

RADIATION THERAPY

Background

- Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells by damaging their DNA. X-rays, gamma rays, and charged particles are types of radiation used for cancer treatment.
- Radiation therapy can damage normal cells as well as cancer cells. Therefore, treatment must be carefully planned to minimize side effects.
- The radiation used for cancer treatment may come from a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near tumor cells (internal radiation therapy, also called brachytherapy), or directly administered either orally or intravenously. If directly administered, systemic radiation therapy uses radioactive substances, such as radioactive iodine, that kill cancer cells.
- Radiation therapy systems have become more complex and have been refined to better target the cancer and minimize surrounding tissue damage through “image guided radiation therapy” (IGRT) and “intensity modulated radiation therapy” (IMRT). The advanced systems rely on computer networks and electronic data storage.
- About half of all cancer patients receive some type of radiation therapy sometime during the course of their treatment. A patient may receive radiation therapy before, during, or after surgery, depending on the type of cancer being treated. Some patients receive radiation therapy alone, and some receive radiation therapy in combination with chemotherapy.
- Treatment often involves short, daily treatments for consecutive weeks or months. Integrated community based care offers patients access to services which is convenient and allows patients to have access to all their care in an integrated, local setting.

Current Federal and NYS Regulations

The federal Atomic Energy Act of 1954 authorizes the Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. NYS, under this law, is an “agreement state” and as such the state agrees to adopt and enforce standards that are comparable or exceed the federal rules.

The DOH Bureau of Environmental Radiation Protection (BERP) oversees the requirements of 10 NYCRR Part 16, the state regulations that comply with this. BERP has amended Part 16 as of May 2013 to update the quality assurance provisions and

require that RT providers be accredited by the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO) or another equivalent organization within 18 months of the effective date of the regulations.

Options

1. CON with licensure and include a requirement to serve Medicaid/uninsured

Options:

- Consider grandfathering for existing practices.

Pros:

- Will subject free standing RT not connected with an Article 28 facility to the same CON need criteria review as RT in an Article 28.
- May enhance quality oversight similar to Article 28 based RT.
- Enhances access to services for the Medicaid and uninsured populations.
- CON review could assist with concerns about over supply and over utilization.

Cons:

- Creates additional requirements for providers that are already regulated by Part 16.
- Some professional associations, insurers are requiring that additional standards be met (accreditation, professional practice guidelines).
- Requires development of a need methodology. In addition, implementation could delay other projects.
- May inhibit expansion of services and innovative care delivery models which may affect patient access to services.

Federal/State Models:

- Most large states have standards for radiation safety in radiation therapy similar to NYS's Part 16. Many have similar QA requirements as well, although NY has been a leader in the area of radiation safety. All providers using radioactive materials must comply with federal NRC requirements; however the vast majority of RT is done using linear accelerators (LINACs) and these generally fall under state regulatory authority.

- CON/licensure in other states varies and must be clearly defined as some states include what NYS would identify as a “character and competence” review in licensure, but assert they do not have CON.
- New Jersey- Since 2004 LINACS removed from CON, licensure continued through policy (not a regulation). Licensing includes a character and competence review and physical plant requirements. There are no accreditation requirements.
- Connecticut- Non-hospital based LINACS require a CON. Licensure is not required for physician practices that have LINACS, but CON is. CON is primarily a need review, with some financial and access reviews and no architectural review. Architecture review is included in licensure.
- Massachusetts- Beginning in 2009 physician based operators could no longer apply for exemptions to “Determination of Need” (DON). Existing practices were grandfathered in over a 6 month period.
- CMS-RT is exempt from the federal Medicare Improvement for Patients and Providers (MIPPA) Act of 2008 (see Advanced Diagnostic Imaging paper). There have been recent proposals to include RT but nothing has been enacted.

FACILITIES AND SERVICES REGULATED BY CON

| Regulated Services | No. of States | States, Districts & Commonwealth |
|---------------------------|----------------------|--|
| Radiation Therapy | 23 | AL, AK, CT, DE, GA, HI, IA, KY, ME, MA, MI, MS, MO, NH, NY, NC, RI, SC, TN, VT, VA, WV, DC |

Source: AHPA, 2011; as found on the website of the NCSL – National Conference of State Legislatures

2. Require Licensure Alone

Options:

- Provide authority for oversight of operations, similar to existing regulations promulgated pursuant to Article 28, eg. 10 NYCRR Part 405 (general hospitals), Part 755 (ASCs), in addition to Part 16 requirements. This operational oversight is known as “licensure”.
- Require utilization of certified electronic health records that are connected to the Statewide Health Information Network for New York (SHIN-NY) and Regional Health Information Organizations (RHIOS).

- Require compliance with Statewide Policy Guidance for sharing of electronic patient health information.

Pros:

- Avoids the issues with CON, yet does provide some oversight.
- Addresses some of the business/practice issues that are outside of radiation safety regulations.
- Patient information will be available to the patient's primary care provider, and any specialists involved in their care.

Cons:

- Redundant to add another DOH regulatory structure in OHSM when BERP area already regulates via Part 16.
- Licensure alone does not address inappropriate utilization or overutilization concerns.
- Licensure requirements may meet with resistance from physicians and other interested parties.

2. Registration of physician practices and require data collection and submission to DOH

Options:

- Require that practices register with DOH and provide data on location, practice size, services, payers and quality measures.

Pros:

- Identify geographic areas that have gaps in coverage and see trends in quality and safety with more focused data.
- Data could be used to assist in review of Article 28 CON applications and licenses.

Cons:

- BERP has some data as RT providers must comply with Part 16. This data does not include payer mix, or any quality measures outside of radiation related

parameters. BERP reviews a large amount of QA data and some treatment data, but very little that is relevant to CON or licensure.

- May be redundant since BERP Part 16 requirements were recently amended to include accreditation and additional quality/safety standards. However, they do not require data collection and reporting directly to DOH.

3. Accreditation

There are many accrediting options for RT. The American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) and The Joint Commission (TJC) have programs. Regulations, such as Part 16, are used to set minimum standards that must be met for simple, straightforward items. Accreditation can then be used to address more complex situations that may involve clinical judgment, are rapidly changing or involve business aspects that drive utilization. BERP is already requiring accreditation for RT via Part 16, but is limited to minimum standards that must be met for straightforward items. National accreditation can then be used to address more complex situations that may involve clinical judgment, are rapidly changing or involve business aspects that drive utilization.

Pros:

- Ensure appropriate credentialing for staff and quality and safety standards.
- May prevent providers from using equipment that is below current standards of care.
- Less burdensome for providers than CON and/or licensure.
- Provides an alternative to DOH licensure and surveillance of sites.
- Consistent with CMS MIPPA requirements.

Cons:

- Does not directly address overutilization.
- Does not address access for Medicaid beneficiaries or destabilization of essential providers.
- Cost to providers for accreditation.
- Accreditation may not have the same requirements as regulation (should vs. shall).
- Does not provide DOH with the quality, safety and other data described in option.

5. Prohibit in-office self-referrals by amending federal or New York State Stark laws.

Pros:

- Directly addresses the issue of overutilization.
- Increases patient choice.
- Reduces unnecessary costs.

Cons:

- Could inhibit patient access to convenient services.