

**Approved November 2024** 

# Introduction

The designation of a hospital, treatment center, or other organization as a Cancer Center of Excellence is intended to recognize organizations that demonstrate excellence in patient-centered coordinated care for persons undergoing cancer treatment and therapy in Florida. The goal of the Cancer Center of Excellence program is to encourage excellence in cancer care in Florida and attract and retain the best cancer care professionals to the state. Further, the designation seeks to increase national recognition of Florida organizations (e.g., as a National Cancer Institute Designated Cancer Center). Collectively, Florida can be a preferred destination for quality cancer care.

The designation of a Cancer Center of Excellence is based on a systems approach to improving the quality of cancer care. The system is composed of three Areas: the health care organization, health care team members, and patients and family members. Each of these Areas contributes to the success of the system and has defined outcomes and rigorous performance measures. If an eligible organization meets all performance measures it may be designated a Cancer Center of Excellence.

The standards in each Area are performance-based, using objective criteria and measurable outcomes to evaluate whether a standard is met. The focus is on outcomes that improve patient care. Healthcare organizations have flexibility in taking different approaches to meeting the standard, so long as the organization meets rigorous high standards and provides improved outcomes for patients. The performance measures are applicable to cancer care across a range of settings, such as community hospitals, academic health centers, and other organizations. In order to improve outcomes, healthcare organizations may be required to meet more stringent standards, or meet performance measures sooner than specified elsewhere, and may be required to adopt additional performance measures.

The process of evaluating performance involves review of written materials and may involve a site visit by a team of evaluators. Evaluators assess practice to verify performance measures are met. If the evaluators determine the organization does not yet meet a standard, the organization is provided recommendations on ways practice can be improved to meet the standard, and an opportunity for the organization to discuss program improvements. The evaluation process is designed to improve the quality of care and will be educational, supportive, and include constructive feedback on specific ways the organization can make improvements. The process is not an audit focused on past practice; instead, it is an evaluation of practice at the time of the visit and focuses on trends and ways the organization has made program changes to improve quality of care. Evaluators are physicians and others with expertise in providing cancer care who meet criteria defined in statute, and who are free from conflicts of interest. The evaluation process requires that the organization make information available on-site to evaluators to verify the accuracy of reported practices.

This manual is intended for use by organizations seeking to be designated a Cancer Center of Excellence, and by those who evaluate applicant organizations. An organization is the legal entity applying for designation as a Cancer Center of Excellence. When an applicant organization has multiple components or partners that exist as a single legal entity, then all the components or partners must meet each performance measure individually, or the applicant organization must demonstrate a substantive relationship among the components that shows that all standards are met. This manual is intended to provide the information

necessary to demonstrate how the organization meets each performance measure. The description includes an explanation of the performance measure; legal and regulatory standards; professional practice standards and guidance; required written materials; and examples of common types of written materials that can be used to demonstrate the outcomes are met.

# **Overview of Performance Measures**

# **Area I: Organization**

The first area concerns the health care organization, the responsibilities of the organization, and how the components of the organization function together as a system to provide high- quality care and continuously improve the quality of care. This Area evaluates responsibilities of the organization, such as maintaining licensure, and providing necessary leadership support to develop and maintain an organizational culture that evaluates and continuously makes improvements to improve care.

#### **Performance Measures**

- I.1 The organization maintains a license in good standing in Florida which authorizes health care services to be provided.
- 1.2 The organization achieves and maintains accreditation by the Commission on Cancer of the American College of Surgeons.
- 1.3 The organization actively and substantially participates in at least one regional cancer control collaborative that is operating pursuant to the Florida Comprehensive Cancer Control Program's cooperative agreement with the Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program.
- I.4. The organization demonstrates excellence in and dissemination of scientifically rigorous cancer research.
- 1.5 The organization demonstrates biomedical researcher training to support the transition of new investigators to independent investigators. The organization provides enhanced cancer care coordination which, must include all of the below:
  - a. Coordination of care by cancer specialists and nursing and allied health professionals.
  - b. Psychosocial assessment and services.
  - c. Suitable and timely referrals and follow-up.
  - d. Providing accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by that center or available through other healthcare organizations. Participation in a comprehensive network of cancer specialists of multiple disciplines, which enables the patient to consult with a variety of experts to examine treatment alternatives.

- e. Family services and support.
- f. Aftercare and survivor services.
- g. Patient and family satisfaction survey results.
- h. Activities that address disparities in health outcomes related to race, ethnicity, language, disability, or other disparity-related factors.
- I.6 The Organization demonstrates an active program of quality and safety improvement, adopts, and implements a continuous comprehensive quality indicator system, reports at a minimum annually on quality metrics and makes a summary of the evaluation available to prospective patients and family members meets and provides enhanced cancer care coordination which, at a minimum, focuses on:
- a. Coordination of care by cancer specialists and nursing and allied health professionals. b. Psychosocial assessment and services.
- c. Suitable and timely referrals and follow-up.
- d. Providing accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by that center or available through other health care organizations.
- e. Participation in a comprehensive network of cancer specialists of multiple disciplines, which enables the patient to consult with a variety of experts to examine treatment alternatives.
- f. Family services and support.
- g. Aftercare and survivor services.
- h. Patient and family satisfaction survey results.
- i. Activities that address disparities in health outcomes related to race, ethnicity, language, disability, or other disparity-related factors.
- I.7 The organization must have an accredited human subject research protection program, and all research is reviewed and approved by an accredited Institutional Review Board (IRB; Human Subjects Research) or Institutional Animal Care and Use Committee (IACUC; Animal Research) to ensure the highest ethical standards for all cancer research.
- 1.8 The organization must enter into research partnerships with at least one other organization, or a research network composed of Florida organizations and participates in a network of Cancer Centers of Excellence when available.
- 1.9 The organization must (a) indicate the specific quality standards (e.g., the American Society of Clinical Oncology (ASCO Certified) Model, Enhancing Oncology Model (EOM), the American Society of Clinical Oncology (ASCO Certified) Model, Quality Oncology Practice Initiative (QOPI) certification, or other recognized quality standards) that are followed, (b) provide a summary of the quality standard model(s) in practice including the term of accreditation and how the institution is incorporating standards into care, and (c) highlight efforts to remain compliant with standards.
- I.10 The organization electronically reports cancer diagnosis and treatment information to the state cancer registry, Florida Cancer Data System (FCDS), following the reporting guidance and timeline outlined in the Florida Cancer Data System Data Acquisition Manual (Authority: Section 385.202 Florida Statutes)

