August 13, 2013

10:00 a.m. to 3:00 p.m.

Conference call (888) 670-3525

Conference code 2922384719

Orange County Health Department

6101 Lake Ellenor Drive

Orlando, Florida 32809

(407) 858-1403

Joint Committee on Performance Standards, Rating System, and Rating Standards for Cancer Centers of Excellence, s. 318.925 Florida Statutes

Meeting Minutes

Attendance

Joint Committee

- Daniel Armstrong, Ph.D., (University of Miami) Miami (BRAC Chair)
- Thomas George, MD, FACP (University of Florida) Gainesville (C-CRAB Chair)
- Zenesha Barkley, DNP, MSN, RN, CNE (Bethune-Cookman) (C-CRAB)
- Joanne Bujnoski, DO, FACRO (Florida Osteopathic Association) Pensacola (C-CRAB)
- Barbara Centeno, MD. (Moffitt Cancer Center) Tampa (BRAC)
- Representative Marti Coley Marianna (C-CRAB)
- Randal Henderson, MD, MBA (University of Florida Jacksonville) Jacksonville (BRAC)
- Edith Perez, MD (Mayo Clinic) Jacksonville (BRAC)
- Brian Rivers, Ph.D., MPH (Moffitt Cancer Center) Tampa (C-CRAB)
- Gerald Robbins, MD (American Cancer Society) New Port Richey (C-CRAB)
- Eric Sandler, MD (Florida Association of Pediatric Tumor Programs) Jacksonville (C-CRAB)

DOH Staff

- John H. Armstrong, MD, FACS Surgeon General and Secretary of Health
- Robert Hood, Ph.D., Manager, Public Health Research Unit
- Sarah Hofmeister, Research Program Analyst, Public Health Research Unit

The meeting was called to order at 10:20 am.

A quorum was present. The quorum is defined as a majority of the 13 members of the Joint Committee, including both chairs.

I. Introduction

The chairs reviewed the statutory charge to the Joint Committee to develop performance standards, a rating system and rating standards to recognize the highest quality providers and designate them as Cancer Centers of Excellence.

II. Perspectives

Representative Coley provided a Legislative perspective on Cancer Centers of Excellence. The Legislative intent is to improve the quality of cancer care, ensure that patients stay in state and are able to receive high quality care, and make Florida a destination for cancer care by recognizing organizations that provide the highest quality of care in the state. It is essential that the Joint Committee develop specific standards that set a high bar for quality, even if fewer organizations receive the Cancer Centers of Excellence designation – quality is most important. The Legislature intends that cancer research is an essential function of a Cancer Center of Excellence, and that organizations must demonstrate that research plays a prominent role in cancer care. To be designated a Cancer Center of Excellence, it will be necessary for a cancer provider to show it conducts high quality research and uses the results to improve cancer care.

Dr. Armstrong provided the perspective from the Department of Health about implementation of the statute. He described other Department activities that being coordinated with the implementation of the Cancer Center of Excellence designation. Dr. Armstrong charged the Biomedical Research Advisory Board, which advises the Surgeon General on the scope and direction of the research grant program, to develop a research agenda by October 2013 that will improve health and health outcomes through research on prevention and care. He has charged the BRAC to consider what will be best for each cancer patient, and whether providing the highest quality care for some cancers might require a regional approach, and to make recommendations on cancer research networks and that these networks include community outreach efforts. He stressed the importance of including community outreach efforts to ensure that if participating in a cancer research trial is the best option for a patient, that each cancer patient in Florida has this option and is able to stay in the state and receive high-quality care close to their family and friends. Dr. Armstrong noted that DOH is expanding the use of the cancer registry in research, and in 2013 reached an agreement to include Department of Veterans Affairs hospitals in the cancer registry, which provides more accurate reporting of cancer incidence in the state.

III. Joint Committee Operating Procedures

The joint committee reviewed and approved without revision a policy describing the authority and operation of the Joint Committee.

Total members voting:

Votes in favor: 11 Votes against: 0 Abstentions: 0

Members not present: 0

IV. Proposed Cancer Center Manual describing performance standards, rating system and rating standards

Staff proposed that the Joint Committee produce a manual that will provide organizations all the information needed to apply for designation, and all the information evaluators need to evaluate organizations.

