



A **QUALITY PROGRAM**  
of the AMERICAN COLLEGE  
OF SURGEONS

## **DRAFT Revised Standards**

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# Chapter 1: Institutional Administrative Commitment

## STANDARD 1.1

### Facility Commitment

Cancer committee authority is established and documented by the facility.

#### DEFINITION AND REQUIREMENTS

Programs provide a letter of authority from facility leadership (e.g. CEO or equivalent) demonstrating the commitment to the cancer committee, which includes but is not limited to:

- A high-level description of the cancer program,
- Any initiatives involving the cancer committee during the survey cycle that were initiated for the purposes of ensuring quality and safety,
- Facility leadership's involvement in the cancer committee, and
- Examples of the current and future financial investment in the cancer program.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### Submitted with Pre-Review Questionnaire

- Letter of authority from facility leadership that includes all required elements.

#### MEASURE OF COMPLIANCE

**Compliance:** Once each survey cycle, the cancer program fulfills the compliance criteria:

1. Cancer committee authority is established and documented by the facility through a letter of authority from facility leadership that includes all required elements.

**Noncompliance:** The program does not fulfill the compliance criteria.

## Chapter 2: Program Scope and Governance

### STANDARD 2.1

#### Cancer Committee Membership

The membership of the cancer committee is multidisciplinary, representing physicians from diagnostic and treatment specialties and non-physicians from administrative, clinical, and supportive services. Cancer committee coordinators and leaders, who are responsible for specific areas of cancer program activity, are designated.

##### DEFINITION AND REQUIREMENTS

The care of patients with cancer requires a multidisciplinary approach and encompasses physician and non-physician professionals. The committee responsible for program leadership is multidisciplinary and represents the full scope of cancer care and services.

Required cancer committee members include at least one physician representing each of the diagnostic and treatment services and representatives from administrative, clinical, and supportive services. Each program assesses the scope of services offered and determines the need for additional cancer committee members based on the major cancer sites seen by the program. Appointments for required members must occur at the first meeting of a calendar year at least once during the survey cycle. The appointments are documented in the cancer committee minutes. If a required member cannot continue to serve on the cancer committee, a new member must be appointed at the next cancer committee meeting and documented in the minutes.

##### **Required physician members are:**

- Cancer Committee Chair  
(Physician of any specialty. Selected according to facility rules and/or bylaws. Can also represent one of the required physician specialties.)
- Cancer Liaison Physician (CLP)  
(The CLP serves as vice-chair. Can also represent one of the required physician specialties and/or the Quality Improvement Coordinator.)
- Diagnostic radiologist
- Pathologist
- Surgeon  
(Can be either a general surgeon involved in cancer care or a surgical specialist involved in cancer care)
- Medical oncologist
- Radiation oncologist  
(If all radiation oncology services are provided by referral and facility's medical staff does not include a radiation oncologist, a radiation oncologist is recommended to be part of the committee but not required.)

##### **Required non-physician members are:**

- Cancer Program Administrator  
(Responsible for the administrative oversight and has budget authority for the cancer program)
- Oncology nurse
- Social worker or case manager
- Certified Tumor Registrar (CTR)

##### **Required coordinator members are:**

The following coordinators are required members of the cancer committee. Appointments must occur at the first meeting of a calendar year at least once during the survey cycle. The appointments are documented in the cancer committee minutes.

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An individual serving in a required physician or non-physician role on the cancer committee can also be appointed to a coordinator role. If an accredited facility has less than 500 analytic cases a year, it may have one individual serve in two coordinator roles. If an accredited facility has more than 500 analytic cases a year, an individual can only serve in one coordinator role.

A Certified Tumor Registrar may only serve as the Multidisciplinary Tumor Board Coordinator or the Cancer Registry Quality Coordinator.

#### **Multidisciplinary Tumor Board Coordinator**

The Multidisciplinary Tumor Board Coordinator is responsible for overseeing Standard 5.1: Multidisciplinary Tumor Board.

#### **Quality Improvement Coordinator**

The Quality Improvement Coordinator is responsible for overseeing Standard 7.3: Quality Improvement Project.

#### **Cancer Registry Quality Coordinator**

The Cancer Registry Quality Coordinator is responsible for overseeing Standard 6.1: Cancer Registry Quality Control Plan and Standard 4.4: Cancer Registry Credentials.

#### **Prevention and Screening Coordinator**

The Prevention and Screening Coordinator is responsible for overseeing Standard 8.2: Cancer Prevention Event and Standard 8.3: Cancer Screening Event. This coordinator has specific experience with screening and prevention initiatives. This role is not a marketing position. It cannot be filled by an American Cancer Society representative.

#### **Clinical Research Coordinator**

The Clinical Research Coordinator is responsible for overseeing Standard 9.1: Clinical Research Accrual. A clinical trial principal investigator, a research data manager or associate, a clinical research nurse, an oncology nurse, or another similar role with clinical research experience is selected to fill this role.

#### **Psychosocial Services Coordinator**

The Psychosocial Services Coordinator is responsible for overseeing Standard 5.3: Psychosocial Distress Screening. An oncology social worker (OSW-C preferred), clinical psychologist, or other mental health professional trained in the psychosocial aspects of cancer care is selected to fill this role.

#### ***Additional required cancer committee member:***

#### **Survivorship Program Director**

The Survivorship Program Director is responsible for overseeing Standard 4.9: Survivorship Program. A physician or advanced practice nurse is selected to fill this role.

#### ***Cancer committee members strongly recommended, but not required, include:***

- Specialty physicians representing the five major cancer sites at the program
- Palliative care professional
- Genetics professional
- Registered Dietitian Nutritionist or nutrition services professional
- Rehabilitation services professional
- Pharmacist
- Pastoral care representative
- American Cancer Society representative

## **SPECIFICATIONS BY CATEGORY**

NCIP facilities are exempt from this standard. Facilities with 500 analytic cases or less each year may have one individual serve in two coordinator roles.

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## DOCUMENTATION

### Submitted with Pre-Review Questionnaire

- Cancer committee minutes that identify the required cancer committee members.

## MEASURE OF COMPLIANCE

**Compliance:** The cancer program fulfills all of the compliance criteria:

1. The membership of the cancer committee includes all required specialties and roles.
2. Committee membership of all required roles is documented in the cancer committee minutes at the first meeting of the calendar year at least once each survey cycle.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria.

**Not Applicable:** NCIP facilities.

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## STANDARD 2.2

### Cancer Committee Meetings

Each calendar year, the cancer committee meets at least once each calendar quarter.

#### DEFINITION AND REQUIREMENTS

Regular cancer committee meetings ensure that administrative responsibilities related to cancer program functions are carried out and standard compliance is met. The cancer committee assembles each quarter, with a minimum of four meetings each calendar year. Cancer committees may choose to hold meetings more frequently in order to meet overall program needs.

*Yearly calendar quarters are defined as:*

- January 1 – March 31
- April 1 – June 30
- July 1 – September 30
- October 1 – December 31

It is recommended that meetings be scheduled in the first month of each quarter to allow for rescheduling needs. It is the cancer committee's responsibility to schedule and reschedule meetings, as appropriate, for each quarter. Compliance is based on meetings held quarterly and not on the total number of meetings held each year. The triennial CoC survey does not qualify as a meeting to comply with this standard.

Cancer committee minutes must contain sufficient details to accurately reflect the activities of the cancer committee as well as demonstrate compliance with CoC standards.

In addition to the cancer committee, programs may choose to establish subcommittees or workgroups to manage specific activities. To be considered for compliance, subcommittee and workgroup activities and reports related to standard compliance must be presented and approved by the cancer committee.

Examples of subcommittees include:

- Multidisciplinary tumor board activity
- Clinical and translational research activity
- Screening and prevention activity
- Quality control of cancer registry data
- Quality management and improvement activity
- Review of policies and procedures
- Survivorship
- Addressing Barriers to Cancer Care

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### Submitted with Pre-Review Questionnaire

- Cancer committee minutes that document the committee's quarterly meetings and activities.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

1. The cancer committee meets at least once each calendar quarter.

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

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## STANDARD 2.3

### Cancer Committee Attendance

Each required cancer committee member or the member's designated alternate attends at least 75 percent of the cancer committee meetings held each calendar year.

#### DEFINITION AND REQUIREMENTS

To successfully complete responsibilities and ensure multidisciplinary input, it is imperative that all required members regularly attend and participate in cancer committee meetings.

Each required member or the designated alternate must attend at least 75 percent of the cancer committee meetings held each calendar year. The cancer committee monitors the attendance of required members. It is recommended that the cancer committee also monitor attendance of non-required members.

Members subject to attendance requirements include the specialists and roles defined as "required members" in Standard 2.1: Cancer Committee Membership.

#### ***Appointing Alternates***

For each required member/role, one designated alternate member can be identified. Designating an alternate is optional. Only one alternate can be appointed for each required member.

The designated alternate must be qualified and appropriately credentialed to serve as an alternate for the role (for example, alternate to a medical oncologist must be another medical oncologist). An individual cannot serve as an alternate if he or she is already a required member of the cancer committee or a designated alternate for another role. A designated alternate can be an existing non-required member of the cancer committee if they are an appropriate choice to fill the alternate role of the committee.

The attendance percentage is calculated based on the attendance of the required role. In other words, the required member plus his or her designated alternate's attendance is considered together.

The identification of required members and designated alternates must take place at the first meeting of the calendar year at least once during the survey cycle. This information is documented in the cancer committee minutes. If a required member or alternate cannot continue to serve on the cancer committee, a new member or alternate must be appointed at the next cancer committee meeting and documented in the minutes.

#### ***Remote Attendance***

Attendance at cancer committee meetings may include participation through teleconference or videoconference calls as long as the remote attendee has access to appropriate meeting documents.

#### SPECIFICATIONS BY CATEGORY

NCIP facilities are exempt from this standard.

#### DOCUMENTATION

##### **Submitted with Pre-Review Questionnaire**

- Cancer committee minutes that include the required member attendance for each cancer committee meeting held during each calendar year.

## **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

1. Each required member or the designated alternate attends at least 75 percent of the cancer committee meetings held.

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

**Not Applicable:** NCIP facilities.

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## Chapter 3: Facilities and Equipment Resources

### IN DEVELOPMENT

## Chapter 4: Personnel and Services Resources

### STANDARD 4.1

#### Physician Credentials

Diagnostic and treatment services are provided by or referred to physicians who are currently American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) board certified (or the equivalent) in their medical specialty or demonstrate ongoing cancer-related education.

#### DEFINITION AND REQUIREMENTS

Cancer patient management is conducted by a multidisciplinary team, including, radiologists, pathologists, surgeons, radiation oncologists, and medical oncologists. All physicians involved in the evaluation and management of cancer patients must:

- Be ABMS or AOA board certified (or the equivalent); or
- Demonstrate ongoing cancer-related education by earning 12 cancer-related continuing medical education (CME) hours each calendar year.

#### *Scope of Standard*

This standard applies to physicians who are involved in the evaluation and management of cancer patients at the accredited facility for at least one calendar year. This standard does not apply to physicians who are in fellowship or residency or physicians within the five years immediately following graduation from fellowship or residency.

#### SPECIFICATIONS BY CATEGORY

NCIP facilities are exempt from this standard.

#### DOCUMENTATION

##### Submitted with Pre-Review Questionnaire

- A copy of the medical staff bylaws that address the requirements of current board certification of physicians; or
- A roster of the board certification status for all physicians involved in the evaluation and management of cancer patients; and
- Documentation of 12 annual cancer-related CME hours for all physicians who are not board certified who are involved in the evaluation and management of cancer patients.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. All physicians involved in the evaluation and management of cancer patients must be board certified (or the equivalent).
2. Physicians who are not board certified must demonstrate ongoing cancer-related education by earning 12 cancer-related CME hours.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** NCIP facilities.

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## STANDARD 4.2

### Cancer Liaison Physician Responsibilities

A Cancer Liaison Physician (CLP) serves in a leadership role within the cancer program and is responsible for evaluating, interpreting, and reporting the cancer program's performance using National Cancer Database (NCDB) data, with preference for areas of concern and/or where expected performance is not being met. The CLP reports on the results of this analysis to the cancer committee at least two times each calendar year.