#### Area II: Healthcare Professionals and Researchers

Physicians and surgeons, nurses, and other health care professionals must follow evidence-based protocols, participate in quality improvement activities, and implement revisions to practice improving outcomes. For example, this can include participating with other professionals in a network of cancer specialists from multiple disciplines to ensure patients receive coordinated care and evaluate all options.

#### **Performance Measures**

II.1 Physicians and all members of the care team provide accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by that center or available through other healthcare organizations.

# **Area III: Patients and Family Members**

Including patients and family members in the areas to be evaluated is based on the recognition that patients and families have opportunities to assist their health care team to improve the quality of their care. This area is focused on how well patients participate in their care to improve outcomes. High-quality organizations have processes in place to evaluate ways to improve this process and incorporate those improvements to assist patients. High-quality professionals are successful in supporting and encouraging patients and have patients who are engaged in improving the quality of care provided by their care team. Examples of ways healthcare professionals can help meet these standards include the use of educational materials, access to support groups provided by the healthcare organization or partners, and patient navigators.

#### **Performance Measures**

- III.1 The organization provides ongoing opportunities for the patient to provide all the information to the health care team that is relevant to care and treatment decisions.
- III.2 The organization provides ongoing opportunities for the patient to communicate concerns and worries that might affect cancer treatment.
- III.3 The organization conducts activities that increase patient participation in follow-up appointments for positive cancer screening tests, cancer treatments, and survivor care visits. The application describes innovative and unique methodologies that ensure patient follow-up. The organization provides ongoing opportunities for the patient to improve their understanding of their cancer.
- III.4 The organization provides ongoing opportunities for the patient to keep follow-up appointments to ensure continuity of care
- III.5 The organization provides ongoing opportunities for the patient to include a friend or family member in the care process.

# **Rating System**

According to Florida Statute, the Department of Health (the Department) will conduct two evaluation cycles per year and will establish application deadlines for each evaluation cycle. Applications must be received by the Department by 5:00 p.m. EST on February 14, 2025, in order to be considered during an application cycle. The following steps outline the designation process:

- An application will be completed and submitted to a designated OneDrive folder for each Center of Excellence.
- Department staff will review applications for completeness and provide written questions to the applicant organization within 30 days of receipt of application.
- An administrative review will be completed by the Department.
- Applications will be forwarded to peer reviewers after conflict of interest is determined.
- If the Department or a peer reviewer requests additional information, the organization has 30 days to respond. The additional information will be incorporated by the Department for consideration.
- Based on the peer review, findings will be forwarded to the State Surgeon General or designee who makes a recommendation to the Governor.

Department staff review applications for completeness and provide written comments to the applicant organization within 30 days of receipt of application. The applicant organization may revise the application based on staff comments within 30 days of receiving comments from the Department and submit a revised application or arrange another time period to resubmit an application. After the Department receives a complete application from the organization, the application is forwarded to a team of evaluators. A team of evaluators may conduct a site visit to verify practice. Evaluators base their review on peer standards of high-performing organizations nationally.

The Department selects evaluators based on criteria defined in statute and verifies that evaluators do not have a conflict of interest in the applicant's organization. An evaluator with a conflict of interest may not participate in review of an organization's application. A conflict of interest exists when an evaluator or their immediate family has a financial interest of any amount or non-financial interest in the organization being evaluated or is associated with an organization that competes for market share with the organization being evaluated. Immediate family member includes the spouse or domestic partner of the evaluator.

Based on review of written information, and information from a site visit, if any, evaluators make an observation about each measure, indicating whether the Standard is Met or Standard is Not Met. Staff and evaluators provide a draft report to the organization within 90. The organization has 30 days to respond with clarifications of errors in fact and program improvements. The draft report is revised by staff to incorporate the response from the organization and is reviewed by the evaluators. Based on the evaluators' review of the organization's response, the draft report is revised as needed and forwarded to the Surgeon General. After approval by the Surgeon General, the Department issues a Cancer Center of Excellence Application Report recommendation and provides this to the Governor. Upon decision of the Governor, the organization is provided a final report and is notified of a decision to grant the Cancer Center of Excellence designation, or whether additional time is needed for the applicant organization to make program improvements.

# **Rating Standards**

The rating standard is pass-fail. If the organization does not meet each of the rigorous performance measures defined below, it is not eligible for designation as a Cancer Center of Excellence. The observation will be either "Standard is Met" or "Standard is Not Met". Rating standards are defined for each performance measure. For example, to meet a standard an organization might be required to publish outcome data for review by prospective patients and family members within a certain time frame defined in the Standard.

