotia*. *For privileges to verify chemotherapy for a pediatric oncology patient, this pharmacist may also have pediatric oncology specialty training (in collaboration with the IWK Health Centre/APPHON).*
9. *Basic Oncology Pharmacy Training*: Training for qualified pharmacists in oncology order verification.
10. *Chemotherapy Preparation Course*: All staff who prepare chemotherapy will have received a certificate from the Nova Scotia Community College/ *Cancer Care Nova Scotia* certificate course in chemotherapy preparation
11. *Oncology Practice Consultant*. Registered nurses with advanced oncology education who support oncology nurses in all districts by providing education, preceptorship and practice support to better enable these nurse to care for cancer patients.

Appendix 4 Definitions

These definitions are taken from *CCNS Systemic Therapy Policies and Procedures for Ordering Cancer Chemotherapy (2004)*

1. *Cancer Chemotherapy*: A single drug or combination of drugs used for the treatment of cancer. The cancer chemotherapy drugs may or may not be cytotoxic. Additional drugs may be added as Supportive Treatment to help ameliorate adverse effects of the cancer treatment or the disease. This does not include hormone agents.
2. *Systemic Therapy*: The use of drugs for the treatment or support of cancer patients. Systemic therapy includes cancer chemotherapy, hormone therapy, immunotherapy and supportive care drugs, and includes drugs given by any route, including oral.
3. *Cancer Chemotherapy Regimen*: The combination of chemotherapy drug or drugs, with predetermined relative or absolute doses, schedule of administration, and often with recommended supportive therapy (e.g. antiemetics, hydration).
4. *Cancer Chemotherapy Cycle*: A drug or combination of drugs, which is given to a patient over a fixed period of time or within a defined interval. Usually the cycle of cancer chemotherapy agent(s) will repeat at the start of the next time period. Most cancer chemotherapy regimens are given in repetitive cycles. Some cancer chemotherapy regimens include cycles with a different drug or combination of drugs planned for the next time period. The duration of a cycle is generally 2 to 8 weeks, and may be followed by the subsequent pre-determined cycle.
5. *District Cancer Committee*: The District Cancer Committee will bring together all those in a District with an interest in cancer care to work towards common goals for integrated cancer care within the District.
6. *Outreach Oncology Program*: Program in regional hospital for cancer care, which includes regular visits by an oncologist. The oncologist may assess cancer patients and order chemotherapy appropriate to the level of chemotherapy delivery for that hospital.
7. *Chemotherapy Administration Unit*: A facility (usually hospital) unit dedicated for the local preparation and delivery of chemotherapy. A Chemotherapy Administration Unit requires a dedicated space for cancer patient drug administration (sometimes called a chemotherapy suite), a dedicated drug preparation area (which may be located in the hospital pharmacy department), dedicated oncology nursing staff (which includes at least one Registered Nurse with Chemotherapy Certification), and on-site medical supervision (by a Community Physician with Chemotherapy Privileges or a Community Physician with Oncology Privileges). For treatment of **pediatric cancer patients**, there should be a properly equipped, dedicated space within the Chemotherapy Administration Unit for administration of chemotherapy to a child, a Registered Nurse with Chemotherapy Certification and pediatric experience, and a pediatrician, if available, or a committed family physician as the physician with prescribing privileges. It is desirable that a Chemotherapy Administration Unit has access to a hospital pharmacist with oncology training.

8. *Systemic Therapy Manual for Cancer Treatment*. A manual listing all drugs and treatment regimens typically used within Nova Scotia. The *Systemic Therapy Manual* is published and updated by the Systemic Therapy Program of *Cancer Care Nova Scotia*.
9. *Provincial Cancer Drug Formulary*. A listing of drugs used in cancer care, with the formulary status of each drug according to the Levels of Care Systemic Therapy Criteria. Drugs are listed as available or restricted appropriate to each facility level. This formulary will be used by all DHAs and managed by the Cancer Systemic Therapy Advisory Committee, of the Department of Health.

Appendix 5 Development of Systemic Therapies Levels of Care Criteria

The Levels of Care project was first discussed at the June 2003 provincial meeting of District Cancer Committees. At that meeting, it was recommended that *Cancer Care Nova Scotia* establish a small representative Steering Committee to oversee the process.

The Steering Committee, chaired by Sheila Scaravelli, VP Patient Care Services, Pictou County Health, first met in January 2004. The membership list of the Steering Committee is in Appendix 7. The Steering Committee developed a Levels of Care framework, which outlines all the components to be considered and defines all the terms. The Steering Committee was informed by the work done by the Clinical Services Steering Committee of the Nova Scotia Department of Health. The process for development of system-wide standards outlined in the Department of Health document *Processes and Procedures Supporting the Department of Health Role in Setting Health System Standards* has been followed.