#### DEFINITION AND REQUIREMENTS

##### ***CLP Eligibility***

The CLP is a physician of any specialty who is an active member of the medical staff. The CLP is considered the physician quality leader of the cancer committee. The CLP serves as vice-chair of the cancer committee and oversees cancer committee meetings if the chair is not in attendance.

It is permissible for the CLP to also serve as the cancer committee chair, but it is encouraged the CLP role and the chair role be filled by two individuals.

##### ***CLP as Quality Champion***

In the role as physician quality leader of the cancer committee, the CLP must identify, analyze, and present NCDB data pertinent and specific to the cancer program to the cancer committee at a minimum of two meetings each calendar year. Data from the NCDB must be used as the basis of the reports. Focus is given to areas of concern or where expected performance is not being met. Reports must be given by the CLP or the CLP's designated alternate.

Documentation of the data presented and the details of the discussion with the cancer committee must be included in the cancer committee minutes. CLP reports do not substitute and cannot duplicate requirements from other standards, except Standard 7.1: Accountability and Quality Improvement Measures.

The CLP must attend the CoC on-site accreditation survey and meet with the site visit reviewer to discuss the cancer program, CLP responsibilities, and the NCDB quality reporting tools.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### **Submitted with Pre-Review Questionnaire**

- Cancer committee minutes documenting CLP reports from at least two separate meetings on data specific to the cancer program, including actions and response.

#### MEASURE OF COMPLIANCE

**Compliance:** The cancer program fulfills all of the compliance criteria:

1. The CLP or the CLP's designated alternate identifies, analyzes, and presents NCDB data specific to the cancer program, with preference for areas of concern and/or where benchmarks are not met, to the cancer committee at a minimum of two meetings each calendar year.
2. The CLP is present during the CoC accreditation survey and meets with the site visit reviewer to discuss CLP activities and responsibilities.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

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## STANDARD 4.3

### Oncology Nursing Credentials

Oncology nursing care is provided by nurses with specialized knowledge and skills demonstrated by a cancer-specific certification or continuing education in oncology nursing.

#### DEFINITION AND REQUIREMENTS

Oncology nursing competency is reviewed each year per hospital policy.

All registered nurses and advanced practice nurses providing direct oncology care must demonstrate one of the following:

- Current cancer-specific certification in their specialty by an accredited certification program; OR
- Ongoing education by earning 12 cancer-related continuing education nursing contact hours each calendar year.

Nurses who are in the process of obtaining a cancer-specific certification do not need to submit documentation of cancer-related continuing education, but must provide documentation of progress toward certification.

#### *Oncology Nursing Certifications*

Oncology nursing certifications that qualify for this standard include, but are not limited to:

- Advanced Oncology Certified Nurse Practitioner (AOCNP®)
- Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®)
- Advanced Oncology Certified Nurse (AOCN®)
- Blood & Marrow Transplant Certified Nurse (BMTCN®)
- Certified Pediatric Hematology Oncology Nurse (CPHON®)
- Certified Pediatric Oncology Nurse (CPON®)
- Certified Breast Care Nurse (CBCN®)
- Oncology Certified Nurse (OCN®)
- Oncology Nurse Navigator-General Oncology Certification (ONN-CG®)

A certification qualifies under this standard as long as it includes cancer-specific criteria. For example, a palliative care certification meets the certification expectations under this standard as long as it contains cancer-specific criteria.

#### *Continuing Education*

Oncology nursing certification is strongly preferred. If a nurse providing direct oncology care is not certified, then the nurse must complete 12 cancer-related continuing nursing education contact hours each calendar year.

#### *Scope of Standard*

This standard applies to registered nurses and advanced practice nurses who provide direct oncology care in the accredited facility for at least one calendar year. Specifically, the standard applies to nurses in medical oncology who give chemotherapy, nurses in radiation oncology, nurse navigators, and nurses who are full-time in the cancer center or cancer clinic within the accredited facility. It does not apply to nurses in the hospital who might have occasional contact with cancer patients and it does not apply to operating room or recovery room nurses.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

## DOCUMENTATION

### Submitted with Pre-Review Questionnaire:

- A roster of nursing certification status for all nurses providing direct oncology care and documentation of 12 cancer-related continuing education nursing contact hours for each nurse providing direct oncology care who does not hold a cancer-specific certification.
- A policy and procedure that states that oncology nursing competency will be evaluated each year per hospital or facility policy.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the program fulfills the compliance criteria:

1. All nurses providing direct oncology care hold a cancer-specific certification or demonstrate ongoing education by earning 12 cancer-related continuing nursing education contact hours each calendar year.
2. Programs have in place a policy and procedure that ensures oncology nursing competency is reviewed each year per hospital policy.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria.

## STANDARD 4.4

### Cancer Registry Credentials

Case abstracting is performed by a Certified Tumor Registrar. Each calendar year, non-CTR members of the cancer registry staff demonstrate completion of cancer-related continuing education applicable to their roles.

#### DEFINITION AND REQUIREMENTS

Certified Tumor Registrars (CTR) apply knowledge obtained from formal education and work experience to correctly interpret and code cancer diagnosis, stage, treatment, and outcomes information for each case that is seen at the CoC-accredited programs that meets CoC reporting requirements. The CTR credential is granted and overseen by the National Cancer Registrars Association.

All cancer registry staff who abstract cases at a CoC-accredited program must either:

- Hold a current Certified Tumor Registrar (CTR) credential; or
- Perform case abstracting under the supervision of a CTR.

These requirements apply to those employed by the program, working on a contract basis, and/or working through a registry service company.

It is encouraged that CTRs attend in-person education.

#### ***Non-credentialed registry staff***

A plan for CTR supervision of non-credentialed staff must be established and include the scope of supervision, quality control, education, and training activities for non-credentialed staff.

Any non-CTR hired to perform abstracting under the supervision of a CTR in a CoC-accredited program must pass the CTR examination within three years of the date hired to perform abstracting. If the person does not successfully obtain the CTR credential within the three-year grace period, then he or she may not perform case abstracting at any CoC-accredited program until the credential is obtained.

Non-credentialed cancer registry staff may perform case finding and follow up, but cannot perform any abstracting on analytic cases unless it is performed under the supervision of a CTR per the documented plan.

#### ***Continuing education requirements***

Each calendar year, members of the cancer registry staff who do not hold a CTR credential must demonstrate completion of three hours of cancer-related continuing education applicable to their roles.

This continuing education requirement applies to all non-credentialed registry staff, including staff abstracting under the supervision of a CTR, staff performing follow-up activities, and registry management or supervisory personnel.

This education includes, but is not limited to, topics in the following areas:

- Advances in cancer diagnosis and treatment
- Changes in cancer program standards
- Changes in data collection requirements

#### ***Scope of Standard***

This standard applies to cancer registry staff (CTRs and Non-CTRs) who work in the accredited facility for at least one calendar year.

## SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

### DOCUMENTATION

#### Reviewed on-site

- When applicable, verification of the date of hire for staff to perform case abstracting in the cancer registry.

#### Submitted with Pre-Review Questionnaire

- Current CTR credentials for all certified cancer-registry staff.
- Plan for CTR supervision of non-credentialed staff who perform case abstracting in the cancer registry.
- Documentation of cancer-related continuing education for non-credentialed members of the cancer registry staff.

### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Case abstracting is performed by a Certified Tumor Registrar.
2. Non-credentialed cancer registry staff in the three-year grace period who abstract cases are supervised by a Certified Tumor Registrar.
3. All non-credentialed cancer registry staff demonstrates completion of three hours of cancer-related continuing education applicable to their roles.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

## STANDARD 4.5

### Genetic Counseling and Risk Assessment

Cancer risk assessment, genetic counseling, and genetic testing services are provided to patients either on-site or by referral to a qualified genetics professional and are evaluated at least once each calendar year. The cancer committee develops and monitors a process for genetic screening/testing and referral for genetic counseling for a specific cancer site each calendar year.

#### DEFINITION AND REQUIREMENTS

Cancer risk assessment and genetic counseling are the processes to identify and counsel people at risk for familial or hereditary cancer syndromes. Purposes of cancer genetic counseling are to: educate patients about their chance of developing cancer, help patients obtain personal meaning from genetic information, and empower patients to make educated, informed decisions about genetic testing, cancer screening, and cancer prevention.

#### ***Policy and Procedure for Genetic Counseling and Risk Assessment Services***

Cancer programs must develop a policy and procedure for providing cancer risk assessment, genetic counseling, and genetic testing services on-site or by referral. Genetic services not provided on-site at the facility must be provided through a formal referral relationship to other facilities and/or local agencies. The policy and procedure must include information/processes for the following:

- Criteria for referral for a genetics evaluation,
- Identification of the genetics professionals available on-site and/or by referral, and
- Identification of the genetics professionals qualified to perform post-test counseling either on-site and/or by referral.

Cancer risk assessment and genetic counseling are performed by a genetics professional with an educational background in cancer genetics and hereditary cancer syndromes. Specialized training in cancer genetics is required. Educational seminars offered by commercial laboratories about how to perform genetic testing are not considered adequate training for cancer.

*Genetics professionals may include:*

- An individual board-certified/board-eligible by American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics and Genomics (ABMGG).
- An Advanced Practice Nurse in Genetics (APNG), or an Advanced Genetics Nursing Certification (AGN-BC) credentialed through the American Nurses Credential Center (ANCC), or a Genetics Clinical Nurse (GCN).
- An advanced practice oncology nurse or Physician Assistant who is prepared at the graduate level (master or doctorate) with specialized education in cancer genetics and hereditary cancer predisposition syndromes. Certification by the Oncology Nursing Certification Corporation (ONCC) is preferred.
- A board-certified/board-eligible physician with experience in cancer genetics (defined as providing cancer risk assessment on a regular basis and undergoing ongoing continuing medical education in cancer genetics and hereditary cancer predisposition syndromes).

#### ***Monitoring Genetic Testing/Screening and Referrals for a Selected Cancer Site***

While it is expected that the program will provide genetics screening for all relevant cancers on an on-going basis, each calendar year programs must identify a process pursuant to evidence-based national guidelines for genetic screening/testing for one specific cancer site to focus on for the year. Examples include, but are not limited to: colon, breast, or ovarian. The policy and procedure documenting the process must include the following:

- Criteria for who receives genetic testing/screening for the selected cancer site, and
- Criteria for needing additional testing and referrals for a genetics consultation for the selected cancer site.

Programs may repeat the same site year-to-year, but it is encouraged the program evaluate different sites over time.

Programs must identify an individual to track whether patients who met the criteria for additional testing received a referral for genetic consultation.

### ***Evaluating the Genetic Counseling and Risk Assessment Services***

Programs that do not have a genetics professional on the cancer committee must identify an individual to oversee compliance with and reporting on this standard. This individual can be a current cancer committee member holding another required member position.

Each calendar year, the cancer committee must review the policy and procedure for genetic counseling and risk assessment and the policy and procedure and the report for its selected cancer site(s).

The cancer committee must review and document in the minutes:

- the number of patients identified as needing additional testing for the chosen cancer site each year, and
- how many patients identified as needing additional testing for the chosen cancer site received a referral for genetic counseling.

It is encouraged, but not required, that programs track whether patients who received referrals for additional testing for the chosen cancer site ultimately had genetic counseling.

## **SPECIFICATIONS BY CATEGORY**

All programs fulfill this standard as written.

## **DOCUMENTATION**

### **Submitted with Pre-Review Questionnaire**

- Policy and procedure for providing cancer risk assessment, genetic counseling, and genetic testing services on-site or by referral that includes all required elements.
- Policy and procedure(s) for genetic testing/screening and referral for genetic counseling for a selected cancer site pursuant to evidence-based national guidelines.
- Cancer committee minutes documenting the review of the genetic counseling and risk assessment policy and procedure, the selected cancer site policy and procedure, the number of patients identified as needing additional screening for the selected cancer site, and the number of patients that were referred for genetic counseling.

## **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Cancer risk assessment, genetic counseling, and genetic testing services are provided to patients either on-site or by referral by a qualified genetics professional.
2. A policy and procedure is in place regarding genetic counseling and risk assessment services and includes all required elements.
3. A policy and procedure is in place for genetic testing/screening and referral for genetic consultation for a selected cancer site pursuant to evidence-based national guidelines.
4. The process for providing and referring cancer risk assessment, genetic counseling, and genetic testing services is monitored and evaluated, contains all required elements, and is documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

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## STANDARD 4.6

### Palliative Care Services

Palliative care services are available to cancer patients either on-site or by referral and are evaluated at least once each calendar year.