#### **Performance Measures**

# Area I: Organization

I.1 The organization maintains a license in good standing in this state which authorizes health care services to be provided.

#### Rationale

Organizations must maintain a license in good standing. Organizations that do not have a license in good standing are not eligible to be designated a Cancer Center of Excellence. Hospitals must maintain current state licensure but may also choose to be Medicarecertified and may choose to be accredited, for example, by The Joint Commission or Centers for Medicare and Medicaid Services. Accredited hospitals meeting *Florida Administrative Code Rule* 59A-3.253(3) may be deemed to be in compliance with the licensure and certification requirements. Each site where cancer care is delivered within the applicant organization must hold a license in good standing.

#### **Regulatory and Guidance References**

Chapter 395, Part I, *Florida Statutes*; Chapter 408, Part II, *Florida Statutes*; *Florida Administrative Code Rule* 59A-3.253(3)

#### **Required Written Materials**

Written materials must include a copy of the organization's license. If there have been any actions against the organization in the previous three years, written materials of the action and the organization's response that are public records must be provided. Written materials must describe the process to obtain and maintain a license. If the organization has also chosen to be accredited, for example, by the Joint Commission, or Centers for Medicare and Medicaid Services, then written materials must include documentation of this, any actions, and any response to actions by the accrediting body.

# Common types of materials that may be used:

- A copy of a current license from Florida's Agency for Healthcare Administration documenting a license in good standing.
- Documentation of accreditation by Centers for Medicare and Medicaid Services, Joint Commission, or other accreditations.
- Records of any pending actions against the organization by any regulatory oversight agency.
- Documentation of the resolution of licensing problems and accreditation problems.

# I.2 The organization achieves and maintains accreditation by the Commission on Cancer of the American College of Surgeons.

#### Rationale

The organization must be accredited by the Commission on Cancer of the American College of Surgeons. Accreditation is based on facility or organization type, and requirements vary. Regardless of the facility or organization type, the organization must meet all requirements specified in this manual. If a program is in the process of merging with another, the entire organization must have current accreditation by the Commission on Cancer.

# **Professional Organization Practice Guidelines**

Web site of the Commission on Cancer of the American College of Surgeons

# **Required Written Materials**

Written materials include a copy of documentation of accreditation by the American College of Surgeons Commission on Cancer. Documentation must describe the cancer program category based on the facility or organization type.

Common types of materials that may be used:

- Documentation of accreditation by the Commission on Cancer of the American College of Surgeons.
- Records of any pending actions against the organization by the Commission on Cancer of the American College of Surgeons, such as notice that an accreditation standard is not met upon a re-accreditation.
- Documentation of the resolution of accreditation problems.
- I.3 The organization actively and substantially participates in at least one regional cancer control collaborative that is operating pursuant to the Florida Comprehensive Cancer Control Program's cooperative agreement with the Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program.

#### Rationale

Florida's cancer collaboratives implement the state's cancer plan at the local level. The collaboratives are voluntary public-private partnerships composed of a broad range of stakeholders, including healthcare professionals, community-based organizations, advocacy groups, patients, cancer survivors, insurance companies and businesses, local government officials, colleges and universities, and others interested in improving cancer care and prevention in the state. As of 2013 there are six collaboratives organized by region. The collaboratives are funded by the Centers for Disease Control and Prevention, through the Department. All collaboratives engage in at least one or more of the following, as appropriate:

- Building partnerships and networks to increase cancer awareness.
- Mobilizing community support for cancer control and prevention.
- Using data and research to assess the cancer burden and identify priorities.
- Engaging in local actions to reduce the cancer burden.
- Conducting evaluations and using the results to improve effectiveness.

The organization must have substantive and meaningful ongoing participation in at least one cancer collaborative. Substantial and meaningful participation involving developing, implementing, and evaluating the essential functions of the collaboratives. For example, the organization might assist a collaborative to assess the current local health status by engaging in health assessments or making available to the collaborative information from current research. The burden of cancers is not the same throughout the state, and the organization could partner with the collaborative in identifying the cancer burden in the region. The organization could host meetings and provide staff support for the community collaborative.

The organization could partner with the collaborative to mobilize other community organizations and build networks. For example, the organization could provide in-kind or direct support for the collaborative to implement a local media campaign to improve treatment and prevention. The organization could provide staff and resources to implement various local cancer control and screening activities. For example, the organization could provide medical staff for screening. The organization could support collaboratives by conducting program evaluations and publishing metrics demonstrating that the collaborative is effective. The evaluation must demonstrate that there is a link between participation and outcomes – for example, increasing the number of patients screened, having patients enter care earlier; providing greater access to care, and improving the number of patients who remain in care, which may require working with community groups to remove barriers.

There are six cancer collaboratives in Florida:

- Northwest Region: Florida Area Health Education Center: http://www.nwfcc.net/.
- Central Region: WellFlorida Council, Inc: http://www.ncfcancercontrol.org/.
- Northeast Region: Health Planning Council of N.E. Florida, Inc.: http://www.neflcancercollaborative.org.
- East Central Region: Health Council of East Central Florida, Inc.: http://www.ecfccc.com/.

- Southeast Region: Health Council of South Florida, Inc.: http://sfccc.med.miami.edu/.
- Southwest Region: Health Council of West Central Florida, Inc.: www.swflccc.com.

# **Professional Organization Practice Guidelines and other Resources**

• <u>National Comprehensive Cancer Control Program, Centers for Disease Control</u> and Prevention.

# **Required Written Materials**

- A plan for community engagement.
- Report demonstrating improved prevention or care outcomes resulting from participating in the collaborative.