The proposed manual will include:

- Standards grouped into three Areas: responsibilities of the healthcare organization, responsibilities of healthcare providers, and responsibilities of patients and families.
- Standards explained in a consistent format, including the following sections: an explanation of the Standard; a list of legal or regulatory compliance requirements; a list of relevant professional practice standards; a list of required written materials; a list of materials that may be commonly used to meet the standard; and a description of the outcomes for each Standard.
- A rating system that is focused on outcomes and is flexible and open to different approaches provided the organization achieves high quality standards.
- A rating standard based on a pass-fail determination for each Standard. In order to be designated a Cancer Center of Excellence the organization will need to pass all Standards (not just a majority of standards, or not just a combined average score, or an aggregate score over a certain amount).
- A brief annual status report detailing quality metrics and ongoing progress to improve the quality of care.

There was consensus to proceed using this framework. However, the Joint Committee did not take a vote to approve the framework pending development and review of specific standards.

V. Discussion of performance standards

The Joint Committee reviewed Standards required by statute, and several additional proposed standards, and identified areas that the Joint Committee will need to clarify or that will require research and additional information from staff. No votes were taken, because this was a preliminary review for purposes of conducting an initial review of the standards and questions that will need to be addressed.

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

Members discussed whether applicant organizations should be required to disclose any problems with licensure that arise during the application process (for example, compliance problems or pending actions).

- Staff will review with the Office of General Counsel prior to next meeting and present results to the Joint Committee.

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

Some members expressed concern that certain organizations in the state will not meet certain eligibility requirements. The chairs clarified this is a requirement in statute and the Legislature required ACOS accreditation. No action is required.

Standard I.3 The organization actively 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. (Required by statute)

Members discussed the need to clarify standards for collaboration and identify minimum performance standards for participating in a collaborative. For example, the Standard may need to define tangible outcomes for participating in collaboratives and link participation to patient outcomes.

- Staff will provide list of collaboratives and a description of their function prior to next meeting and present results to the Joint Committee.

Standard I.4. The organization demonstrates excellence in and dissemination of scientifically rigorous cancer research. (Required by statute)

Members discussed the need to address the following in future meetings:

- Define excellence in research and establish a threshold of acceptable progress
- Define dissemination of research, and establish a threshold of the amount of activity and appropriate mechanisms (e.g., dissemination in professional publications; dissemination within the organization in a way that makes results available to patients; dissemination to communities).
- Define "rigorous" research, and whether this should be limited to clinical trials, or include health systems research and quality improvement research
- Clarify the extent to which researchers at the organization must initiate research and develop their own studies (demonstration of research leadership), or whether participation in research networks, research consortia, cooperative groups or industry-sponsored research counts toward this standard, and whether listing of results in clinicaltrials.gov would count as an acceptable standard.
- Clarify whether the standard should include consideration of authorship and the impact factor of publications as part of the evaluation (e.g., if a researcher enrolls 20 patients in a national trial that results in benefits to patients count, even if this role results only in an acknowledgement rather than authorship on a publication?)
- Define acceptable thresholds for research infrastructure (e.g., auditing, monitoring data integrity)

Standard I.5 The organization integrates training and education of biomedical researchers and health care professionals. (Required by statute)

Members discussed the need to address the following in future meetings:

- What type of training and education programs are acceptable (scientific training, training in grant writing, training research integrity and human participant protections)
- The amount of research training required
- Ways of demonstrating that research training and education resulted in improvements in the workforce and improved participation in research, and improvements in the quality of research
- Whether diversity in the biomedical workforce and cancer professionals should be included

Standard I.6 (Required by statute) 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 providers.

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.

Members discussed the need to address the following in future meetings:

- Define coordination of care, and thresholds for adequate coordination
- Establish operational criteria for enhanced care coordination
- Specify how to evaluate whether enhanced coordination impacts health outcomes
- Define family services, survivor services, aftercare and other terms and develop thresholds of acceptable performance (for example, whether referral to an external organization for palliative care is acceptable)
- Include prevention activities within each of these elements
- Determine if clinical trial staff or research liaison fits in this arena as part of the cancer care coordination

Standard I.7 The organization adopts evidence-based practice standards, and periodically evaluates of the implementation of these standards and makes a summary of the evaluation available to prospective patients and family members.