#### DEFINITION AND REQUIREMENTS

Palliative care refers to patient- and family-centered care that optimizes quality of life. The availability of palliative care services is an essential component of cancer care, beginning at the time of diagnosis and being continuously available throughout treatment and surveillance, and, when applicable, during bereavement.

Palliative care is provided per evidence-based national treatment guidelines and includes palliative care provided by oncology teams and, as needed, consultation with palliative care specialists. It is recommended that the following specialties provide palliative care services: physicians, nurses, mental health professionals, social workers, and spiritual counselors.

Palliative care is integrated in the continuum of cancer care. Types of palliative care services include, but are not limited to:

- Team-based care planning that involves the patient and family
- Pain and non-pain symptom management
- Communication among patients, families, and provider team members
- Continuity of care across a range of clinical settings and services
- Attention to spiritual comfort
- Psychosocial support for patients and families
- Bereavement support for families and care team members

Palliative care services on-site will vary depending on the scope of the program, local staff expertise, and patient population. The cancer committee will define and identify in a policy and procedure the following:

- On-site and off-site palliative care services,
- the palliative care team available on-site, and
- criteria for referral to a palliative care specialist.

Palliative care services not provided on-site at the facility must be provided through a formal referral relationship to other facilities and/or local agencies.

#### ***Evaluating the Palliative Care Services***

Programs that do not have a palliative care professional on the cancer committee must identify an individual to oversee compliance with and reporting on this standard. This individual can be a current cancer committee member holding another required member position.

Each calendar year, the cancer committee monitors, evaluates, and makes recommendations for improvements, as needed, to palliative care services and/or referrals annually. The evaluation is documented in the cancer committee minutes.

During this evaluation, the cancer committee must:

- Assess the approximate number of cancer patients referred for palliative care services and for what services or resources,
- Discuss the criteria utilized to trigger referrals to palliative care services, and
- Discuss areas of improvement or barriers for palliative care services for cancer patients.
  - Examples include, but not limited to, barriers to access of palliative care services, addition of palliative care services, emergency department usage, or improving the timeliness of referrals.

## SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

### DOCUMENTATION

#### Submitted with Pre-Review Questionnaire

- Policy and procedure for providing palliative care services on-site or by referral.
- Cancer committee minutes that document the required yearly evaluation of the palliative care services.

### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Palliative care services are available to cancer patients either on-site or by referral.
2. A policy and procedure is in place regarding palliative care services that includes all required elements.
3. The process for providing and referring palliative care services to cancer patients is monitored and evaluated. A report is given to the cancer committee, contains all required elements, and is documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

## STANDARD 4.7

### Rehabilitation Care Services

Policies and procedures are in place to guide referral to appropriate rehabilitation care services on-site or by referral.

#### DEFINITION AND REQUIREMENTS

Rehabilitation care is patient-centered care that optimizes patient functional status and quality of life (QOL) through preventive, restorative, supportive, and palliative interventions. The availability of rehabilitation care services is an essential component of comprehensive cancer care, beginning at the time of diagnosis and being continuously available throughout treatment, surveillance, and when applicable, through end of life.

Rehabilitation professionals associated with cancer rehabilitation typically include, but are not limited to:

- Physiatrists
- Physical therapists
- Occupational therapists
- Speech language pathologists

Types of rehabilitative care services may include, but are not limited to:

- Assessment and screening for physical dysfunction, impairments, and disabilities
- Interventions to manage identified functional impairments and disabilities
- Assessment and management of pain and non-pain symptoms
- Assessment of cognitive function
- Lymphedema management
- Physical activity recommendations during and after treatment
- Vocational rehabilitation

The cancer program defines and identifies in a policy and procedure the rehabilitation care services provided on-site and by referral. Rehabilitation services not available at the facility must be provided through a formal referral relationship to other facilities and/or agencies. The cancer committee will define and identify in a policy and procedure the following:

- On-site and off-site rehabilitation care services,
- the rehabilitation care team available on-site,
- criteria for performing functional assessments, and
- criteria for referral to a rehabilitation care specialist.

#### ***Evaluating Rehabilitation Care Services***

Programs that do not have a rehabilitation professional on the cancer committee must identify an individual to oversee compliance with and reporting on this standard. This individual can be a current cancer committee member holding another required member position.

Each calendar year, the cancer committee must monitor, evaluate, and make recommendations for improvements, as needed, to rehabilitation care services and/or referrals. The content of the review and any recommendations for improvement are documented in the cancer committee minutes.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

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## DOCUMENTATION

### Submitted with Pre-Review Questionnaire

- Policy and procedure defining rehabilitation services that are provided on-site and by referral.
- Cancer committee minutes documenting the annual review of the rehabilitation care services.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. The cancer committee develops policies and procedures to guide referral to appropriate rehabilitation care services on-site or by referral.
2. The process for referring or providing rehabilitation care services to cancer patients is monitored and reviewed by the cancer committee and documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

DRAFT

## **STANDARD 4.8**

### **Oncology Nutrition Services**

Oncology nutrition services are provided, on-site or through referral, by Registered Dietitian Nutritionists (RDN) with knowledge and skills to address nutrition and hydration requirements and recommendations throughout the continuum of cancer care, including prevention, diagnosis, treatment, survivorship, and palliative care. If an RDN is not available, then a policy must be in place for healthcare professionals on the patient's oncology care team to address patient nutrition needs. Each calendar year, the cancer committee monitors and evaluates the on-site oncology nutrition and hydration services and/or referral services.

#### **DEFINITION AND REQUIREMENTS**

Multi-modality cancer treatments can impair a cancer patient's ability to consume, digest, and absorb essential nutrition and hydration. Registered Dietitian Nutritionists (RDN) are uniquely trained to address cancer and treatment-related symptom management, nutrition support, and quality-of-life concerns through medical nutrition therapy and education. In addition, RDNs are qualified to discuss diet, nutrition and lifestyle recommendations for survivorship, health promotion and disease prevention.

Oncology nutrition services are provided by RDNs either on-site or by referral and the cancer program defines and identifies the nutrition services provided on-site and by referral. Nutrition services not available at the facility must be provided through a formal referral relationship to other facilities and/or agencies. If an RDN is not available, then a policy must be in place for healthcare professionals on the patient's oncology care team to address patients' nutrition needs.

Components of oncology nutrition services include, but are not limited to:

- Screening and nutrition assessment for risk and diagnosis of malnutrition, nutrition-related problems, and overweight and obesity
- Medical nutrition therapy
- Nutrition counseling
- Nutrition education
- Management and coordination of enteral and parenteral nutrition

#### ***Evaluating Oncology Nutrition Services***

Programs that do not have a nutrition professional on the cancer committee must identify an individual to oversee compliance with and reporting on this standard. This individual can be a current cancer committee member holding another required member position.

Each calendar year, the cancer committee must monitor, evaluate, and make recommendations for improvements to on-site oncology nutrition and hydration services and/or referral services. The content of the review and any recommendations for improvement are documented in the cancer committee minutes.

#### **SPECIFICATIONS BY CATEGORY**

All programs fulfill this standard as written.

## DOCUMENTATION

### Submitted with Pre-Review Questionnaire

- Policies and procedures for providing oncology nutrition services, on-site or by referral, to a Registered Dietitian Nutritionist. If a RDN is unavailable to the program, then the policy and procedure for healthcare professionals on the patient's oncology team to address patient nutrition needs.
- Cancer committee minutes that document the committee's monitoring and evaluation of the provision of on-site oncology nutrition and hydration services and/or referral services and any recommendation for improvement.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Oncology nutrition services are provided, on-site or by referral, by Registered Dietitian Nutritionists. If RDN is unavailable to a program, then a policy must be in place for healthcare professionals on the patient's oncology care team to address the patient nutrition needs.
2. The process for referring or providing oncology nutrition services to cancer patients is monitored and reviewed by the cancer committee and documented in the cancer minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

## A note on the revised survivorship standard

The survivorship standard (Standard 3.3) was reviewed extensively with input from our member organizations, CoC surveyors, and with input from meetings hosted by the American Society of Clinical Oncology, the American Cancer Society, the National Cancer Policy Forum, and the National Cancer Institute.

We are extremely proud of the success of this standard in bringing attention to the rapidly evolving field of survivorship, and increasing focus of our accredited cancer programs on the needs of cancer survivors.

The new standard will emphasize the development of survivorship care programs that can provide management of toxicities of treatment, rehabilitation needs, psychological support, screening for recurrent and new cancers, and specific support programs that would be identified by the cancer committee. The delivery of survivorship care plans can be an important part of survivorship care. We recommend their use, but they are not the only component and are no longer required to meet the revised version of the standard.

The following revised survivorship standard requires a survivorship program team comprised of essential personnel such as physicians, advanced practice providers, nurses, social workers, nutritionists, and/or physical therapists. The team is led by a survivorship program director, who can be a physician or advanced practice provider currently within the program who has a special interest in survivorship. Notably, it is not expected that programs hire new personnel to fill the director position.

We will utilize feedback received during this public comment period to refine and clarify these requirements. As soon as possible thereafter, we will release information regarding 2019 compliance with the current version of Standard 3.3.

### STANDARD 4.9 Survivorship Program

The cancer committee oversees the development and implementation of a survivorship program directed at meeting the needs of cancer patients treated with curative intent.

#### DEFINITION AND REQUIREMENTS

The cancer program has a survivorship care program in place that includes the following elements documented in a written plan:

- Designated director of the survivorship care program who must be a member of the cancer committee
- An identified team responsible for the development of survivorship care delivery models and activities
- A survivorship program that addresses the needs of cancer survivors, through care and consultative services provided either on-site or by referral.
- A survivorship program report that describes the program and planned future program development. The report will be presented to the cancer committee, with discussion, annually. The report also includes a status update on the previous report's planned improvement(s).

#### ***Survivorship and Follow-up Care***

The care of cancer survivors is an on-going activity. Cancer survivors may require services shortly after treatment completion or many years after. Therefore, on-going care, as determined by the individual patient needs, will be provided with appropriate interventions to mitigate the complications of patients' cancer and treatment toxicities. The survivorship program addresses this continuing need.

## ***Components of the survivorship program***

### **Survivorship Program Team: Leadership and Personnel**

The cancer committee appoints a director of the survivorship program who is responsible to the cancer committee for the development and execution of the survivorship program. The Survivorship Program Director is a required member of the cancer committee.

The Survivorship Program Director will develop a survivorship program team. Members may include physicians, advanced practice providers, nurses, social workers, nutritionists, physical therapists and similar personnel.

The survivorship program team evaluates and develops the survivorship program. Programs determine the frequency and format of the survivorship program team meetings. The team must meet separately from the full cancer committee meeting.

### **Target Population**

The survivorship program is established to meet the needs of cancer survivors. While definitions of survivors include those from diagnosis through their lifespan, including those with metastatic disease, the CoC is focusing on the development of services for patients treated with curative intent. Additional activities reaching the broader group of cancer survivors is encouraged, but not required under this standard.

### **Services**

Cancer survivors need a variety of services dependent on their diagnosis, the treatments they receive, co-morbidities, and personal needs. These may include, but are not limited to:

- treatment summaries and survivorship care plans
- screening for cancer recurrence,
- screening for new cancers,
- physical therapy,
- nutritional services,
- psychological support, or
- cardiac consultation.

The requirement for some of these services are outlined in other standards for CoC accreditation and should be available to all cancer patients, including those undergoing diagnostic evaluation, treatment, and post-treatment survivorship care. The survivorship program policy and procedure includes a comprehensive list of services available for cancer survivors. Services may be available on-site or by referral.

### **Treatment Summaries and Survivorship Care Plans (SCP)**

The CoC recommends and encourages that patients receive a treatment summary and survivorship care plan (SCP), but delivery of such plans is not a required component of this standard.

Delivery of SCPs may be utilized as one of the services offered to survivors to meet the requirements of this standard. If so, then the program defines the population to receive care plans. Suggested components of the treatment summary and SCP are outlined in the reference below (Mayer, et al).