# Common types of materials that may be used

- Meeting minutes.
- Evaluation reports.

# I.4. The organization demonstrates excellence in and dissemination of scientifically rigorous cancer research.

#### Rationale

High-quality cancer care depends upon research, such as clinical trials and comparative effectiveness research, to inform medical decisions. The organization must describe the health impact of the research conducted by its researchers, and how the results of research are used to improve patient care at that organization. There is a need to improve the evidence upon which cancer therapy is based.

Research excellence is defined as significant participation in rigorous scientific research that contributes to the national impact in cancer. The organization's reputation is strengthened through research. One indication of research excellence is that the project has been subjected to scrutiny and analysis by scientific peers and is found to involve sound research design and other standards of scientific quality. Scientific peer review can occur in several ways, including scientific review by external funding organizations and scientific review by regulatory agencies such as the FDA. Approval by an Institutional Review Board or Institutional Animal Use and Care Committee, when these committees perform a review of scientific merit, can indicate scientifically rigorous research.

Another indication of rigorous research is funding because projects that meet standards of scientific quality are further ranked in terms of other criteria such as significance or health impact. Rigorous research advances the field, settles issues of uncertainty, and may be used to establish clinical guidelines. The organization must demonstrate that the research

conducted is rigorous and improves cancer care, which may include evidence of grant funding, professional recognition and awards, comparative rankings, and peer-reviewed publications.

The organization must demonstrate that it conducts research that is scientifically rigorous, and that rigorous research is conducted across a comprehensive research program. This must include three components:

- Evidence of active involvement in clinical research,
- Evidence of national impact in one of the six research areas listed below, and
- Evidence of research in at least one other area listed below.

#### **Research Areas**

- Basic research: Fundamental theoretical or experimental investigative research
  to advance knowledge without a specifically envisaged or immediately practical
  application. Directed to understanding the events related to the development or
  prevention of cancer at the molecular, cellular, and organismic levels, as well
  as the discovery and development of new anticancer drugs or other anticancer
  therapies.
- Translational research: Research that translates new knowledge, mechanisms, and techniques generated by advances in basic science research into new approaches for prevention, diagnosis, and treatment of cancer that is essential for improving health, for example in clinical trials. Translational research can be categorized into one of four categories, which include T1 (Lab to Patient); T2: (Patient to Clinical); T3: (Clinical to Community); and T4: (Community to Policy)
- Clinical research: Research that gathers evidence of the benefits and harms of various cancer treatment options, and that directly involves a particular person or group of people, or that uses materials from humans, such as their behavior or samples of their tissue. Clinical research can involve trials of new cancer drugs, as well as behavioral health interventions.
- Population science: Research into the health outcomes of a group of individuals, including the distribution of such cancer outcomes within the group, including outcomes, patterns of health determinants, and policies and interventions that link these two. Investigates the circumstances under which cancer occurs in populations, including the epidemiology of human behavior and lifestyle factors, as well as molecular epidemiology and gene-environment interactions.
- Health services research (health systems research): Research on health organizations, institutions, and systems to ensure that new cancer treatments and research knowledge actually reaches the cancer patients for which they are intended and are implemented correctly to improve care. Examines the interface of the health care system with patients, with the goal of improving access and reducing barriers to optimal health care. Research in this area could also examine the effects of public policy and laws on public health and access to care, and on reducing barriers to and disparities in health care.

Examples may include ways to improve quality of care by improving access; reorganizing and coordinating systems of cancer care; helping clinicians and patients change behaviors and make more informed choices; providing reminders and point-of- care decision support tools; and strengthening the patient-clinician relationship.

• Cancer control and prevention research: Research that investigates how scientifically obtained information can be efficiently and effectively applied to defined groups of people or at the community level to reduce the burden of cancer, which includes prevention. Patient-centered outcomes research involving the conduct and synthesis of research comparing the harms and benefits of different strategies to prevent, diagnose, and monitor health conditions in "real- world" settings. In contrast to health services research which typically focuses on health organizations and care delivery, cancer control and prevention research focuses on community settings and community-based approaches to prevention, screening, and monitoring.

The organization must disseminate research results and data through such mechanisms as publishing in peer-reviewed journals, but also through making data sets available when appropriate, or through patents, or through licensing of intellectual property such as copyrights and trademarks. Rigorous research is more likely to be disseminated through highly ranked peer-reviewed journals, and the organization must describe the number of publications and the quality of the journals. Because research results are regularly not implemented in practice, the organization must describe ways that research results are disseminated within the organization to ensure that research results are incorporated into practice and result in improvements in practice, when appropriate. The organization must describe when research findings from its researchers changed clinical practice or otherwise had an impact on the quality of cancer care.

The organization must provide a list of peer-reviewed publications from the organization's investigators over the last three years that have made a state, national, or international impact on cancer prevention, early detection, treatment, policy or particularly illustrate programmatic excellence in cancer control. This information should be provided in the format of a table and must include PubMed Central (PMC) identification numbers.

List peer-reviewed publications for the last three years using the following sample.

Peer Reviewed Publications				
Date Journal Title of Publication PubMed Cer				

List the top five creative or novel publications by year using the following sample.

Top Five Creative or Novel Peer-Reviewed Publications by Year				
Year 1 (Date, Training title. brief description, credentials)	Year 2 (Date, Training title. brief description, credentials)	Year 3 (Date, Training title. brief description, credentials)		

# **Professional Organization Guidelines and Consensus Statements**

Delivering High-Quality Cancer Care ASCO

#### **Regulatory and Guidance References**

None.

