



Ambulatory Services Recommendations

PHHPC

Health Planning Committee

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Advanced Medical Imaging

Potential Issues to be Addressed

- Utilization
- Quality and Patient Safety
- Cost

Physician Self-Referrals

- Stark Laws:
 - Federal
 - State – Public Health Law (PHL) § 238-a(2)(b)
- In-Office Ancillary Services Exception

Federal Efforts – Improve Quality and Control Cost

- Medicare Improvements for Patient and Providers Act of 2008
 - Requires Accreditation
- Deficit Reduction Act of 2005
 - Caps technical component



Current Regulatory Environment

Registration and Inspections

Article 28 Providers and Private Physician Offices:

- All x-ray equipment (CT, x-ray, fluoroscopy) is routinely inspected by the registering agency every 1-4 years.
- Nuclear medicine licensees, including PET, are inspected approximately every 3 to 5 years.
- MRI and ultrasound are not inspected.
- Inspection and registration are focused on image quality assurance and radiation safety, not need assessment or clinical practice.

Certificate of Need (CON) Requirements

Article 28 Providers:

- Hospital applications to operate MRIs and CTs subject to limited CON review.
- D&TC applications to operate MRIs and CTs subject to administrative CON review.
- No CON review for PET scanners.

Note: An Article 28 CON review does not take into account the impact of physician-owned equipment in the service area.

Private Physician Offices:

- No CON review required.

Advanced Imaging Services: States with CON

Regulated Services	No. of States	States, Districts & Commonwealth
Computer Tomography (CT) Scanners	13	AK, CT, HI, ME, MI, MO, NY, NC, RI, VT, VA, WV, DC
Magnetic Resonance Imaging (MRI) Scanners	19	AK, CT, HI, KY, ME, MA, MI, MS, MO, NH, NY, NC, RI, SC, TN, VT, VA, WV, DC
Mobile Hi Technology (CT / MRI / PET, etc)	16	AK, CT, HI, KY, ME, MI, MO, NH, NY, NC, RI, SC, VT, VA, WV, DC
Positron Emission Tomography (PET) Scanners	20	AK, CT, DE, GA, HI, KY, ME, MA, MI, MS, MO, NH, NC, RI, SC, TN, VT, VA, WV, DC



Potential Recommendations based on 12/4 Discussion

Uniform Definition

- Define advanced diagnostic imaging using the Federal definition as defined in the Medicare Improvements for Patients and Providers (MIPPA) language, modified as needed.

Definition: Language

- MIPPA definition of advanced medical imaging:
 - Section 135(B) Advanced Diagnostic Imaging Services Defined – In this subsection, the term ‘advanced diagnostic imaging services’ includes –
 - (i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and
 - (ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

Accreditation

Article 28 Providers and Private Physician Offices:

- Secure third party accreditation by a national accreditation organization approved by the Department. This will establish health care standards and address quality/patient safety.
- If a provider loses its accreditation, the provider and the accrediting body (through a collaborative agreement) would be required to report such change to the Department of Health in a timely fashion.
 - DOH has developed Part 16 amendments that will require accreditation of all CT operators. This recommendation would extend accreditation requirements to MRI and PET scans.

Evidence-Based Practice

- Referring practitioners should be required to use evidence-based practice guidelines to determine appropriateness of medical imaging options. This will address excess utilization and quality/safety.
- All Article 28 facilities and private physician offices that refer patients for advanced medical imaging would be required to implement evidence-based practice guidelines that are acceptable to the Department. They may adopt existing recommendations such as the American College of Radiology's (ACR) "Appropriateness Criteria" or other practice guidelines approved by the Department including developing their own.

Radiation Dose/Effects: Provider and Public Education

- The Department should work with provider associations to provide outreach and education to practitioners who prescribe CT scans (or other medical imaging studies as determined by the Department) regarding ionizing radiation and risks.
- The Department should promote public education campaigns on the benefits and risks of advanced medical imaging.

Certificate of Need/ Expanded Registration

- Retain current CON requirements for Article 28 providers.
- Require expanded registration for all providers. This will provide information to identify gaps in coverage.