### ***Annual Review of the Survivorship Program***

Each year, the cancer committee reviews the activities of the survivorship program. Of the services provided to the cancer program's survivorship population, the cancer program chooses three services on which to do an in-depth review. For each of the three chosen services, the report includes:

- The estimated number of patients impacted by each of the chosen services,
- The cancer sites impacted by each of the chosen services,
- Resources/processes utilized to enhance each of the chosen services, and

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- Identification of opportunities for improvement for each of the chosen services and plans for implementing improvements.

## **SPECIFICATION BY CATEGORY**

All programs fulfill this standard as written.

## **DOCUMENTATION**

### **Submitted with Pre-Review Questionnaire**

- Policy and procedure defining the survivorship program requirements
- Cancer committee minutes that document the required yearly evaluation of the survivorship program.

## **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the program fulfills all of the following compliance criteria:

1. The cancer committee identifies a survivorship program team, including its designated director and members.
2. The survivorship program is monitored and evaluated. A report is given to the cancer committee, contains all required elements, and is documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

## Chapter 5: Patient Care: Expectations and Protocols

### STANDARD 5.1

#### Multidisciplinary Tumor Board

Each calendar year, the cancer program holds multidisciplinary tumor board(s) to evaluate patient management. The Multidisciplinary Tumor Board Coordinator monitors and evaluates the multidisciplinary tumor board activity and reports the findings to the cancer committee.

##### DEFINITION AND REQUIREMENTS

Cancer outcomes are better when patients are managed according to the principles of multidisciplinary team evaluation. Multidisciplinary evaluation is associated with improved clinical decision making, clinical outcomes, and patient experience.

##### *Policy and Procedure*

Cancer programs have a policy and procedure to govern multidisciplinary tumor board [hereinafter “tumor board”] activity. The policy and procedure must, at a minimum, address:

- Multidisciplinary participation,
- Frequency and format of tumor board(s),
- Elements of discussion, including the requirement to discuss clinical and/or pathologic stage, treatment planning using evidence-based guidelines, options and availability for genetic testing, and options and eligibility for clinical trials,
- Number of cases presented and percentage of prospective cases presented, and
- Methods to address areas that fall below the levels established in the policy.

##### *Multidisciplinary Participation*

The cancer program identifies the multidisciplinary composition of its tumor board(s) and attendance rates of physician participants. The Multidisciplinary Tumor Board Coordinator must monitor and evaluate physician attendance at each tumor board.

Multidisciplinary physician attendance at a general tumor board must include a representative from surgery, pathology, radiology, radiation oncology, and medical oncology. Programs may define the specialties required for specialty- or site-specific tumor boards.

Additional physician or non-physician specialists recommended for attendance are: genetic counselors, clinical research professionals, palliative care providers, psychosocial providers, rehabilitation providers, and supportive services.

##### *Format and Cases Presented*

Programs may evaluate the need for a general tumor board and any specialty- or site-specific tumor board. Programs may either:

- Hold a general multidisciplinary tumor board
  - Specialty- or site-specific conferences may be held in addition to the general multidisciplinary tumor board
- Hold specialty- or site-specific multidisciplinary tumor boards as long as there is a mechanism to present cases for evaluation at a multidisciplinary tumor board that do not fit into the defined specialty or site-specific tumor boards.

The frequency of multidisciplinary tumor boards is determined by the cancer program and is included in the policy and procedure.

Discussion of the following must occur for each case presented at multidisciplinary tumor board:

- Clinical and/or pathologic stage,
- Treatment planning using evidence-based guidelines,
- Options and eligibility for genetic testing, and
- Options and eligibility for clinical research studies.

Each year, the cancer program must present a minimum of 15 percent of the annual analytic caseload to multidisciplinary tumor board. Of those presented, a minimum of 80 percent must be prospective presentations.

Prospective cases include, but are not limited to:

- Newly diagnosed and treatment not yet initiated or treatment initiated and discussion of additional treatment is needed, or
- Previously diagnosed, initial treatment completed, and discussion of adjuvant treatment or treatment for recurrence or progression is needed, or
- Previously diagnosed and discussion of supportive or palliative care is needed.

The same case may be discussed more than once and counted each time as a prospective presentation as long as treatment management issues are discussed.

#### ***Multidisciplinary Tumor Board Coordinator Report***

The Multidisciplinary Tumor Board Coordinator must evaluate and report to the cancer committee each of the following items:

- Tumor board frequency
- Multidisciplinary physician attendance depending on the defined requirements in the tumor board policy and procedure
- Number of cases presented and percentage of prospective cases
- Elements of the discussion for each case, including, but not limited to whether the following were discussed:
  - Clinical and/or pathologic stage,
  - Treatment planning using evidence based national guidelines,
  - Options and eligibility for genetic testing, and
  - Options and eligibility for clinical research studies
- Evaluate the types of cases presented at multidisciplinary tumor board to analyze whether the case mix presented at multidisciplinary tumor board(s) is consistent with the case mix that is accrued to the program.
- An action plan to resolve any areas that do not meet the requirements of the program's policy and procedure.

The method to document multidisciplinary tumor board activity is left to the discretion of the cancer committee.

#### **SPECIFICATIONS BY CATEGORY**

NCIP are exempt from this standard.

## DOCUMENTATION

### Reviewed on-site

- The site-visit reviewer will attend a multidisciplinary tumor board.

### Submitted with Pre-Review Questionnaire

- The multidisciplinary tumor board policy and procedure.
- The Multidisciplinary Tumor Board Coordinator's report.
- Cancer committee minutes documenting the Multidisciplinary Tumor Board Coordinator's report.

Note: All documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. The cancer program has a policy and procedure for multidisciplinary tumor boards that includes all required information.
2. The Multidisciplinary Tumor Board Coordinator monitors and evaluates the multidisciplinary tumor board(s) and presents a report on multidisciplinary tumor board activity to the cancer committee that includes all required elements and any action plans to resolve issues not meeting the policy.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** NCIP facilities.

## STANDARD 5.2

### College of American Pathologists Synoptic Reporting

Ninety percent of the eligible cancer pathology reports are structured using synoptic reporting format as defined by the College of American Pathologists (CAP) cancer protocols, including containing all core data elements within the synoptic format.

#### DEFINITION AND REQUIREMENTS

Ninety percent of eligible pathology reports are formatted using the synoptic reporting format as outlined in the College of American Pathologists (CAP) Cancer Protocols.

*The synoptic format is defined as a structured format that includes all of the following:*

- All core elements must be reported (whether applicable or not),
- All core elements must be reported in a 'diagnostic parameter pair' format i.e. data element followed by its response (answer),
- Each diagnostic parameter pair must be listed on a separate line or in a tabular format to achieve visual separation (refer to CAP Cancer Protocols for exceptions to this rule), and
- All core elements must be listed together in synoptic format in one location in the pathology report.

Note: Please refer to the CAP Cancer Protocols for specific guidance and examples.

*For CoC-accredited programs, "eligible cancer pathology reports" are defined as:*

- Definitive surgical resection of primary invasive malignancies and ductal carcinoma in situ (DCIS), and
- Definitive surgical resection in patients who have received neoadjuvant therapy AND who have residual tumor.

*The following do not need to be reported using the CAP Cancer Protocols:*

- Definitive surgical resection in which no residual tumor is present,
- Additional surgical procedure performed after definitive resection (for example, resection of positive margins or node biopsy/resection),
- Diagnostic biopsy, cytology specimens, or other diagnostic procedures done prior to definitive surgical therapy,
- Surgical resection for recurrent tumor,
- In situ carcinomas (except for DCIS), or
- Special studies (for example, biomarker or prognostic testing).

#### SPECIFICATIONS BY CATEGORY

PCP are exempt from this standard.

#### DOCUMENTATION

##### Reviewed on-site

- The site visit reviewer will review the standardized synoptic pathology reports for eligible patients.

## MEASURE OF COMPLIANCE

**Compliance:** During the survey cycle, the cancer program fulfills the compliance criteria:

Ninety percent of the eligible cancer pathology reports are structured using synoptic reporting format as defined by the College of American Pathologist (CAP) cancer protocols, including containing all core data elements within the synoptic format.

**Noncompliance:** The program does not fulfill the compliance criteria during the survey cycle.

**Not Applicable:** PCP facilities.

DRAFT

## STANDARD 5.3

### Psychosocial Distress Screening

Psychosocial services are available on-site or by referral. Each calendar year, the cancer committee implements a policy and procedure for providing and monitoring psychosocial distress screening and referral for psychosocial care. The psychosocial distress screening process is evaluated, documented, and the findings are reported to the cancer committee by the Psychosocial Services Coordinator.

#### DEFINITION AND REQUIREMENTS

##### **Psychosocial Services Policy and Procedure**

Services that address physical, psychological, social, spiritual, and financial needs that result from a cancer diagnosis must be available on-site or by referral with an established policy and procedure in place to inform patients how to access them.

##### **Psychosocial Distress Screening**

Cancer programs must implement a policy and procedure for psychosocial distress screening for cancer patients. The process identifies psychological, social, financial, and behavioral issues that may interfere with a patient's treatment plan and adversely affect treatment outcomes. The process also provides patients identified with distress the appropriate resources and/or referral for psychosocial needs.

##### ***Timing of Screening:***

Cancer patients must be screened for distress at least one time during the patient's first course of treatment. Additional screenings may be provided per cancer program or healthcare provider discretion, but are not required by this standard.

The following patients are not included in compliance for this standard:

- Biopsy only or class of "00" patients,
- Patients who are admitted to the hospital with a history of cancer, but for non-cancer related issues, and
- Inpatients with a current diagnosis of cancer who are treated for a non-cancer issue and do not receive cancer treatment.

##### ***Method***

The mode of administration (patient questionnaire or clinician-administered questionnaire) is determined by the cancer committee and may be tailored to the workflow of the practice. Medical staff, including medical assistants, nurses, social workers, and physicians, who administer or interpret the screening tool must be properly trained.

The policy and procedure must address the sites of service where screenings occur, including at the CoC-accredited facility and/or with designated providers (for example, offices of medical oncologists and/or radiation oncologists affiliated with the CoC program). The policy and procedure must include processes for assessment and treatment (on-site or by referral) appropriate for the source of distress identified by the screening, including the psychosocial, physician, spiritual, and mental health resources available to patients on-site or by referral.

##### ***Tools***

The cancer committee selects and approves the psychosocial distress screening tool to be administered. Preference is given to standardized, validated instruments or tools with established clinical cutoffs. The cancer committee determines the cutoff score used to identify distressed patients.

Direct clinician contact is required for patients whose results exceed the defined cutoff score identified in the policy and procedure, even when screening is completed electronically. Direct clinician contact means discussing results with the patient face-to-face, by telephone, or by telemedicine.

### **Assessment and Referral**

If there is clinical evidence of moderate or severe distress based on the results of the distress screening, a member of the patient's oncology team (physician, nurse, social worker, psychologist, and/or contracted mental health professional) must assess the patient to identify the problems initiating the distress. This assessment will confirm the distress screening results and identify the appropriate referrals as needed.

### **Documentation**

The screening process, timing of screening, identified tool, and distress level triggering a referral to services are documented in the policies and procedures.

The distress screening(s) results, referral for provision of care, and any follow-up are documented in the patient medical record to facilitate integrated, high-quality care.

The Psychosocial Services Coordinator is required to oversee this activity and report to the cancer committee each year. Reports must include one year's worth of data.

The annual psychosocial services summary must include, but is not limited to:

- Number of patients screened
- Number of patients referred for distress resources or further follow-up
- Where patients were referred (on-site or by referral)

## **SPECIFICATIONS BY CATEGORY**

All programs fulfill this standard as written.

## **DOCUMENTATION**

### **Submitted with Pre-Review Questionnaire**

- Policies and procedures that ensure patient access to psychosocial services either on-site or by referral.
- The psychosocial distress screening policy and procedure.
- The annual psychosocial services summary that documents all required elements.
- Cancer committee minutes that document discussion of the process and tools providing, monitoring, and evaluating the psychosocial distress screening.