# Required Written Materials (a minimum of three are required)

- Description of changes in clinical practice or the development of clinical guidelines as a result of the organization's research.
- Policies on review of scientific merit.
- List of funded research projects.
- Table that includes the number of publications and list of journals by research
  area for each year and a narrative summary of the top five publications for each
  year grouped by the type(s) of research conducted by the applicant (An
  appendix of all publications may be included).
- A metric that measures the impact and productivity of a scientist or scholar such as the Hirsch index (h-index)
- A metric used by Google Scholar to measure the number of a researcher's publications that have at least 10 citations such as the i10index
- Patents and other intellectual property.

#### Common types of materials that may be used

- · Research plan.
- Evaluation reports.
- 1.5 The organization must demonstrate biomedical researcher training to support the transition of new investigators to independent investigators. The organization provides enhanced cancer care coordination which, must include all of the below:
  - a. Coordination of care by cancer specialists and nursing and allied health professionals.

- b. Psychosocial assessment and services.
- c. Suitable and timely referrals and follow-up.
- d. Providing accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, Family services and support.
- e. Aftercare and survivor services.
- f. Patient and family satisfaction survey results.
- g. Activities that address disparities in health outcomes related to race, ethnicity, language, disability, or other disparity-related factors. whether provided by that center or available through other healthcare organizations. Participation in a comprehensive network of cancer specialists of multiple disciplines, which enables the patient to consult with a variety of experts to examine treatment alternatives.

#### Rationale

Integrating the education of biomedical researchers and healthcare professionals is indispensable to the goal of improving cancer care. Clinical experience brings to biomedical research the unique perspective of asking clinically meaningful scientific questions based on the direct experience with patients. Research experience provides clinicians the expertise necessary to critically evaluate the findings from research and evaluate possible changes in clinical practice. The organization should have a substantive and rigorous program to develop the research capacity of clinician- scientists, and the ability of professionals from all disciplines to function in teams, where some members have primary interests and responsibility for patient care, and some members have interests primarily in research. Cancer care is interdisciplinary and requires training in interdisciplinary teams, including but not limited to oncology-trained physicians, radiation therapists/dosimetrists, residents, fellows, nurses, pharmacists, nutritionists, social workers, mid-level providers, and many others. By ensuring high- quality interdisciplinary training for cancer providers and researchers, the pipeline and diversity of capable caregivers and investigators with be available for the Florida cancer workforce.

The organization must have a process to evaluate the effectiveness of the cancer clinical and research education programs with emphasis on activities to integrate the training of clinicians and researchers.

The organization must demonstrate the clinical training of health professionals who provide specialized care for cancer patients through nationally accredited processes of training and education.

The organization must demonstrate biomedical researcher training to support the transition of new investigators to independent investigators.

#### **Professional Organization Practice Guidelines**

- Accreditation Council for Graduate Medical Education
- National Institutes of Health Office of Intramural Training and Education

# **Regulatory and Guidance References**

None available.

#### **Required Written Materials**

- Documentation of institutional or extramural support that has been targeted toward career growth for early career investigators during the last three years.
- When relying upon other accreditation bodies to meet parts of this measure, documentation of accreditation using the most current accreditation standards.
- Report educational outcome measures.

# Common types of materials that may be used

- Written materials describing how the organization integrates the education of biomedical researchers and healthcare professionals.
- Evaluation reports on the effectiveness of the education program.
- Education plans showing a team-based approach.
- Summary of educational activities in the last year involving interdisciplinary teams, including the professions for whom the education was designed.
- Publications of participation/abstracts in meetings and peer review journals
- Department evaluations.
- Awarded grants.
- Scholarly visiting professorships, not at parent institution.
- Participation in expert panels.
- Accreditation Council for Graduate Medical Education (ACGME) reports.
- Oncology Nursing Society (ONS) certification and/or certification of nursing trainees.

# List training for the last three years using the following sample:

Cancer-Related Healthcare Training				
Date	Training Title	Brief Description of Program	Trainee Credentials	

Total Numbe	
Year 1	
Year 2	
Year 3	

List the top five creative or novel training topics by year using the following sample:

Top Five Creative or Novel Training Topics By Year				
Year 1 (Date, Training title, brief description, credentials)	Year 2 (Date, Training title, brief description, credentials)	Year 3 (Date, Training title, brief description, credentials)		

- I.6 The Organization demonstrates an active program of quality and safety improvement, adopt, and implement a continuous comprehensive quality indicator system, report at a minimum annually on quality metrics and make a summary of the evaluation available to prospective patients and family members, meets and provide enhanced cancer care coordination which, at a minimum, focuses on:
  - a. Coordination of care by cancer specialists and nursing and allied health professionals.
  - b. Psychosocial assessment and services.
  - c. Suitable and timely referrals and follow-up.
  - d. Providing accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by that center or available through other health care organizations.
  - e. Participation in a comprehensive network of cancer specialists of multiple disciplines, which enables the patient to consult with a variety of experts to examine treatment alternatives.
  - f. Family services and support.
  - g. Aftercare and survivor services.
  - h. Patient and family satisfaction survey results.
  - i. Activities that address disparities in health outcomes related to race, ethnicity, language, disability, or other disparity-related factors.

#### Rationale

Members of the care team must coordinate with each other, and with primary and specialist care teams to implement the patient's care plan and deliver comprehensive, efficient, and patient-centered care. Organizations must demonstrate the systematic integration of support for the patient and family, including behavioral health specialists, clinically licensed social workers, case managers, patient navigators, counseling services, spiritual support, cancer support groups, and financial counselors. The organization must have knowledge of community resources. If the organization provides patient care at multiple locations or through partners, these resources must be provided throughout the patient journey and monitored by the organization to ensure effectiveness.