The Steering Committee decided that the first aspect of cancer care to be addressed would be Systemic Therapy. The Atlantic Provinces Pediatric Hematology/Oncology Network (APPHON) had begun a similar process for pediatric hematology/oncology across the Atlantic Provinces. Efforts have been made by both CCNS and APPHON to keep these projects connected.

The Systemic Therapy Expert Working Group was convened in the fall of 2004. Representatives of the three professions most involved in systemic therapy (medicine, nursing, pharmacy) from both cancer centre and district-level perspectives were involved (membership list included in Appendix 7) in the development of the criteria. Two *Cancer Care Nova Scotia* staff, Larry Broadfield, Manager of Systemic Therapy and Jill Petrella, Quality Coordinator, supported and facilitated the group discussion.

A literature search was conducted as well as an environmental scan of the organized community cancer programs in Canada. Very little information was obtained through the literature search. The American Society of Clinical Oncology position statement *Criteria for Facilities and Personnel for the Administration of Parenteral Systemic Antineoplastic Therapy* (Journal of Clinical Oncology 22:22 Nov 2004) was obtained. Cancer Care Ontario shared its standards for space and equipment, which are listed in Appendix 3. Information was also obtained from the Saskatchewan Cancer Agency and Cancer Care Manitoba, both of which have well-established formal community cancer programs.

However, the criteria in this document were primarily generated through discussion by members of the Working Group and were decided by consensus. The primary rationale for all decisions was safety. The draft criteria were brought to the Steering Committee for discussion in February 2005 and the Steering Committee recommended that they be sent to key stakeholders for review and comment.

In February 2005, 140 copies of the draft criteria were sent to all DHA Vice-Presidents of Patient Care, Community Care, and Medicine, Directors of Pharmacy, known chemotherapy

nurses and all oncologists and hematologists for review and comment. Feedback was received in March, 2005. There was feedback from all disciplines and all districts but not all disciplines in all districts.

Generally, the feedback was positive in terms of the concept and the approach. Suggestions were made to clarify or improve the document and these changes were incorporated. There were some concerns from some areas about the availability of resources in these areas. However, the Impact Assessment step in the development process is designed to identify resource issues.

There were 3 major areas that required further discussion by the Working Group and Steering Committee:

- The role of nurses and physicians in preparing chemotherapy
- The ordering of cytotoxic chemotherapy by non-oncologists
- Addressing facilities with “unique” capabilities.

The Working Group and the Steering Committee decided:

- Only pharmacists or pharmacy technicians should prepare chemotherapy
- Cytotoxic chemotherapy should only be ordered by or in consultation with an oncologist.
- Revised criteria for Basic and Intermediate facilities to include “the presence of additional resources and expertise will be considered for allowance of selected Intermediate/Advanced level regimens as negotiated with CCNS.”

These decisions were communicated to all stakeholders. Concern was expressed about the decision to limit chemotherapy preparation to pharmacists and pharmacy technicians as it would prevent some facilities from providing chemotherapy. As a result, this issue was discussed with the College of Registered Nurses of Nova Scotia and the Nova Scotia College of Pharmacists. Chemotherapy preparation is within the scope of practice for Registered Nurses in Nova Scotia, therefore, it was agreed to remove the restriction on chemotherapy preparation by profession and instead to require anyone preparing chemotherapy to take the same training.

Cancer Care Nova Scotia and the Nova Scotia Community College partnered on the development of a chemotherapy preparation certificate course, which was piloted in spring 2008. The intent is that all persons, regardless of professional background or discipline, who prepare chemotherapy in Nova Scotia will take this course by June 2009.

In 2007, Cancer Care Ontario (CCO) published its standards *Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment*. In February 2008, questions were raised about the CCNS requirement of having an on-site ICU for Intermediate-level facilities. The CCO standards only require “access to” an ICU. It was decided to reconvene the Systemic Therapy Working Group to review the CCNS standards in light of the CCO document and other changes that have occurred in the Nova Scotia cancer system since 2005.

In May 2008, the Working Group reviewed and revised the standards. Significant changes:

- Those preparing chemotherapy must take the CCNS Nova Scotia Community College chemotherapy preparation course. Discipline-specific restrictions removed.
- Changed the requirement from “on-site” ICU to “on-site emergency department and access to an ICU” in keeping with the Cancer Care Ontario standards.
- Changed the requirement for an “on-site” pharmacist for Intermediate level facilities to “timely access” to an oncology pharmacist within the district.
- Oncologic emergencies section has been rewritten with emphasis at the Basic and Intermediate levels on having a chemotherapy emergency response plan.

