Cancer Center of Excellence

Performance Standards, Rating System, and Rating Standard

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, attract and retain the best cancer care professionals to the state, and help Florida organizations be recognized nationally as 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 healthcare organization, healthcare 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 Standards. If an eligible organization meets all Performance Standards 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 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 Standards are applicable to cancer care across the 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 standards sooner than specified elsewhere, and may be required to adopt additional performance standards.

The process of evaluating Performance Standards involves review of written materials and may involve a site visit by a team of evaluators. Evaluators assess practice to verify Performance Standards are met, or that the organization has not yet met a standard. If the determination of evaluators is that 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 throughout 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 practice.

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 Standard 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 the organization meets each Performance Standard. The description include an explanation of the Performance Standard; 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.

Performance Standards

Area I: Organization

The first Area concerns the healthcare 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 standards

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

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

Standard 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.

Standard I.4. The Organization demonstrates excellence in and dissemination of scientifically rigorous cancer research.

Standard I.5 The organization integrates rigorous cancer training and education of biomedical researchers and health care professionals.

Standard I.6 The organization meets provides enhanced cancer care coordination which, at a minimum, focus 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

Standard I.7 The organization 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.

1.8 Standard I.8. 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.

Standard I.9 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.

Area II: Healthcare professionals and researchers

Physicians and surgeons, nurses and other healthcare professionals must follow evidence-based protocols, participate in quality improvement activities, and implement revisions to practice to improve 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 standards:

Standard 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 health care 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 healthcare 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 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 standards:

Standard III.1 The organization should provide ongoing opportunities for the patient to provide all the information to the healthcare team that is relevant to care and treatment decisions.

Standard III.2 The organization should provide ongoing opportunities for the patient to communicate concerns and worries that might affect cancer treatment.

Standard III.3 The organization should provide ongoing opportunities for the patient to improve their understanding of their cancer.

Standard III.4 The organization should provide ongoing opportunities for the patient to keep follow up appointments to ensure continuity of care

Standard III.5 The organization should provide ongoing opportunities for the patient to include a friend or family member in the care process.

Rating System

Under statute, the Department of Health 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. Eastern time on the date specified in order to be considered during an application cycle. Department staff review applications for completeness and provide written comments to the applicant organization within 30 days. The applicant organization may revise the application based on staff comments within 30 days 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 spouse or domestic partner of the evaluator.

Based on review of written information, and information from a site visit, evaluators make an observation about each Standard, indicating whether the Standard is Met or Standard is Not Met. Staff and evaluators provide a Draft Report to the organization within 60 days of the site visit. 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 Site Visit 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.

The organization that has received a Cancer Center of Excellence designation will submit a progress report annually detailing quality metrics and ongoing progress to improve the quality of care.

Rating Standards

The rating system is pass-fail. If the organization does not meet each of the high Performance Standards 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 Standard is Not Met. Rating standards are defined for each Performance Standard. For example, in order 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 Standards

Area I: Organization

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

Explanation

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 Medicare-certified and may choose to be accredited, for example, by The Joint Commission or CMS. Accredited hospitals meeting Chapter 59A-3.253(3), Florida Administrative Code 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 be hold a license in good standing.

Regulatory and Guidance References
Chapter 395, Part I, Florida Statutes; Chapter 408, Part II, Florida Statutes; Chapter 59A-3.253(3), Florida Administrative Code.

Required Written Materials
Written materials should 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 should be provided. Written materials should describe the process to obtain and maintain a license. If the organization also has chosen to be accredited, for example, by the Joint Commission, or CMS, then written materials should 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 Center for Medicaid Services, or Joint Commission, or other accreditations
- Records of any pending actions again the organization by any regulatory oversight agency
- Documentation of the resolution of licensing problems and accreditation problems

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

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

Professional Organization Practice Guidelines

- Web site of the American College of Surgeons Commission on Cancer: http://www.facs.org/cancer/

Required Written Materials
Written materials should 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 Commission on Cancer accreditation.
- Records of any pending actions again the organization by the Commission on Cancer, such as notice that an accreditation standard is not met upon a re-accreditation.
- Documentation of the resolution of accreditation problems.

Standard 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.

Explanation
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 of Health. 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 of their activities and use the results to improve their effectiveness.

The organization should have substantive and meaningful ongoing participation in at least one cancer collaborative. Substantial and meaningful participation involves 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 should 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

- National Comprehensive Cancer Control Program, Centers for Disease Control and Prevention
  http://www.cdc.gov/cancer/ncccp/

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

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

Explanation

High-quality cancer care depends upon research, such as clinical trials and comparative effectiveness research, to inform medical decisions. The organization should 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, and to do so in a rigorous way. Scientifically rigorous research is defined by the standards of quality generally accepted by a community of researchers. One indication of rigorous research is that the project has been subjected to the scrutiny analysis by scientific peers and is found to involve sound research design and other standards of scientific quality. Scientific peer review can occur in a number of 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 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 should 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 should demonstrate that it conducts research that is scientifically rigorous, and that rigorous research is conducted across a comprehensive research program, including at least four of the following 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 in 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 system to ensure that new cancer treatments and research knowledge actually reaches 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, diagnosis 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 should describe the number of publications and the quality of the journals. Because research results are regularly not implemented in practice, the organization should 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 should describe when research findings from its researchers changed clinical practice or otherwise had an impact on the quality of cancer care.