The organization must have a process for communicating diagnosis and treatment options that includes patient education materials, information about personal considerations, and information about clinical trials and other treatment options relevant to patient needs. The cancer care physician must discuss clinical trials in person and may discuss a clinical research network with patients. The organization must coordinate care with the patient's primary care physician and other treating physicians, for example, by distributing a summary of the treatment plan and a coordinated care plan.

The organization must have a comprehensive and integrated system to allow patients access to pain services, evidence-based complementary care options, bereavement support, counseling on quality of life, and hospice care. Cancer care teams must provide end-of-life care consistent with their needs, values, and preferences. The organization must have a coordinated and transparent reporting infrastructure for obtaining information from patients and family members about their experience with the cancer care journey. The organization must obtain feedback from patients and family members, evaluate feedback, and use that information to improve care.

## **Professional Organization Practice Guidelines**

- Web site of the Commission on Cancer of the American College of Surgeons
- Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis, Institute of Medicine

#### **Required Written Materials**

- Written materials, such as policies and procedures or electronic decision system screenshots that describe care coordination.
- Plan to ensure coordinated care.
- Treatment plans.
- Survivorship care plans.
- Summary of the evaluation of care coordination.
- Summary of evaluation of patients' experiences with the cancer care journey.
- Plan for ongoing training that ensures patient access to culturally and linguistically competent professionals and support staff.

 Plan and summary of activities that address reduction/elimination of disparities in health outcomes related to race, ethnicity, language, disability, or other disparity- related factors.

# Common types of materials that may be used

- Cancer committee minutes that document care coordination.
- Summary of peer review of cancer care.
- Examples of chart notes recording that the clinician discussed care options, including clinical trials with the patient.
- Education materials for patients about taking part in clinical trials.
- Education materials for patients about pain management and palliative care options.

I.7 When conducting cancer research the organization must have an accredited human research protection program and have research reviewed by an accredited Institutional Review Board to ensure the highest ethical standards. For organizations engaging in basic or pre-clinical research, an accredited Institutional Animal Care and Use Committee (IACUC; Animal Research) is required to review and approve research protocols involving animals.

#### Rationale

The organization must have an accredited human research protection program and Institutional Review Board for review of research involving human participants. Accreditation of human research protection programs is an established standard of practice. Government agencies including the National Cancer Institute, and industry sponsors, require accreditation. Regulatory agencies find fewer compliance problems in accredited organizations. For organizations engaging in basic or pre-clinical research, an accredited Institutional Animal Care and Use Committee (IACUC; Animal Research) is required.

# **Professional Organization Practice Guidelines**

- <u>Preserving Public Trust: Accreditation and Human Research Participant</u>
   Protection Programs PubMed
- Association for Accreditation of Human Research Protection Programs
- National Cancer Institute Central IRB
- Institutional Animal Care and Use Committee Guidebook

# **Regulatory and Guidance References**

- National Cancer Institute Central IRB Policies.
- Institutional Animal Care and Use Committee Guidebook

# **Required Written Materials**

Documentation of current accreditation.

# Common types of materials that may be used

- Human research protection program plan.
- Summary of program evaluations and annual reports to accreditation organizations.

I.8 Enters into a research partnership with at least one other organization, or a research network composed of Florida organizations, and participates in a network of Cancer Centers of Excellence when available.

#### Rationale

The organization must demonstrate substantive mutual collaboration and participation in research. Substantive collaboration focuses on organization commitments and roles, not the roles of individual researchers, such as having researchers serve as co- investigators on grants. Substantive collaboration includes commitment of the leadership of all participating organizations, sharing research resources such as registries, equipment, laboratory services, personnel, community outreach, and other resources. Substantive collaboration may include

sharing staff and taking into account participation in shared research initiatives when conducting employee evaluations. The organization must have a process for periodically evaluating the effectiveness of research collaborations.

# **Professional Organization Practice Guidelines**

 National Center for Translational Sciences - Clinical and Translational Science Awards Program

# **Regulatory and Guidance References**

None available.

# **Required Written Materials**

- Written materials such as policies describing research partnerships.
- Records showing financial support for organizational research collaborations.
- Inter-organization agreements or memoranda of understanding.

# Common types of materials that may be used

- Plan for organizational collaboration.
- List of collaborative research studies.
- Summary of evaluation of research collaboration.

I.9 The applicant must (a) indicate the specific quality standards (e.g., the American Society of Clinical Oncology Model (ASCO Certified), Enhancing Oncology Model (EOM), the American Society of Clinical Oncology Model (ASCO Certified), Quality Oncology Practice Initiative (QOPI) certification or other recognized quality standards) that are followed, (b) provide a summary of the quality standard model(s) in practice including the term of accreditation and how the institution is incorporating standards into care, and (c) highlight efforts to remain compliant with standards

#### Rationale

Adopting a continuous comprehensive quality indicator system is associated with improved cancer treatment outcomes. The organization must describe a process for adopting comprehensive standards and have a process to evaluate standards annually at a minimum. The organization must collect quantitative data about treatment outcomes and compare with evidence-based standards, including consensus standards, or other practice standards such as emerging findings in the research literature. The organization must have a comprehensive system of quality improvement and performance improvement. The organization must adopt and implement a continuous comprehensive quality indicator system and report annually on quality metrics. The organization must show how outcomes at the organization improve over time and how outcomes compare with established benchmarks. The organization must implement advances balancing innovations in the field and the need to have sufficient evidence to ensure the efficacy of the intervention. The organization must incorporate the results of outcome-tracking research and other information when evaluating standards. The organization must have an organizational culture committed to improving quality.