Expanded Registration

- Require expanded registration with data submission for all Article 28 and private physician offices that have advanced medical imaging equipment or purchase new equipment.
 - E.g. location, practice size, services, and payer mix
- Require that all expanded registration data be collected and maintained by one point of contact in the Department.
- No more than three years after expanded registration/data submission is begun and data is analyzed, evaluate if any further actions are indicated.

Regulatory Amendments

- Amend Title 10, Part 16 regulations to add definition of advanced medical imaging.
- Revise Part 16 regulations to require all advanced medical imaging providers to obtain accreditation by accrediting organizations approved by the Department and use evidence-based guidelines.
- Revise Part 16 regulations to require all advanced medical imaging providers, including Article 28 and private physician offices, to submit expanded registration data to the Department.



Advanced Medical Imaging Discussion



Radiation Therapy

What is included in RT?

- External beam radiation – LINACS
- Brachytherapy
- Advanced RT systems - IGRT and IMRT
- Approximately 50% of cancer patients receive RT

Potential Issues to be Addressed

- Access
- Utilization
- Quality and Patient Safety
- Cost

Federal and NYS Oversight

- Atomic Energy Act of 1954 - NRC regulates radioactive materials
- RT exempt from MIPPA Act of 2008
- DOH-BERP - Part 16
 - “agreement state” for NRC compliance
 - “licensed” or “registered” if they meet Part 16
 - Amendments to Part 16 in May 2013 enhance QI and require accreditation by ACR, ACRO, or equivalent organization within 18 months

Other States

- All providers that use radioactive materials must comply with NRC requirements
- Most large states have RT requirements similar to Part 16



Current Regulatory Environment

Registration and Inspection

Article 28 Providers and Private Physician Offices:

- All radiation producing therapy equipment is registered by NYS or NYC DOH.
- All radiation producing therapy equipment is routinely inspected by the registering agency every 2 years.
- Inspection and registration are focused on quality assurance and radiation safety, not need assessment, clinical practice or appropriateness.

Accreditation

Article 28 Providers and Private Physician Offices:

- Part 16 amendments that went into effect May 2013, require all RT facilities to become accredited by either ACR or ACRO by the end of 2014. Through the accreditation process, the use of evidence-based practice guidelines will be required to ensure consistency with best practices.
 - The American College of Radiology (ACR) and the American College of Radiation Oncology (ACRO) have established practice guidelines for radiation therapy.
 - Use of these guidelines will assist in addressing the concerns raised about the appropriate use of certain types of RT, such as intensity modulated radiation therapy (IMRT) for prostate cancer cases.

CON Requirements

- CON required for Article 28 RT providers.
 - Full CON review required.
 - An Article 28 CON review does not take into account the impact of physician-owned RT in the service area.
- CON not required for private physician offices that provide RT.



Potential Recommendations based on 12/4 Discussion

Accreditation

- Extend third party accreditation requirements to include the following:
 - If a provider loses its accreditation, the provider and the accrediting body (through a collaborative agreement) would be required to report such change to the Department of Health in a timely fashion.

Certificate of Need/ Expanded Registration

- Retain CON for Article 28 radiation therapy providers.
- Require expanded registration for all providers. This will provide information to identify gaps in coverage.

Expanded Registration

- Require expanded registration with data submission for all providers including existing providers that have radiation therapy equipment or new providers purchasing such equipment.
 - E.g. location, practice size, services, and payer mix
- Require that all expanded registration data be collected and maintained by one point of contact in the Department.
- No more than three years after expanded registration/data submission is begun and data is analyzed, evaluate if any further actions are indicated.

Proton Beam Therapy

- These recommendations do not apply to the proton beam therapy (PBT) medical technology demonstration.

Regulatory Amendments

- Amend Title 10, Part 16 to require if a radiation therapy provider loses its accreditation, the provider and the accrediting body would be required to report such change to the Department of Health in a timely fashion.
- Revise Part 16 regulations to require all radiation therapy providers, including Article 28 and private physician offices, to submit expanded registration data to the Department.



Radiation Therapy Discussion