There was consensus that a Cancer Center of Excellence should report adherence with quality indicators and outcomes.

Members discussed the need to address the following in future meetings:

- Define and identify thresholds for evidence-based practice, based on the principle that the role of the Standard is to impact care. For example, there has been large-scale research on quality indicators that shows how adoption of certain clinical procedures can have measurable impacts on mortality, and that it may be best to focus on certain cancers, and specifically require organizations to implement certain practices, when these have been shown to demonstrably improve morbidity and mortality (e.g., defining targets for diagnosis and treatment such as from time of mammography to time of treatment)
- Decide whether to require adoption of certain specific quality indicators or require organizations to be certified by the Quality Oncology Practice Initiative (QOPI-certified) which includes peer-review and external auditing, or whether to allow organizations flexibility in which external metrics to adopt.
- Whether to focus on one cancer in the initial application cycle, such as lung cancer or breast cancer, or to focus on one where there is evidence about standards of care that impact mortality.
- Consider defining the organization must demonstrate the process through which this is met as opposed to the specific program or measurement

Standard I.8. When conducting research, has studies reviewed by an accredited human research protection program and IRB, to ensure the highest ethical standards.

There was consensus to require that a Cancer Center of Excellence have cancer research reviewed by an accredited IRB, such as the Association for Accreditation of Human Research Protection Programs. No further action required.

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.

Members discussed the need to address the following in future meetings:

- Define acceptable research partnerships; decide whether relationships with drug companies constitute acceptable partnerships
- Specify acceptable thresholds of collaboration and participation in a research network
- Provide examples of research networks and collaborations

- Whether to require a center of excellence to collect information in addition to that required by the cancer registry, vital statistics and the trauma registry.

Staff will provide information about geocoding in the cancer registry and vital statistics data and the trauma registry and present results, including a publication that utilizes cancer registry geo-coded data to the Joint Committee

Area II: Healthcare providers and researchers

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 providers (required by statute)

Members discussed the need to address the following in future meetings:

- Specify ways of evaluating whether physicians provide accurate and complete info on treatment options for all patients, and clarify how much information needs to be provided, and how this should be documented
- Whether to require evaluation of the effectiveness of the communication of information to patients
- Reporting of performance outcomes in annual reports to the Joint Committee (perhaps through a few specific priority cancers: lung, pancreas, sarcoma, as examples)
- Assurance of organizational infrastructure for outcomes-based evidence reporting

Area III: Patients and family members

Standard III.1 Patients should provide all the information to the healthcare team that is relevant to care and treatment decisions.

Standard III.2 Patients need to communicate concerns worries that might affect cancer treatment.

Standard III.3 Patients should read or view educational materials to improve their understanding of their cancer.

Standard III.4 Patients should make sure they keep follow up appointments to ensure continuity of care

Standard III.5 Patients should include a friend or family member in the care process.

Standard III.6 The organization demonstrates meaningful community outreach activities to support cancer patients and caregivers, prevention efforts, and education.

There was consensus on the need to develop standards around patients and family members, however the draft standards may not be the right ones.

Members discussed the need to address the following in future meetings:

- how to evaluate the organizational culture to assess whether patient needs are prioritized
- how to evaluate the success of organizational efforts, using something more than patient satisfaction measures
- way of including patients and community members in development of questions
- evaluation of the culture by which the organization engages with the community

VI Discussion of rating system and rating standard

Members discussed the need to address in future meetings standards for conflict of interest of evaluators who will conduct site visits.

- Suggested ratings included a “yes”, “no” or “no + comment” for applications in meeting the standards. Only a “yes” score would satisfy the requirement. Application information and data would be confirmed at the site visit.
- Staff will review with the Office of General Counsel and report to the Joint Committee.

VII Public Comment

A suggestion was made to adopt ensure that a Cancer Center of Excellence adopts policies to require a smoke-free campus, provides support services for smoking cessation as part of care integration, and actively participates in community-based tobacco-prevention activities.

VIII Adjournment

The meeting adjourned at 2:45 p.m.