# **Professional Organization Practice Guidelines**

- Delivering High-Quality Cancer Care ASCO
- Quality On<u>cology Practice Initiative</u>
- International Organization Standards for Quality Management

# **Required Written Materials**

- Plan for adoption and review of performance measures.
- Publication of outcome measures as specified by the Department.

## Common types of materials that may be used

 Documentation of accreditation by the Quality Oncology Practice Initiative or that a site visit has been scheduled.

- Documentation of another process showing outcome measures meeting or exceeding national standards.
- I.10 The organization electronically reports cancer diagnosis and treatment information to the state cancer registry, Florida Cancer Data System (FCDS), following the reporting guidance and timeline outlined in the Florida Cancer Data System Data Acquisition Manual (Authority: Section 385.202 Florida Statutes).

#### Area II: Healthcare Professionals and Researchers

#### **Performance Measures**

II.1 Physicians and all members of the care team provide accurate and complete information on the highest evidence-based treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by that center or available through other healthcare organizations.

#### Rationale

Healthcare professionals must seek out feedback from peers about the treatment plan, and regularly review this with the team. For example, physicians must have the treatment plan reviewed by other members of the treatment team periodically and on an ongoing basis for each patient, whether in a small care team or a multidisciplinary tumor board. Physicians must discuss clinical trial options in person with patients and discuss with the patient how treatment and research options address the personal needs and values of the patient. There must be documentation that these discussions occurred. Physicians must participate in interdisciplinary care teams.

# **Professional Organization Practice Guidelines**

- National Comprehensive Cancer Network Guidelines: http://www.nccn.org.
- American College of Surgeons Commission on Cancer Care: http://www.facs.org/cancer/.

# **Regulatory and Guidance References**

None available

#### **Required Written Materials:**

- Written materials for tumor boards or other ways of evaluating care plans.
- Metrics on the effectiveness of care based on patient outcomes.
- Publication of patient outcomes in a way that allows patients and family members to evaluate care at the organization.

Common types of materials that may be used:

- Websites that publish patient outcomes.
- Comparison of patient outcomes between the organization and other nationally- ranked programs, including a description of the methods used to conduct the evaluation.
- Organizations must provide a list of training and career development activities for cancer-related healthcare professions. Include a list of training programs, a brief description of the program, the type of trainee (i.e., medical student, resident, fellow, nursing student, nurse, public health, social work, etc.), and the number of trainees participating by year over the last three years. Provide information in a table format similar to the examples below.

# List the top five creative or novel training topics by year using the following sample:

Top Five Creative or Novel Training Topics By Year				
Year 1 (Date, Training title, brief description, credentials)	Year 2 (Date, Training title, brief description, credentials)	Year 3 (Date, Training title, brief description, credentials)		

# **Area III: Patients and Family Members**

#### **Performance Measures:**

- **III.1** The organization provides ongoing opportunities for the patient to provide all the information to the health care team that is relevant to care and treatment decisions.
- **III.2** The organization must provide ongoing opportunities for the patient to communicate concerns and worries that might affect cancer treatment.
- **III.3** The organization provides ongoing opportunities for the patient to improve their understanding of their cancer.
- **III.4** The organization provides ongoing opportunities for the patient to keep follow up appointments to ensure continuity of care.
- **III.5** The organization provides ongoing opportunities for the patient to include a friend or family member in the care process.

Including patients and family members in shared decision-making is based on the recognition that patients and families have opportunities to assist the care team to improve the quality of

their care. This area is focused on how well patients participate in their care to improve outcomes.

Patient participation is the process of acquiring information, considering information, and discussing concerns with the care team. Patient-centered communication fosters healing relationships and trust. When the care team and patient communicate effectively there is an exchange of information, response to emotions, and management of uncertainty. These behaviors are associated with improved patient-based outcomes. Organizations must have clearly defined processes to engage patients in these types of activities, evaluate the effectiveness of their process, and use the results to improve the process. High-quality organizations have processes in place to evaluate ways to improve ways they involve patients in care and incorporate improvements to assist patients. High-quality professionals are successful in supporting and encouraging patients and have patients who are engaged in improving the quality of care provided by their care team. Examples of ways healthcare professionals can help meet these standards include the use of educational materials, access to support groups provided by the healthcare organization or partners, and patient navigators. The evaluation of these standards focuses on the processes the organization uses to empower patients.

# **Professional Organization Practice Guidelines**

- <u>Delivering High-Quality Cancer Care: Charting a New Course for a System in</u> Crisis, Institute of Medicine
- Web site of the Commission on Cancer of the American College of Surgeons
- Quality Oncology Practice Initiative

# **Regulatory and Guidance References**

None available.

# **Required Written Materials**

- Policies and procedures requiring documentation that health care professionals are required to implement standards III.1-III.5.
- Summary of ongoing evaluation of the organization's efforts to empower patients.

#### Common types of materials that may be used

- Patient education materials.
- Patient "Bill of Rights".
- Description of systems such as ways of providing patients reminders and followup calls from members of the care team.
- Information about community resources such as support groups.

- Education about ongoing follow-up with the cancer care team after treatment is concluded.
- Patient surveys showing patients are asked whether standards III.1-III.5 were discussed with them, and that the results are used to improve the process when appropriate.

