

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

Manual of Standards for Licensing of Ambulatory Care Facilities

Radiation Oncology: Radiology Oncology Services Quality Improvement Methods

Hospital Licensing Standards

Radiation and Radiation Oncology: Radiation Therapy Continuous Quality

Improvement Methods

Stroke Centers

Adopted Repeal and New Rule: N.J.A.C. 8:43G-7A Appendix

Adopted Amendments: N.J.A.C. 8:43A-1.3, 2.2, 2.3, 2.4, 2.5, 2.8, 2.9, 3.3, 3.4, 3.6, 3.7, 12.7, 16.3, 23.3, 28.3, 28.7, 29.1, 30.7, 30.10, 33.1, and 33.4; and 8:43G-2.13, 5.16, 7.23, 7.28, 7A.6, 12.12, 15.1, 16.1, 23.6, 28.19, 28.24, and 32.23

Proposed: August 19, 2019, at 51 N.J.R. 1316(a).

Adopted: March 18, 2021, by Judith M. Persichilli, RN, BSN, MA, Commissioner, Department of Health, in consultation with the Health Care Administration Board.

Filed: March 31, 2021, as R.2021 d.039, **without change**.

Authority: N.J.S.A. 26:2H-1 et seq., particularly 26:2H-5.

Effective Date: May 3, 2021.

Expiration Dates: November 21, 2021, N.J.A.C. 8:43A; and

December 18, 2024, N.J.A.C. 8:43G.

Summary of Public Comments and Agency responses:

The Department of Health (Department) received two comments on the notice of proposal. The number in parentheses following each comment corresponds to the commenter number listed below.

1. Laura I. Thevenot, Chief Executive Officer, American Society of Radiation Oncology (ASTRO), Arlington, VA.

2. Molly Gabel, MD, Medical Director, Radiation Oncology Services, Summit Medical Group, Berkeley Heights, NJ, and Associate Professor, MD Anderson Cancer Center, Camden, NJ.

1. COMMENT: The commenter states: “The American Society for Radiation Oncology (ASTRO) appreciates the New Jersey Department of Health accepting our petition for rulemaking, and we support the proposed amendments to [N.J.A.C.] 8:43A-30.7, Radiation oncology services quality improvement methods, and [N.J.A.C.] 8:43G-28.19, Radiation therapy continuous quality improvement methods of the New Jersey Administrative Code to include ASTRO’s Accreditation Program for Excellence (APEX®) as a recognized accrediting body for radiation oncology facilities. ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO’s highest priority has always been ensuring patients receive the safest, most effective treatments. ASTRO believes it is essential for New Jersey radiation oncology facilities to have choice in accreditation programs. [APEX®] was created to support quality

improvement in radiation therapy practices and establishes standards of performance derived from white papers and consensus practice guidance for radiation oncology. The mission of [APEX®] is to recognize facilities by objectively assessing the radiation oncology care team, policies and procedures, and the facility. Facilities that obtain [APEX®] accreditation demonstrate a commitment to delivering safe, high-quality patient care.” (1)

2. COMMENT: The commenter states: “As medical director for a newly developed service in radiation oncology at Summit Medical group, when designing our department, I purposefully chose to design my department based on the [APEX®] quality standards and policies. Although I recognize that until several years ago, the only accreditation institutions that were offered were from the American College of Radiology and the American College of Radiation Oncology, our society developed a Program for Accreditation that is much more relevant and meaningful to our patient population. Each standard, which we must abide by, ensures that patients are getting [evidence-based] care and that all aspects of their care are addressed in detail before and after their course of radiation treatments. For example, [APEX®] requires that we document a plan of care for pain for all patients, that we discuss with and document the intent of the treatment course (i.e. the curative, postoperative, palliative) prior to consenting the patient, that we ensure radiation safety both according to [the New Jersey Department of Environmental Protection] but also for patients who may be pregnant or have an implantable electronic medical device. Lastly, patterns of care are addressed to ensure that the practitioners are not prolonging radiation treatment plans for financial gain. I, and my colleagues, respectfully request that you endorse [APEX®]

as a New Jersey accepted accreditation institution, not for the sake of New Jersey physicians but for the sake of the patients that we treat.” (2)

RESPONSE TO COMMENTS 1 AND 2: The Department acknowledges the commenters’ support of the rulemaking and takes no position as to the commenters’ representations.

Federal Standards Statement

42 CFR Part 416 establishes standards applicable to ambulatory care facilities in New Jersey. 42 CFR 416.40 requires ambulatory surgical centers to comply with State licensure requirements.

The Social Security Act, at 42 U.S.C. § 1396(a)(29) and 42 U.S.C. § 1396(g), and its implementing regulations at 42 CFR Parts 431, 482, and 483, establish standards applicable to hospitals in New Jersey. 43 CFR 482.11(b) requires hospitals to be licensed or approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

A Federal standards analysis is not required because the adopted repeal, amendments, and new rule would be consistent with, but not exceed, these applicable Federal standards.

Full text of the adoption follows:

TEXT