Professional Organization Guidelines and Consensus Statements

- *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, Institute of Medicine (2013).
- Doris McGartland Rubio, PhD, Ellie E. Schoenbaum, MD, Linda S. Lee, PhD, David E. Schteingart, MD, Paul R. Marantz, MD, MPH, Karl E. Anderson, MD, Lauren Dewey Platt, PhD, Adriana Baez, PhD, and Karin Esposito, MD, PhD Defining Translational Research: Implications for Training. Acad Med. 2010 March; 85(3): 470–475.

Regulatory and Guidance References

None

Required Written Materials

- 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
- List of publications in peer-reviewed journals
- Patents and other intellectual property

Common types of materials that may be used

- Research plan
- Evaluation reports

Standard I.5 The organization integrates rigorous cancer training and education of biomedical researchers and health care professionals.

Explanation

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 should 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 should demonstrate the clinical training of health professionals who provide specialized care for cancer patients through national accredited processes of training and education.

The organization should demonstrate biomedical researcher training through external peer reviewed scientific programs to support the transition of new investigators to independent investigators, nationally recognized programs such as K, T, R25 or similar career development awards.

Professional Organization Practice Guidelines

- Accreditation Council for Graduate Medical Education
  http://www.acgme.org
- National Institutes of Health Office of Intramural Training and Education
  https://www.training.nih.gov/programs

Regulatory and Guidance References

None available

Required Written Materials

- List of clinician-investigators who have secured grant funding awards for new investigators, including fellowships, individual and institutional career awards, training grants, and other awards targeted at new investigators during the past three years.
- When relying upon other accreditation bodies to meet parts of this Standard, 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.

Standard I.6 The Organization meets and provides enhanced cancer care coordination which, at a minimum, focus 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

Explanation

Members of the care team should 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 should demonstrate the systematic integration of support for the patient and family, including behavioral health specialists, clinical licensed social workers, case managers, patient navigators, counseling services, spiritual support, cancer support groups, and financial counselors. The organization should have knowledge of community resources. If the organization provides care at multiple locations or through partners, these resources should be provided throughout the patient journey and monitored by the organization to ensure effectiveness.
The organization should 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 should discuss clinical trials in person, and may discuss a clinical research network with patients. The organization should 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 should 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 should provide end-of-life care consistent with their needs, values, and preferences.
The organization should 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 should obtain feedback from patients and family members, evaluate feedback, and use that information to improve care.

Professional Organization Practice Guidelines

- American College of Surgeons Commission on Cancer Care http://www.facs.org/cancer/
- Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis, Institute of Medicine (2013).

Required Written Materials

- Written materials, such as policies and procedures or electronic decision system screen shots 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

Standard I.7 The organization 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.

Explanation

Adopting a continuous comprehensive quality indicator system is associated with improved cancer treatment outcomes. The organization should describe a process for adopting comprehensive standards, and have a process to evaluate standards annually at a minimum. The organization should 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 should have a comprehensive system of quality

improvement and performance improvement. The organization should adopt and implement a continuous comprehensive quality indicator system and report annually on quality metrics. The organization should show how outcomes at the organization improve over time and how outcomes compare with established benchmarks. The organization should implement advances balancing innovations in the field and the need to have sufficient evidence to ensure the efficacy of the intervention. The organization should incorporate the results of outcome-tracking research and other information when evaluating standards. The organization should have an organizational culture committed to improving quality.

Professional Organization Practice Guidelines

- Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis, Institute of Medicine (2013).
- Quality Oncology Practice Initiative
  http://qopi.asco.org
- International Organization for Standardization ISO 9000 Standards for Quality Management
  http://www.iso.org/iso/iso_9000

Required Written Materials

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

Common types of materials that may be used

- Documentation of accreditation by QOPI or that a site visit has been scheduled
- Documentation of another process showing outcome measures meeting or exceeding national standards

Standard I.8. 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.

Explanation

The organization must have an accredited human research protection program and Institutional Review Board for review of research involving human participants. Accreditation of the 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.

Professional Organization Practice Guidelines

- Preserving Public Trust: Accreditation and Human Research Protection Programs. Institute of Medicine. (2001).
- Association for Accreditation of Human Research Protection Programs

http://www.aahrpp.org
- National Cancer Institute Central IRB
  https://ncicirb.org/cirb/

Regulatory and Guidance References
- National Cancer Institute Central IRB Policies
  https://ncicirb.org/cirb/

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

Standard I.9 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.

Explanation
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
- Review of the Clinical and Translational Science Awards Program at the National Center for Advancing Translational Sciences. Institute of Medicine. (2013).

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

Area II: Healthcare professionals and researchers

Performance standards:

Standard 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 health care organizations

Explanation

Healthcare professionals should seek out feedback from peers about the treatment plan, and regularly review this with the team. For example, physicians should 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 should 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 should be documentation that these discussions occurred. Physicians should 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

- Web sites 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

Area III: Patients and family members

Performance standards:

Standard III.1 The organization should provide ongoing opportunities for the patient to provide all the information to the healthcare team that is relevant to care and treatment decisions.

Standard III.2 The organization should provide ongoing opportunities for the patient to communicate concerns and worries that might affect cancer treatment.

Standard III.3 The organization should provide ongoing opportunities for the patient to improve their understanding of their cancer.

Standard III.4 The organization should provide ongoing opportunities for the patient to keep follow up appointments to ensure continuity of care

Standard III.5 The organization should provide 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, and 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

- Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis, Institute of Medicine (2013).
- American College of Surgeons Commission on Cancer Care http://www.facs.org/cancer/
- Quality Oncology Practice Initiative http://qopi.asco.org

Regulatory and Guidance References

None available

Required Written Materials

- Policies and procedures requiring documentation that healthcare 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 follow-up 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.