Thank you for continuing your commitment to the Cancer Center of Excellence Award designation. For technical assistance and questions, send emails to <a href="mailto:Research@flhealth.gov">Research@flhealth.gov</a>.

# **Cancer Center of Excellence Applicant Checklist** Not Met Explanation Area I. Organization of Performace Measures Met **Measure I.1** Does the applicant maintain a license in good standing in Florida which authorizes health care services to be provided? Was a copy of the license submitted? Does the application address If there have been any actions against the organization in the previous three years? If so, were written materials of the action and the organization's response that are public records provided? Does the application indicate if the organization is accredited, for example, by the Joint Commission, or Centers for Medicare and Medicaid Service? If so, were written materials of the action, and the organization's response provided? **Measure I.2** Does the applicant achieve and maintain accreditation by the Commission on Cancer of the American College of Surgeons? Does documentation describe the cancer program category based on the facility or organization type? Measure I.3 Does the applicant actively and substantially participates in at least one regional cancer control collaborative that is operating pursuant to the Florida Comprehensive Cancer Control Program's cooperative agreement with the Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program? Does the application describe substantial and meaningful participation involving developing, implementing, and evaluating the essential functions of the collaboratives?

Measure I.4 Does the institution demonstrate excellence in and dissemination of scientifically rigorous cancer research?		
Does the application describe the health impact of the research conducted by its researchers, and how the results of research are used to improve patient care at that organization?		
Does the application describe the organizations efforts to disseminate research results and data through such mechanisms as publishing in peer-reviewed journals, but also through making data sets available when appropriate, or through patents, or through licensing of intellectual property such as copyrights and trademarks?		
Does the application demonstrate that the research conducted is rigorous and improves cancer care, which may include evidence of grant funding, professional recognition and awards, comparative rankings, and peer-reviewed publications?		
Does the organization demonstrate that it conducts research that is scientifically rigorous, and that rigorous research is conducted across a comprehensive research program. This must include three components:		
•Evidence of active involvement in clinical research •Evidence of national impact in one of the six research areas listed below, and		
•Evidence of research in at least one other area listed below		
Measure I.5 Does the institution demonstrate biomedical researcher training to support the transition of new investigators to independent investigators? Does the application summarize efforts for enhanced cancer care coordination which, at a minimum, focuses on:		
a. Coordination of care by cancer specialists and nursing and allied health professionals.		
b. Psychosocial assessment and services.		
c. Suitable and timely referrals and follow-up.		
d. Providing accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether		
provided by that center or available through other healthcare organizations.		
e. Participation in a comprehensive network of cancer specialists of multiple disciplines, which enables the patient to consult with a variety of experts to examine treatment alternatives.		
f. Family services and support.		
g. Aftercare and survivor services.		
h. Patient and family satisfaction survey results.		
i. Activities that address disparities in health outcomes rela		

<b>Measure I.6</b> Does the institution demonstrate an active program of quality and safety improvement, adopts and implements a continuous comprehensive quality indicator system, reports at a minimum annually on quality metrics, and makes a summary of the evaluation available to prospective patients and family members?		
Does the application provide a summary of the quality standard model(s) in practice including the term of accreditation and how the institution is incorporating standards into care, andPsychosocial assessment and services.		
Does the application highlight efforts to remain compliant with standards. Suitable and timely referrals and follow-up.		
<b>Measure I.7</b> Does the application describe the organization's accredited human subject research protection program for cancer research? Is all research reviewed and approved by an accredited Institutional Review Board (IRB; Human Subjects Research) or Institutional Animal Care and Use Committee (IACUC; Animal Research) to ensure the highest ethical standards?		
<b>Measure I.8</b> Does the application summarize research partnerships with at least one other organization or a research network composed of Florida organizations?	Ø	
Does the application discuss participation in a network of Cancer Centers of Excellence when available?		
<b>Measure I.9</b> Does the applicant indicate the specific quality standards (e.g., the American Society of Clinical Oncology Model (ASCO Certified), Enhancing Oncology Model (EOM), the American Society of Clinical Oncology Model, Quality Oncology Pratice Initiative (QOPI) Certification or other recognized quality standards) that are followed?		
Does the applicant provide a summary of the quality standard model(s) in practice including the term of accreditation and how the institution is incorporating standards into care?		
Does the applicant highlight efforts to remain compliant with standards?		
Measure I.10 Does the applicant indicate whether the Institution Electronically reports cancer diagnosis and treatment information for all Florida residents to the state cancer registry, Florida Cancer Data System (FCDS), following the reporting guidance and timeline outlined in the FCDS Data Acquisition Manual (Authority: Section 385.202 Florida Statutes).		

Area II. Healthcare Professionals and Clinical Researchers		No	Explanation
<b>Measure II.1</b> Does the applicant summurize efforts by physicians and all members of the care team provide accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by that center or available through other healthcare organizations.?			
Area III: Patients and Family Members	Yes	No	Explanation
<b>Measure III.1</b> Does the applicant summurize efforts to provide ongoing opportunities for the patient to provide all the information to the health care team that is relevant to care and treatment decisions?			
<b>Measure III. 2</b> Does the applicant summurize efforts to provide ongoing opportunities for the patient to communicate concerns and worries that might affect cancer treatment.			
Measure III.3 Does the applicant summarize efforts to provide ongoing opportunities for the patient to improve their understanding of their cancer			
<b>Measure III.4</b> Does the applicant summarize efforts to provide ongoing opportunities for the patient to keep follow-up appointments to ensure continuity of care.			
Measure III.5 Does the applicant summuarize efforts to provide ongoing opportunities for the patient to include a friend or family member in the care process			