## **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Policies and procedures are in place to ensure patient access to psychosocial services either on-site or by referral.
2. The cancer committee implements a policy and procedure that includes all requirements for providing and monitoring psychosocial distress screening and referral for psychosocial care.
3. Cancer patients are screened for psychosocial distress at least once during the first course of treatment.
4. The psychosocial distress screening process is evaluated, documented, and the findings are reported to the cancer committee by the Psychosocial Services Coordinator. The coordinator's report includes all required elements and is documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

## **Introduction to the *Operative Standards for Cancer Surgery (OSCS)* accreditation standards**

### **What are the *Operative Standards for Cancer Surgery* manuals?**

Standards 5.4 through 5.9 were developed from standards described in *Operative Standards for Cancer Surgery (OSCS)*, a surgical manual published by a collaboration between the American College of Surgeons and the Alliance for Clinical Trials in Oncology. OSCS Volume I was published in 2015 and covered operations for cancers of the colon, breast, pancreas, and lung. OSCS Volume II followed in 2018 and covered operations for cancers of the rectum, thyroid, stomach, esophagus, and skin (melanoma).

These manuals provide concrete recommendations regarding the effective technical conduct of surgical operations and review the quality of the evidence upon which those recommendations are based. The manuals focus exclusively upon the decisions that surgeons make from skin incision to skin closure. The recommendations they provide are based upon the strongest available evidence.

### **Why CoC accreditation standards?**

Commission on Cancer (CoC) accreditation reaches approximately 70% of patients with newly-diagnosed cancer each year. Incorporation of the OSCS recommendations as CoC accreditation standards is a step toward improving oncologic outcomes by reducing the variation in the way cancer operations are performed across the United States.

A workgroup of cancer specialists evaluated the guidelines included in OSCS Volumes I and II to identify guidelines best suited as the basis for accreditation standards. This resulted in six standards on five cancer sites: breast, skin (melanoma), colon, rectum, and lung.

### **What is the expectation for standardized synoptic operative reporting?**

Compliance with Standards 5.4 through 5.9 will be evaluated on the basis of clinical documents including the operative report and the pathology report. To facilitate review and to conform to best clinical practice, use of standardized synoptic operative reports is also mandated. At present, only the data elements required to evaluate compliance with the standards are necessary; however, facilities are encouraged to use complete synoptic reports for all oncologic operations. The elements required to be presented in standardized synoptic format are described in each standard.

### **To whom do these standards apply?**

In all cases, standards apply to patients undergoing operations designed with potentially curative intent. It is understood that clinical circumstances may be such that adherence to a technical standard may not be appropriate. For example, tumor resection in an elderly patient with significant comorbidities may be performed primarily for palliation of symptoms; in such a case, the need for a thorough lymphadenectomy is likely superseded by the need for an expeditious surgical procedure. The objective of the operation should be clearly defined as part of the operative note.

## STANDARD 5.4

### Breast Sentinel Node Biopsy

All sentinel nodes for breast cancer must be identified, removed, and subjected to pathologic analysis to ensure that sentinel lymph node mapping and sentinel lymphadenectomy provide accurate information for breast cancer staging.

#### DEFINITION AND REQUIREMENTS

Sentinel node biopsy is a standard operative procedure utilized to determine whether breast malignancies of epithelial origin have spread to the regional lymph nodes. This procedure is performed to determine staging and prognostic information that can affect treatment decisions and determine prognosis.

Sentinel nodes are defined as nodes having uptake of a localization substrate (radioactive tracer and/or colored dye) that has been previously injected into the affected breast, a node to which an afferent colored lymphatic travels, or dominant palpable lymph nodes that are suspicious, as identified by the operating surgeon.

This standard is satisfied if a diligent search has been made for sentinel nodes, with those nodes removed when present, and documentation of those specifics. Operative reports must indicate that all colored, radioactive, and/or suspicious nodes were removed, in addition to any non-colored nodes at the end of a colored lymphatic.

Although the number of sentinel nodes a patient has cannot be controlled and the rate of positivity reflects case mix, current data suggests that the average number of sentinel nodes removed is typically  $\geq 1.9$ , with an overall positivity rate of 20-30%. In general, fewer than six sentinel lymph nodes are removed. When performing a sentinel node biopsy in patients who have undergone neoadjuvant chemotherapy, removing a clipped node and/or at least two to three sentinel nodes and/or using multiple substrates for sentinel node identification improves the false negative rate.

#### ***Synoptic Operative Report Requirements***

Operative reports for patients undergoing breast sentinel node biopsy must include the following minimum elements in synoptic format:

- Documentation of what substrates were used for sentinel node biopsy (dye and/or radiotracer),
- Indication that all colored nodes were removed, if dye was used as the substrate for localization. If non-colored nodes are present at the end of a dye filled lymphatic channel, that these were present and removed,
- Indication that all radioactive nodes were removed, if radionuclide was used as the substrate for localization, and
- Indication that all palpably suspicious nodes were removed, if present.

#### PATIENT CRITERIA

This standard applies to patients undergoing nodal staging in a curative setting for patients having breast cancers of epithelial origin.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION:

##### **Reviewed on-site**

- The site visit reviewer will review the standardized synoptic operative reports for patients with breast cancer of epithelial origin who underwent nodal staging in a curative setting.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

All sentinel nodes for breast cancer are identified, removed, and subjected to pathologic analysis.

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

**Not Applicable:** Programs that do not have any patients that meet the patient criteria.

DRAFT

## STANDARD 5.5

### Breast Axillary Dissection

Axillary dissection for breast cancer constitutes removing level I and II lymph nodes within an anatomic triangle comprised of the axillary vein, chest wall, and latissimus dorsi, while preserving key neurovascular structures.

#### DEFINITION AND REQUIREMENTS

Axillary lymph node dissection (ALND) is a staging and therapeutic procedure that serves two purposes: (1) to provide important staging and prognostic information that can affect treatment decisions and determine prognosis, and (2) provides local control in certain settings where sentinel node biopsy, systemic and endocrine therapies, and radiotherapy, alone or combined, have not yet demonstrated adequate local control within the axilla.

The standard has been satisfied if dissection to established axillary boundaries is complete and documented. The boundaries of an ALND for breast cancer include the level I and II axillary lymph nodes. Their complete removal constitutes dissection within the following boundaries: the axillary vein, the latissimus dorsi muscle, and the serratus anterior muscle and chest wall. The long thoracic nerve and the thoracodorsal nerve shall be preserved unless visibly involved with cancer. The intercostobrachial nerve should be spared when possible. Although the numbers of lymph nodes retrieved in an ALND after neoadjuvant chemotherapy tends to be fewer, the surgical techniques that guide ALND are the same.

Level III nodes may be removed if clinically involved or suspicious at operation, although the benefit of their removal is isolated to local control, with limited data to support their removal.

Axillary dissection of levels I and II should be complete, with resection of all tissue within the boundaries specified above.

Programs are encouraged to review the number of lymph nodes retrieved in patients who did not receive neoadjuvant therapy.

#### ***Synoptic Operative Report Requirements***

Operative reports for patients undergoing axillary dissection must include the following minimum elements in synoptic format:

- Documentation that resection was performed within the boundaries of the axillary vein, chest wall (serratus anterior), and latissimus dorsi,
- Indication that the long thoracic and thoracodorsal nerves were spared during dissection,
- Documentation of attempts to spare the intercostobrachial nerve during dissection, and
- If one or more level III nodes is/are removed, then an explanation is included why.

#### PATIENT CRITERIA

This standard applies to patients undergoing axillary dissection with diagnostic or therapeutic intent for patients having breast cancers of epithelial origin.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### **Reviewed on-site**

- The site visit reviewer will review the standardized synoptic operative reports for patients with breast cancer of epithelial origin who underwent axillary dissection with diagnostic or therapeutic intent.

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## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

Axillary dissections for breast cancer remove level I and II lymph nodes within an anatomic triangle comprised of the axillary vein, chest wall, and latissimus dorsi, while preserving key neurovascular structures.

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

**Not Applicable:** Programs that do not have any patients that meet the patient criteria.

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## STANDARD 5.6

### Primary Cutaneous Melanoma

Margin width for wide local excision of melanoma is 1 cm for melanomas <1 mm thick, 1 to 2 cm for melanomas 1 to 2 mm thick, and 2 cm for melanomas > 2 mm thick. The margin width for wide local excision of a melanoma in situ is at least 5 mm.

#### DEFINITION AND REQUIREMENTS

“The margin width for wide local excision of melanoma is based on the Breslow thickness of the primary tumor.... The margin is measured circumferentially at the level of the skin from either residual gross tumor and/or the previous biopsy scar.” *Operative Standards for Cancer Surgery, Volume II*, pg 390.

The depth of resection should include the skin and all underlying subcutaneous tissue to the level of the underlying fascial plane. For in situ disease, the wide local excision need only include the skin and the superficial subcutaneous fat.

#### **Synoptic Operative Report Requirements**

Operative reports for patients undergoing a local excision of a primary cutaneous melanoma must include the following minimum elements in synoptic format:

- Original Breslow thickness of the lesion,
- Margin (in cm) from the edge of the lesion or the prior excision scar,
- Depth down to the fascia, and
- If cosmetic concerns or anatomic limitations in the hands, feet, or face dictate smaller margins, then documentation why.

#### PATIENT CRITERIA

This standard applies to patients undergoing curative local excision of a primary cutaneous melanoma lesion. Mucosal, ocular, and subungual melanomas are excluded. Cosmetic concerns or anatomical limitations on the hands, feet, or face may dictate smaller margins. If so, operative report must include documentation why.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### Reviewed on-site

- The site visit reviewer will review the standardized synoptic operative reports for patients who underwent a curative local excision for primary cutaneous melanoma.

#### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Margin width for wide local excision of melanoma is 1 cm for melanomas less than 1 mm thick.
2. Margin width for wide local excision of melanoma is 1 to 2 cm for melanomas 1 to 2 mm thick.
3. Margin width for wide local excision of melanoma is 2 cm for melanomas greater than 2 mm thick.
4. The margin width for wide local excision of a melanoma in situ is at least 5 mm.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** Programs that do not have any patients that meet the patient criteria.

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## STANDARD 5.7

### Colon Resection

Resection of the tumor-bearing bowel segment and complete lymphadenectomy is performed en bloc with proximal vascular ligation at the origin of the primary feeding vessel(s).

#### DEFINITION AND REQUIREMENTS

“Proximal vascular ligation with en bloc lymphadenectomy ensures complete resection of the associated lymph nodes for pathologic evaluation. The number of lymph nodes resected surgically and evaluated pathologically reflects the completeness of the lymphadenectomy and is an indicator of surgical quality and oncologic outcomes.” *Operative Standards for Cancer Surgery Volume I*, page 288.

#### **Synoptic Operative Report Requirements**

Operative reports for patients undergoing resection for colon cancer must include the following minimum elements in synoptic format:

- Tumor location (right colon, transverse colon, or left colon),
- The level of ligation with anatomic guidance,

<b>Tumor location</b>	<b>Anatomic Guidance</b>
Right colon (cecum, ascending colon, and hepatic flexure)	Ileocolic artery and vein
Transverse colon (hepatic flexure, transverse colon, and splenic flexure)	Middle colic artery and vein
Left colon (splenic flexure, descending colon, left colon, or sigmoid colon)	Inferior mesenteric artery and vein

- If the anatomic guidance is other than listed above, then documentation why, and
- If a patient is excluded, then documentation why.

#### PATIENT CRITERIA

This standard applies to all curative resections for colon cancer and applies to all operative approaches. Exclusions to this standard may include metastatic disease, poor functional status, advanced age, or significant comorbidities. If a patient is excluded, the operative report must include documentation on why the patient was excluded.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### **Reviewed on-site**

- The site visit reviewer will review the standardized synoptic operative reports for patients who underwent resection for colon cancer.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

Resection of the tumor-bearing bowel segment and complete lymphadenectomy is performed en bloc with proximal vascular ligation at the origin of the primary feeding vessel(s).

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

**Not Applicable:** Programs that do not have any patients that meet the patient criteria.

DRAFT

## STANDARD 5.8

### Total Mesorectal Excision

Total mesorectal excision (TME) is performed for all patients with middle (5-10 cm) and low (0-5 cm) rectal cancers. This maneuver includes a complete removal of the rectum including all mesorectal lymph nodes.