In June 2012, the Levels of Care standards were revised by the Systemic Therapy Coordinating Committee (who assumed responsibility for these standards from the Working Group). Significant changes were:

- Addition of a mechanism for sites to administer a drug above the assigned level on a case-by-case basis with review by the Oncology Practice Consultant and/or Manager of the Systemic Therapy Program
- Extension of explanation for levels assigned to specific drugs and/or regimens to include the need for specialist supervision of patients for higher risk clinical outcomes from drugs with lesser risk from administration.
- Inclusion of Accreditation Canada standards for Ambulatory Systemic Therapy for Cancer as an additional organizational standard
- Inclusion of Distress Screening as an expectation with all new systemic therapy treatment patients and at other key transition points.
- Inclusion of clinical associates and nurse practitioners as legitimate consultants to order chemotherapy for administration at the local site or for transfer to another site.
- Redefinition of physician coverage in each level, to ensure that a physician is readily available on-site for urgent or emergent medical care, and that a physician (the same or other) in the community be responsible for ongoing medical care and symptom management of the patient following the chemotherapy treatment visit(s).

Appendix 6**Levels of Care Steering Committee Members**

Sheila Scaravelli	VP Patient Care Services	Pictou Co Health Authority (Chair)
Charlene Porter	Patient Navigator	GASHA
David Rippey	Senior Medical Advisor	NS Department of Health
Donna Grant	Clinical Nurse Educator	Capital Health Cancer Care Program
Dorothy Barnard	Pediatric Hematologist/ Oncologist	IWK/Atlantic Provinces Pediatric Hematology Oncology Network
Heather Wolfe	Quality Manager	Colchester-East Hants Health Authority
Jill Petrella	Quality Coordinator	<i>Cancer Care Nova Scotia</i>
Karen Jenkins	Chemotherapy Nurse	Annapolis Valley Health
Larry Broadfield	Manager, Systemic Therapy	<i>Cancer Care Nova Scotia</i>
Mark Dorreen	A/Head, Medical Oncology	Capital Health Cancer Care Program
Mona Baryluk	Director, Cancer Centre	Cape Breton District Health Authority
Nancy Gillam	Chemotherapy Nurses	Capital Health Cancer Care Program
Roland Genge	Pharmacist	South Shore Health
Shelagh Leahey	Family Physician	South West Health
Shelley Jones	A/Health Services Manager	IWK
Theresa Marie Underhill	Chief Operating Officer	<i>Cancer Care Nova Scotia</i>

Systemic Therapy Working Group Members (Original)

Mimi Davis	Medical Oncologist	Nova Scotia Cancer Centre
Gerry Farrell	Family Physician/ Palliative Care	Pictou Co Health
Roland Genge	Pharmacist	South Shore Health
Nancy Gillam	Chemotherapy Nurse	Nova Scotia Cancer Centre
Mohamed Hussein	Hematologist	Cape Breton Cancer Centre
Jeannie Kennedy	Chemotherapy Nurse	GASHA
Lorraine Parkin	Pharmacist	Nova Scotia Cancer Centre
Larry Broadfield	Manager, Systemic Therapy	<i>Cancer Care Nova Scotia</i>
Jill Petrella	Quality Coordinator	<i>Cancer Care Nova Scotia</i>

Systemic Therapy Working Group Members (2008)

Mickie Al-Molky	Levels of Care Coordinator	Atlantic Provinces Pediatric Hematology Oncology Program
Mimi Davis	Medical Oncologist	Capital Health Cancer Care Program
Gerry Farrell	Family Physician/ Palliative Care	Pictou Co Health
Roland Genge	Pharmacist	South Shore Health
Nancy Gillam	Chemotherapy Nurse	Capital Health Cancer Care Program
Dianna Hutt	Chemotherapy Nurse	Annapolis Valley Health
Mohamed Hussein	Hematologist	Cape Breton Cancer Centre
Jeannie Kennedy	Chemotherapy Nurse	GASHA (corresponding)
Sue MacEachern	VP Patient Care Services	Colchester East Hants Health Authority
Lorraine Parkin	Pharmacist	Capital Health Cancer Care Program
Larry Broadfield	Manager, Systemic Therapy	<i>Cancer Care Nova Scotia</i>
Jill Petrella	Quality Coordinator	<i>Cancer Care Nova Scotia</i>