#### DEFINITION AND REQUIREMENTS

“Total mesorectal excision (TME) of rectal cancer leverages existing tissue planes to perform a complete resection of the tumor and the associated draining lymph nodes. By maintaining the intact fascia propria of the rectum and operating in the space between the mesorectum and the presacral fascia, the surgeon can achieve a resection with a negative margin, while simultaneously preserving neurovascular structures.” *Operative Standards for Cancer Surgery Volume II*, page 194.

Per College of American Pathologists (CAP) cancer protocol template for rectal cancer resections, whether the TME was complete, near complete, or incomplete must be documented in curative resection of rectal adenocarcinoma pathology reports in synoptic format.

Complete and near complete TME offer similar oncologic outcomes relative to local recurrence and survival and are considered as meeting the expectations of this standard. Conversely incomplete TME is associated with a significantly higher risk of local recurrence and cancer related death.

#### PATIENT CRITERIA

This standard applies to operations for curative rectal adenocarcinoma and all resectional operative approaches. Exclusions to this standard may include metastatic disease, poor functional status, advanced age, or significant comorbidities. If a patient is excluded, the operative report must include documentation on why the patient was excluded.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### Reviewed on-site

- The site visit reviewer will review the standardized synoptic pathology reports for rectal cancer patients with middle and low rectal cancers.

#### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

Total mesorectal excision is performed for all patients with middle and low rectal cancers and results in a complete or near complete mesorectal excision. The TME includes a complete removal of the rectum, including all mesorectal lymph nodes.

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

**Not Applicable:** Programs that do not have any patients that meet the patient criteria.

## STANDARD 5.9

### Pulmonary Resection

The surgical pathology report following any curative intent pulmonary resection for primary lung malignancy must contain lymph nodes from at least one (named and/or numbered) hilar station and at least three distinct (named and/or numbered) mediastinal stations.

#### DEFINITION AND REQUIREMENTS

“The hilum and mediastinum should be thoroughly staged at the time of the lung resection, even in patients who are undergoing nonanatomic parenchyma-sparing resections such as...[a] wedge resection.” *Operative Standards for Cancer Surgery Volume I*, page 93.

For reference, double digit stations are hilar (10 or higher) and single digit stations are mediastinal (1-9).

As required by the College of American Pathologists (CAP) cancer protocol template for pulmonary resections, the nodal stations examined by the pathologist must be documented in curative pulmonary resection pathology reports in synoptic format. Surgeons are expected to identify on the histology requisition form the station from which each group of nodes has been taken.

#### PATIENT CRITERIA

This standard applies to the primary surgical procedure for curative pulmonary resections for non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), and carcinoid tumors of the lung. This standard applies to all operative approaches.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### Reviewed on-site

- The site visit reviewer will review the standardized synoptic pathology reports for curative intent pulmonary resections.

#### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills the compliance criteria:

The surgical pathology report following any curative intent pulmonary resection for primary lung malignancy must contain lymph nodes from at least one (named and/or numbered) hilar station and at least three distinct (named and/or numbered) mediastinal stations.

**Noncompliance:** The program does not fulfill the compliance criteria each calendar year.

**Not Applicable:** Programs that do not have any patients that meet the patient criteria.

## Chapter 6: Data Surveillance and Systems

### A note on National Cancer Database (NCDB) submission standards

At this time, Standards 5.2 (Rapid Quality Reporting Systems Participation), Standard 5.5 (Data Submission), and Standard 5.6 (Accuracy of Data) remain as detailed in the 2016 Cancer Program Standards and subsequent communications. Standards regarding data submission will be updated along with the infrastructure upgrade to the National Cancer Database and will be incorporated into this chapter at that time.

For the most up-to-date information on submitting NCDB data, please visit [Cancer Programs News](#).

### STANDARD 6.1

#### Cancer Registry Quality Control Policy

Each calendar year, the cancer committee implements a policy and procedure to annually evaluate the quality of cancer registry data and activity, including procedures to monitor and evaluate each required control component.

##### DEFINITION AND REQUIREMENTS

High-quality cancer registry data is essential to accurately assess treatment outcomes and patient survival. The cancer committee ensures the quality of cancer registry data by establishing and implementing a quality control policy and procedure to monitor and evaluate multiple areas of cancer registry activity and the accuracy and completeness of abstracted data.

The Cancer Registry Quality Coordinator works cooperatively with registry staff and other applicable departments to implement the quality control policy and procedure. The coordinator is required to monitor each area of cancer registry activity and recommends corrective action if any area falls below the measures specified in the plan. The results, recommendations, and outcomes of recommendations must be reported to the cancer committee at least annually and documented in the cancer committee meeting minutes.

The quality control policy and procedure, at a minimum:

- A. Sets the review criteria
- B. Sets the quality control timetable
- C. Specifies the quality control methods, sources, and individuals involved:
  - Random sampling of annual analytic caseload
  - Review by designated person(s)
    - Reviewer(s) may be CTR(s), Advanced Practice Registered Nurse(s), Physician's Assistant(s), physician(s), fellow(s), or resident(s)
    - A CTR cannot review his or her own cases.
  - External audits (such as state or central cancer registry case-finding audits) may be used to fulfill part of this requirement
- D. Identifies the activities to be evaluated for all cases each year:
  - Casefinding
  - Abstracting timeliness
  - The percentage of information coded as unknown (usually coded as 9 or a string of 9s)
- E. Identifies the activities to be evaluated for the accuracy of abstracted data in a minimum of 10 percent of the annual analytic caseload (up to 200 cases annually) each year:
  1. Class of case

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2. Primary site
3. Histology
4. Grade
5. American Joint Committee on Cancer (AJCC) Stage or other appropriate staging system as appropriate for cancer site
6. First course of treatment
7. Follow-up information, specifically:
  - date of first recurrence,
  - type of first recurrence,
  - cancer status, and
  - date of last cancer status.

F. Establishes the minimum quality benchmarks and required accuracy. Cancer registry data submitted to the NCDB meet the established quality and timeliness criteria included in the annual NCDB Call for Data.

G. Maintains documentation of the quality control activity:

- Review criteria
- Cases reviewed
- Identified data errors and resolutions
- Reports the percentage of accuracy to the cancer committee annually of the review of elements listed in sections D and E above. The report must be documented in the cancer committee minutes.

Patient data reviewed under the cancer registry quality control plan for Standard 6.1 cannot be used as an in-depth analysis review for compliance to Standard 7.2, Monitoring Compliance with Evidence-Based Guidelines.

## SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

For INCP: The minimum requirement of a 10 percent review (up to 200 cases annually) applies to each facility within a network.

## DOCUMENTATION

### Submitted with Pre-Review Questionnaire

- An up-to-date quality control policy and procedure. This documentation includes the process for resolving conflicts identified during the quality control review and any audit reports from the state or central registry that were used in the evaluation of the cancer registry data.
- Cancer committee minutes documenting that the results of the annual quality control evaluation were presented and reviewed by the cancer committee.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. The cancer committee establishes and implements a quality control policy and procedure to evaluate the required areas of the cancer registry.
2. The Cancer Registry Quality Control Coordinator, under the direction of the cancer committee, performs or oversees the required quality control review as outlined in the policy and procedure.
3. The results, recommendations, and outcomes of recommendations are reported to the cancer committee and documented in the cancer committee meeting minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

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## STANDARD 6.2

### Follow Up of Patients

For all eligible cases, an 80 percent follow-up rate is maintained from the cancer registry reference date. A 90 percent follow-up rate is maintained for all eligible analytic cases diagnosed within the last five years or from the cancer registry reference date, whichever is shorter.

#### DEFINITION AND REQUIREMENTS

Long-term follow-up is essential to evaluate outcomes of cancer care. Accurate follow-up data enables the program to compare outcomes with regional, state, or national statistics. Follow-up information is obtained at least annually for all analytic cases of living patients included in the cancer registry database.

All reportable cases are followed up, except the following:

- Residents of foreign countries
- Cases reportable by agreement
- Patients whose age exceeds 100 years and who are without contact for more than 12 months
- Patients diagnosed on or after January 1, 2006 and classified as Class of Case 00

Methods to obtain follow-up information include, but are not limited to, the following:

- Following or managing physician(s)
- Program inpatient or outpatient services
- Pathology reports or death certificates
- Patient or patient's family
- Internet sources (such as death index, patient locator software, obituary listings)
- Communication with other facilities

The cancer committee monitors the use of (unknown) values to ensure complete data reporting. This monitoring is extremely important for information describing the date of first recurrence, type of first recurrence, and cancer status.

It is expected that all CoC-accredited programs will provide follow-up information and assistance to the referring cancer programs of treatment or follow-up care.

#### SPECIFICATIONS BY CATEGORY

For PCP: annual follow-up information is obtained for eligible analytic cases until the patients reach the age of 26 years. Once patients reach the age of 26 years, follow-up attempts are to continue, but the data for the patients are excluded from the follow-up calculations. For PCP, a 60 percent follow-up rate is maintained for all eligible analytic cases from the cancer registry reference date.

Programs in all categories undergoing initial survey for accreditation are exempt from this standard.

#### DOCUMENTATION

##### Reviewed on-site

- The site visit reviewer reviews the current follow-up report.

## MEASURE OF COMPLIANCE

**Compliance:** The cancer program fulfills all of the compliance criteria:

1. An 80 percent follow-up rate is maintained for all eligible analytic cases from the cancer registry reference date.
2. For PCP facilities, a 60 percent follow-up rate is maintained for all eligible analytic cases from the cancer registry reference date.
3. A 90 percent follow-up rate is maintained for all analytic cases diagnosed within the last five years or from the cancer registry reference date, whichever is shorter.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** Programs undergoing initial survey for accreditation.

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## Chapter 7: Quality Improvement

### STANDARD 7.1

#### Accountability and Quality Improvement Measures

Each calendar year, the expected Estimated Performance Rate (EPR) is met for each accountability measure and quality improvement measure as defined by the Commission on Cancer (CoC).

##### DEFINITION AND REQUIREMENTS

The CoC requires accredited cancer programs to treat cancer patients according to nationally accepted accountability and quality improvement measures indicated by the CoC quality reporting tool, Cancer Program Profile Reports (CP<sup>3</sup>R).

Each calendar year, the cancer program reviews concordance with the expected EPR of the accountability and quality improvement measures as defined by the CoC. If the cancer program is not meeting the expected EPR of a measure(s), then a corrective action plan must be developed and executed in order to improve performance. The corrective action plan must document how the program will investigate the issue for each measure with the goal of resolving the deficiency and improving compliance.

The cancer committee's review of compliance with required accountability and quality improvement measures and monitoring activity is documented in the cancer committee minutes. The action plan and any corrective action taken are included in the documentation.

Programs with no cases eligible for assessment in a selected measure are exempt from requirements for that individual measure.

##### SPECIFICATIONS BY CATEGORY

Programs in all categories undergoing initial survey for accreditation and PCP facilities are exempt from this standard.

For INCP: Expected EPRs for facilities that are part of an INCP are evaluated individually and as an INCP overall. Each facility that is part of an INCP is required to individually meet all expected EPRs, and the INCP as an entire program is also required to meet all expected EPRs.

##### DOCUMENTATION

###### Submitted with Pre-Review Questionnaire

- Cancer committee minutes documenting the presentation and review of required CP<sup>3</sup>R accountability and quality improvement measures. Documentation includes any required action plans.

Note: All documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. Using, CP<sup>3</sup>R, the cancer committee monitors the program's expected Estimated Performance Rates for accountability and quality improvement measures selected by the CoC.
2. The monitoring activity is documented in the cancer committee minutes.
3. For each accountability and quality improvement measure selected by the CoC, the quality reporting tools shows a performance rate equal to or greater than the expected EPR specified by the CoC. If the expected EPR is not met, the program has implemented an action plan that reviews and addresses program performance below the expected EPR.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** Programs in all categories undergoing initial survey for accreditation and PCP facilities.

DRAFT

## STANDARD 7.2

### Monitoring Concordance with Evidence-Based Guidelines

Each calendar year, the cancer committee designates a physician member to complete an in-depth analysis to assess and verify that cancer program patients are evaluated and treated according to evidence-based national treatment guidelines. The study and results are presented to the cancer committee and documented in cancer committee minutes.

#### DEFINITION AND REQUIREMENTS

Each calendar year, a physician member of the cancer committee performs an in-depth analysis of the diagnostic evaluation and treatment of individual patients to determine whether it is concordant with recognized evidence-based national guidelines. The study must be a retrospective review of individual patient evaluation and treatment information, which includes a patient medical record review.

*The annual in-depth analysis must include all of the following components:*

1. The choice of a patient population to review. Sources for the assessment must include one of the following study topics:
  - All cases from a specific cancer site, to a maximum of 300 cases; or
  - Based on an identified need, concern, or problem with a specific cancer site; or
  - Based on uncommon cancer cases (i.e. cases not generally presented at multidisciplinary tumor boards).

2. Through a review of each patient, which includes review of the medical record, determination whether the pre-treatment initial diagnostic evaluation process is concordant with evidence-based national treatment guidelines for each patient being reviewed.

Initial evaluation is the steps in an evidence-based national treatment guideline that are sufficient to accurately determine the extent of disease using AJCC stage or other appropriate staging, including prognostic indicators. Initial evaluation indicated will differ by cancer site. However, review of the initial evaluation should include pathology, diagnostic imaging, laboratory tests, and consultations recommended within the specific guideline(s) being reviewed.

3. Through a review of each patient, which includes review of the medical record, a determination whether the first course of treatment is appropriate for the stage of disease or prognostic indicators and is concordant with evidence-based national treatment for each patient being reviewed.

4. A reporting format that permits analysis and provides an opportunity to recommend performance improvements based on data from the analysis.

5. A presentation of a report detailing all required elements of the study, including the results of the analysis, to the cancer committee. The report is documented in the cancer committee minutes. The documentation includes any recommendations for improvement.

Analysis and treatment discussions for patients at multidisciplinary tumor boards do not fulfill the requirements for Standard 7.2. Any problems identified with the diagnostic evaluation or treatment planning process may serve as a source for a quality project under Standard 7.3: Quality Improvement Project.

#### SPECIFICATIONS BY CATEGORY

NCIP and PCP facilities are exempt from this standard.

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## DOCUMENTATION

### Submitted with Pre-Review Questionnaire

- A report of the in-depth analysis which documents the completed analysis, including identification of the patient pool reviewed, methodology, and results.
- Cancer committee minutes that document that the conclusions and the results of the analysis were reported and any recommendations for improvement.

Note: All documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. A physician member of the cancer committee conducts an in-depth analysis to ensure that initial diagnostic evaluation and first course of treatment provided to patients is concordant with evidence-based national treatment guidelines and is appropriate for AJCC stage or other appropriate staging system, including prognostic indicators.
2. The report detailing all of required elements of the study, including the results of the analysis and any recommendations for improvement, are reported to the cancer committee and documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** NCIP and PCP facilities.

## STANDARD 7.3

### Quality Improvement Project

Each calendar year, the Cancer Liaison Physician and the Quality Improvement Coordinator, under the direction of the cancer committee, conducts at least one quality improvement project based on an identified cancer-specific quality-related problem.

#### DEFINITION AND REQUIREMENTS

Under the guidance of the Cancer Liaison Physician, the Quality Improvement Coordinator, and the cancer committee, the cancer program must measure, evaluate, and improve its performance through at least one quality improvement project each year.

This quality improvement (QI) project requires the program to identify a problem, understand what is causing the identified problem through use of a recognized performance improvement methodology, and implement a planned solution to the problem. Reports on the status of the QI project must be given to the cancer committee at least twice each calendar year and documented in the cancer committee minutes.

#### **Quality Improvement Project Required Components**

##### **1. Review Data to Identify the Problem**

The QI project must be focused on an already-identified, quality-related problem specific to the cancer program.

The following (in order of preference) may be used to identify the focus of the QI project:

- Problems identified in a NCDB accountability or quality improvement measure
- Problems identified in a Standard 7.2: Monitoring Compliance with Evidence Based Guidelines study
- Problems identified through annual review of clinical services identified in Chapter 5 standards reviews (i.e. palliative care services, genetics services, operative standards).
- Problems identified through review of NCDB data other than accountability or quality improvement measures, including CQIP.

##### **2. Write the Problem Statement**

The QI project must have a problem statement. The problem statement must identify:

- A specific, already-identified, quality-related problem specific to the cancer program to solve through the QI project,
- The baseline and goal metrics (must be numerical), and
- Anticipated timeline for completing the QI project and achieving the expected outcome.

The problem statement cannot state that a study is being done to see if a problem exists, rather it must already be known that a problem exists.

##### **3. Choose and Implement Performance Improvement Methodology and Metrics**

The Quality Improvement Coordinator and the CLP must identify the content experts needed to execute the quality improvement project. For example, if the QI project is on the BCSRT accountability measure, then at least one breast surgeon and one radiation oncologist is included on the project team.

A recognized, standardized performance improvement tool must be chosen and used to conduct the QI project (e.g. Lean, DMAIC, or PDCA/PDSA).

In line with the performance improvement tool selected, the team conducts analysis to identify all possible factors contributing to the problem. This may involve a literature review and/or a root-cause analysis. Based on the results, an intervention is developed that aims to fix the cause of the problem being studied.

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A project calendar must be identified, which includes the project's launch date, when status updates will be given at cancer committee meetings, and a goal wrap-up date.

Projects should last approximately one year. But if additional time is needed, it may be extended for a second year (for a total of two years). However, a new project must be initiated at the beginning of each calendar year even if a previous QI project is still in progress. If the QI project is going to extend into the second year, then a status update to the cancer committee must be given at the last meeting of the first calendar year.

### **5. Implement Intervention and Monitor Data**

The intervention chosen in step 3 must be implemented. If oversight of the implementation suggests the intervention is not working, then it must be modified.

### **6. Present Quality Improvement Project Summary**

Once the project has been completed, a document summarizing the project and the results must be presented and discussed with the cancer committee and documented in the cancer committee minutes. If possible, results are compared with national data.

The summary presentation must include:

- Summary of the data reviewed to identify the problem to study
- The problem statement
- The QI project team members
- Performance improvement tool utilized
- The intervention implemented
- If applicable, any adjustments made to the intervention
- Results of the implemented intervention

#### **Cancer Committee Reports**

The Cancer Liaison Physician or the Quality Improvement Coordinator must provide updates to the cancer committee on the quality improvement project's status at least twice each calendar year. Status updates, at a minimum, indicate the current status of the QI project and any planned next steps. The final summary and results report may qualify as one of the required quarterly reports.

## **SPECIFICATIONS BY CATEGORY**

All programs fulfill this standard as written.

## **DOCUMENTATION**

#### **Reviewed on-site**

- Documentation of QI project team's work from throughout the project (i.e. minutes, literature used).

#### **Submitted with Pre-Review Questionnaire**

- Document summarizing at least one QI project each calendar year, which includes all required elements:
  - Summary of the data reviewed to identify the problem to study
  - The problem statement
  - The QI project team members
  - Performance improvement tool utilized
  - The intervention implemented
  - If applicable, any adjustments made to the intervention
  - Results of the implemented intervention

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- Cancer committee minutes documenting quarterly status updates and presentation of the QI project summary.

Note: All documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

## MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. One quality improvement project based on an identified quality-related problem is initiated each year. The QI project documentation includes how the project measured, evaluated, and improved performance through implementation of a recognized, standardized performance improvement tool.
2. Status updates are provided to the cancer committee two times. Reports are documented in the cancer committee minutes.
3. A final presentation of a summary of the quality improvement project is presented after the QI project is complete. The summary presentation includes all required elements.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

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## STANDARD 7.4

### Cancer Program Goal

The cancer committee establishes and monitors at least one cancer program goal each calendar year.

#### DEFINITION AND REQUIREMENTS

Annual goal setting provides direction for the strategic planning of cancer program activities. The cancer committee establishes goals appropriate and relevant to the cancer program and its patient population.

Goals must be directed toward the scope, coordination, practices, processes, and provision of services for cancer care at the program.

Each calendar year, the cancer program establishes, and documents in the cancer committee minutes, one cancer program goal. It is recommended the goal-setting tool known as **SMART** (Specific, Measurable, Achievable, Realistic, and Timely) be used when establishing the goal.

The cancer committee must document substantive status updates on goal progress at two subsequent meetings after the goal's establishment in the same calendar year. For example, the status update may include any progress made, road blocks encountered, or a description of any necessary next steps.

Goals should last approximately one year. If additional time is needed, a goal may be extended for a second year (for a total of two years). However, a new goal must be established at the beginning of each calendar year even if a previous goal is still in progress. If the goal is going to extend into the second year, then a status update must be provided at the last meeting of the first calendar year. Additionally, there must be at least one additional status update documented in the cancer committee minutes during the second year. By the end of the second year, the cancer program must document in the cancer committee minutes that the goal is either completed or retired.

A goal established under this standard cannot duplicate requirements or be an improvement on requirements from another standard or be a program or initiative submitted to meet requirements of another standard.

#### SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

#### DOCUMENTATION

##### Submitted with Pre-Review Questionnaire

- Cancer committee minutes documenting the establishment and status updates of the cancer program goal.

#### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. One cancer program goal is established each calendar year and documented in the cancer committee minutes.
2. At least two substantive status updates on goal progress are documented in the cancer committee minutes in the same calendar year as its establishment.
3. For any goal extended into a second year, at least one status update is documented in the minutes during the second year to indicate whether the goal was completed or retired.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

## Chapter 8: Education: Professional and Community Outreach

### STANDARD 8.1

#### Addressing Barriers to Care

A navigation team is established to identify barriers to care for patients with cancer and implement a process to overcome the identified barrier.

#### DEFINITION AND REQUIREMENTS

##### *Navigation Team*

Each calendar year, the cancer committee identifies a navigation team to address barriers to care. Each year, the navigation team identifies at least one patient, system, or provider-based barrier to accessing health and psychosocial care that their cancer patients are facing and develops and implements a plan to address the barrier.

The navigation team may include professionals specializing in: psychosocial care, financial assistance, nurse navigation, or any other specialty deemed appropriate by the cancer committee. Representatives from the community, including an American Cancer Society representative or a patient representative, may be part of the navigation team.

##### *Cancer Barriers Analysis*

The navigation team reviews and analyzes the strengths and barriers of the cancer program. Resources for identifying strengths and barriers include, but are not limited to:

- Cancer Quality Improvement Program (CQIP) reports
- Cancer patient satisfaction surveys
- Patient focus groups
- Use of state cancer registry data compared to your cancer center data
  - Are you treating the main cancers that occur in your area?
  - Are you reaching vulnerable populations?
- Population health resources from public health work done locally and regionally
- Community Needs Assessment
- Analysis of unique features of your institution and/or state (e.g. affordable or adequate lodging for patients receiving care at a rural facility)

##### *Identification of Barriers*

Programs determine the frequency and format of the navigation team meetings. This team must meet separately from the full cancer committee meeting. Each calendar year, the team identifies barriers that are specific to the cancer program and chose one to focus on for the upcoming year. Examples include, but are not limited to:

- Gaps in community resources
- Identified populations in need
- Uninsured or underinsured
- Healthcare provider shortages

Each calendar year, the navigation team provides a report to the full cancer committee. This report must state:

- What barrier was chosen
- What resources/processes were utilized to identify and address this barrier
- Metrics related to outcomes of reducing the chosen barrier
- Plans for the upcoming year

## SPECIFICATIONS BY CATEGORY

All programs fulfill this standard as written.

### DOCUMENTATION

#### Submitted with Pre-Review Questionnaire:

- Minutes and/or any relevant documentation from the navigation team meetings.
- Cancer committee minutes documenting the navigation team's report to the cancer committee.

### MEASURE OF COMPLIANCE

**Compliance:** Each calendar year, the program fulfills the compliance criteria:

1. The cancer committee identifies a navigation team.
2. The navigation team identifies at least one barrier to focus on for the year and identifies resources and processes to address the barrier.
3. At the end of the year, the navigation team evaluates the resources and processes adopted to address the barrier to care and identifies strengths and areas for improvement.
4. The navigation team reports all required information to the cancer committee once each year.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria.

## STANDARD 8.2

### Cancer Prevention Event

Each calendar year, the cancer committee partners with a community organization and offers at least one cancer prevention event designed to reduce the incidence of a specific cancer type. The prevention event is consistent with evidence-based national guidelines and interventions for cancer prevention.

#### DEFINITION AND REQUIREMENTS

According to the National Cancer Institute, cancer prevention is “action taken to decrease the chance of getting a disease or condition. For example, cancer prevention includes avoiding risk factors (such as smoking, obesity, lack of exercise, and radiation exposure) and increasing protective factors (such as getting regular physical activity, vaccination, staying at a healthy weight, and having a healthy diet).”

The cancer committee partners with a community organization to hold at least one event each year focused on decreasing the number of diagnoses for a specific type of cancer. Examples of community organizations include, but are not limited to, a church, a school, the American Cancer Society, or a health district.

#### ***Planning the prevention event according to evidence-based national guidelines***

The planned event must be consistent with evidence-based national guidelines and interventions. Potential sources for evidence-based national guidelines and interventions include, but are not limited to:

- Agency for Healthcare Research and Quality
- American Cancer Society
- Cancer Control P.L.A.N.E.T.
- National Cancer Institute
- Centers for Disease Control and Prevention
- American Institute for Cancer Research/World Cancer Research Fund
- US Preventative Services Task Force Recommendations

Prevention events focus on at least one of two intended results: (1) a change in behavior that reduces the risk a cancer will develop, and/or (2) an increase the participant’s knowledge and awareness of cancer risks.

Examples of behavioral risk reduction events include, but are not limited to:

- Smoking/tobacco/vaping cessation
- Alcohol avoidance
- Nutrition, physical activity, and weight loss programs
- HPV vaccinations
- Radon exposure reeducation
- Avoidance of sun exposure
- Chemoprevention

Cancer education and risk awareness lectures or events are considered a prevention activity when they address one of the above behavioral risk reduction areas.

Examples of non-compliant events include, but are not limited to:

- Programs held only on the Internet, through social media, or through a mail campaign without real-time interaction with participants
- Prevention education given in the regular course of business or required by the standard of care
- Events or programs that educate about cancer screening or reduction of late-stage at diagnosis.

### ***Prevention and Screening Coordinator reporting to the cancer committee***

While it is encouraged that cancer programs hold as many cancer prevention events as appropriate for their needs, only one event is required to be submitted for purposes of this standard.

The Prevention and Screening Coordinator must report a summary of the event to the cancer committee that includes the following:

- The cancer site on which the event focused,
- The partnering community organization,
- Target audience,
- Guideline(s) used in planning the prevention event, and
- The type of prevention event held (behavioral risk reduction or cancer education/risk awareness lecture).

### **SPECIFICATIONS BY CATEGORY**

NCIP facilities are exempt from this standard. VACP programs are exempt from the requirement to partner with a community organization.

### **DOCUMENTATION**

#### **Submitted with Pre-Review Questionnaire**

- Cancer committee minutes that document all required elements of the cancer prevention event.

### **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. The cancer committee partners with a community organization and offers at least one cancer prevention event focused on a specific cancer site.
2. The cancer prevention event is consistent with evidence-based national guidelines and interventions.
3. A summary of the cancer prevention event is presented to the cancer committee and documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** NCIP facilities.

## STANDARD 8.3

### Cancer Screening Event

Each calendar year, the cancer committee partners with a community organization to offer at least one cancer screening event designed to decrease the number of individuals who present with late-stage cancer. The screening event is consistent with evidence-based national guidelines and interventions and has a formal process developed to follow up on all positive findings.

#### DEFINITION AND REQUIREMENTS

Cancer screening events apply screening guidelines to detect cancers at an early stage, which improves the likelihood of increased survival and decreased morbidity.

The cancer committee partners with a community organization to hold at least one event each year focused on decreasing the number of individuals with late-stage cancer. Examples of community organizations include, but are not limited to, a church, a school, the American Cancer Society, or a health district.

#### ***Planning the screening event according to evidence-based national guidelines***

The planned event must be based on evidence-based national guidelines and interventions and have a formal process for follow up on all positive findings.

Resources for evidence-based national guidelines and interventions include, but are not limited to:

- Agency for Healthcare Research and Quality
- American Cancer Society
- American Society of Clinical Oncology
- National Comprehensive Cancer Network
- National Cancer Institute
- National Colorectal Cancer Roundtable

Examples of screening events include, but are not limited to:

- Breast (imaging and physical examination)
- Colon (colonoscopy, flexible sigmoidoscopy, fecal immunochemical testing, or fecal occult blood testing)
- Cervical (Papanicolaou testing with or without HPV DNA testing)
- Skin (clinician-directed total body skin exams)
- Lung (low-dose computed tomography)
- Head and neck (oral examination)

Examples of non-compliant programs/events include, but are not limited to:

- Screening programs performed in the regular course of business or required by the standard of care.
- Events or programs that educate about cancer screening or reduction of stage at diagnosis that do not provide an actual screening.

#### ***Prevention and Screening Coordinator reporting to the committee***

While it is encouraged that cancer programs hold as many cancer screening events as appropriate for their needs, only one event is submitted for purposes of this standard.

The Prevention and Screening Coordinator must report a summary of the event to the cancer committee that includes the following:

- The cancer site on which the event focused,
- The partnering community organization,
- Target audience,

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- Guideline(s) used in planning the screening event, and
- The process for follow up for all positive findings.

## **SPECIFICATIONS BY CATEGORY**

NCIP programs are exempt from this standard. VACP programs are exempt from the requirement to partner with a community organization.

## **DOCUMENTATION**

### **Submitted with Pre-Review Questionnaire**

- Cancer committee minutes that document all required elements of the cancer screening event.

## **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. The cancer committee partners with a community organization and offers at least one cancer screening event.
2. The cancer screening event is consistent with evidence-based national guidelines and interventions and has a process for follow up on all positive findings.
3. A summary of the cancer screening event is presented to the cancer committee and documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** NCIP facilities.

## Chapter 9: Research: Basic and Clinical

### STANDARD 9.1

#### Clinical Research Accrual

The cancer program has a policy and procedure in place for identifying participant eligibility for clinical research studies and how to provide clinical research information to patients. As prescribed for cancer program category, the required percentage of patients is accrued to cancer-related clinical research studies each calendar year. The Clinical Research Coordinator documents and reports clinical research information and enrollment to the cancer committee each calendar year.

#### DEFINITION AND REQUIREMENTS

Clinical research advances science and ensures that patient care approaches the highest possible level of quality. Cancer programs are required to accrue participants to eligible, cancer-related clinical research studies each calendar year either on-site or by referral.

#### *Clinical Research Information and Screening Processes*

The cancer program must establish a screening policy and procedure to identify participant eligibility for clinical research studies and how to provide clinical research information to patients. Through the Clinical Research Coordinator, the cancer committee evaluates and assesses the eligibility and screening processes to identify and address barriers to enrollment and participation.

#### *Cancer-Related Research Studies Eligible for Accrual*

Research studies eligible to count as accruals must: (1) be cancer-related, (2) be approved by an internal or external Institutional Review Board (IRB) that is responsible for the review and oversight of the research study, and (3) have informed, written patient consent (unless consent is waived by the IRB).

Categories of cancer-related clinical research studies eligible for accrual:

- Basic Science
- Device Feasibility
- Diagnostic
- Health Services Research
- Prevention
- Screening
- Supportive Care
- Treatment

Definitions for these categories may be found on the National Cancer Institute Clinical Trial Reporting Program User Guide (see Primary Purpose Value Definitions).

Additional categories of cancer-related clinical research studies for accrual are:

- Cancer-specific biorepositories or tissue banks  
(Cancer specific-biobanks that collect cancer tissue or blood samples specifically for cancer research purposes)
- Economics of care related to cancer care

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(Assesses the costs and effectiveness of cancer interventions and/or analyzes the financial impact of oncology care on patients)

- Genetic studies  
(Studies that examine contributing genes or how different exposures could modify the effect of a gene mutation that may be at risk for cancer development OR genetic assessments that examine genetic polymorphisms and mutations for early risk assessment)
- Patient registries with an underlying cancer research focus  
(Epidemiological studies. Must have underlying cancer research focus.)

Humanitarian Use Devices studies cannot be counted as an accrual under this standard

### **Calculating Compliance**

The denominator used to calculate compliance with this standard is the number of annual analytic cases. The numerator is the number of patients enrolled in eligible research studies who were:

- Diagnosed and/or treated at your program or facility and enrolled in a cancer-related clinical research study within your program or facility,
- Diagnosed and/or treated at your program or facility and enrolled in a cancer-related clinical research study within a staff physician's office of your program or facility,
- Diagnosed and/or treated at the program or facility, then referred by your program or facility for enrollment onto a cancer-related clinical research study through another program or facility, or
- Referred to your program or facility for enrollment onto a cancer-related clinical research study through another program or facility.

Researchers and clinical trial investigators who accept referral of subjects from other programs for the purpose of participation in a cancer-related research study must cooperate with the data management team of the cancer program from which the patient was referred.

If a patient is enrolled in two different trials/studies, then the patient may be counted in the numerator twice. However, it qualifies as one accrual if one patient is enrolled into two arms of one protocol or one patient is enrolled into a sub-study of one protocol.

Minimum required accrual percentages each calendar year:

Category	Percentage Requirement
ACAD	6
CCCP	4
CCP	2
FCCP	2
HACP	Exempt
INCP	6
NCIP	20
PCP	30
VACP	2

### **Clinical Research Coordinator**

The Clinical Research Coordinator must track and report to the cancer committee:

- The specific clinical research studies where patients were accrued, including the trial/study name and, when applicable, the clinicaltrial.gov trial number,
- Number of patients accrued to each individual clinical research study,

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- Open clinical research studies with identification of those with a nearing end date
- New trials that will be added, and
- If the required accrual percentage is not met, the report identifies contributing factors and identifies an action plan to address those factors.

The report and analysis must be documented in the cancer committee minutes.

## **SPECIFICATIONS BY CATEGORY**

HACP facilities are exempt from this standard.

For INCP: Clinical research accrual percentages are calculated based on cumulative accrual percentage met collectively across the network facilities.

## **DOCUMENTATION**

### **Reviewed on-site**

- Tracking documents that detail the number of patients accrued to specific clinical research studies. Documentation must include the names of the clinical research studies, and when applicable, the clinicaltrials.gov trial number. Documentation must also include the number of patients accrued to each research study.

### **Submitted with Pre-Review Questionnaire**

- Cancer committee minutes documenting the Clinical Research Coordinator's report that includes all required elements.
- Policy and procedure for screening patients for clinical research studies and for providing patients with information on clinical research studies.

Note: All documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

## **MEASURE OF COMPLIANCE**

**Compliance:** Each calendar year, the cancer program fulfills all of the compliance criteria:

1. The program has a screening policy and procedure to identify participant eligibility for clinical research studies and how to provide clinical trial information to patients. These processes are assessed to identify and address barriers to enrollment and participation.
2. The number of accruals to cancer-related clinical research studies meets or exceeds the required percentage.
3. The Clinical Research Coordinator reports all required information to the cancer committee and the report is documented in the cancer committee minutes.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria each calendar year.

**Not Applicable:** HACP facilities.

## STANDARD 9.2

### Commission on Cancer Special Studies

The cancer program participates in special studies as selected by the Commission on Cancer.

#### DEFINITION AND REQUIREMENTS

Hypothesis-based special studies are designed to evaluate patient care, set benchmarks, and provide feedback to improve patient care in cancer programs.

The CoC will periodically design and conduct special studies. Based on study criteria, selected accredited programs will be required to participate in each study for standard compliance.

The cases included in the study and due date will be specified in the study documentation provided by the CoC. To fulfill the standard, all selected programs must submit all requested information for the cases identified by the specified deadline.

#### SPECIFICATIONS BY CATEGORY

Upon request, all cancer programs fulfill this standard as written. Programs in all categories undergoing initial survey for accreditation are exempt from this standard.

#### DOCUMENTATION

The program uploads all required documentation or data as required for the special study.

#### MEASURE OF COMPLIANCE

**Compliance:** As requested, the cancer program fulfills all of the compliance criteria:

1. The program participates in each special study.
2. Complete data and documentation submitted by the established deadline for each special study.

**Noncompliance:** The program does not fulfill one or more of the compliance criteria as requested.

**Not Applicable:** Programs in all categories undergoing initial survey for accreditation or if the program was not selected to participate in a special study.