Ambulatory Services Recommendations

Health Planning Committee

December 4, 2013

Non-Hospital Surgery Recommendations

Ambulatory Surgery

- Currently Ambulatory Surgery is highly regulated by both CMS and NYS.

- Recommendation:
  - Make no changes to current regulatory oversight of ambulatory surgery

Current Oversight: Office-based Surgery

- PHL 230-d, enacted in 2007, requires that surgical or invasive procedures involving more than minimal sedation or local anesthesia or liposuction of 500mls or greater performed by designated licensees (includes physicians, physician assistants and specialist assistants) in a non-Article 28 setting to become accredited and file adverse event reports with the Patient Safety Center.
  - Currently there are approximately 1000 accredited OBS practices.
- As of February 2014 this law will apply to podiatrists privileged to perform ankle surgery.

Office-based Surgery Advisory Committee

- Existing statute (PHL 230-d) developed with guidance of the Committee on Quality Assurance in OBS appointed by the Public Health Council.
  - OBS Advisory Committee continues to provide feedback and guidance to the Department on matters related to OBS. Recommendations endorsed by the Committee will be highlighted as part of the presentation.

Guiding Tenets of OBS Reform

- Primacy of patient safety and quality
- Importance of adherence to standards of practice and delivery of appropriate care in OBS settings - consistent with the Triple Aim.
- Necessity of data to assure quality and safety, advance the science and contribute to healthcare planning and consumer decision making.

Registration

- Require registration of all new and existing OBS/OBA practices with the Department and submission of data as determined by the Department.

Definitions

- Clarify that neuraxial and major upper and lower extremity regional nerve blocks are included in OBS definition of "greater than minimal sedation or local anesthesia."
- Define office-based anesthesia (OBA) as general anesthesia, neuraxial anesthesia, major upper and lower extremity regional nerve blocks, moderate and deep sedation.
- Limit OBS/OBA procedural time to six hours and limit post-procedure time to meet discharge criteria to six hours.

Accreditation and Reporting of Adverse Event and other Data

- Require all physician practices performing procedures (including non-invasive procedures) utilizing more than minimal sedation to become accredited and file adverse event reports.
- Require all podiatry practices performing procedures (involving the foot as well as the ankle) utilizing more than minimal sedation to become accredited and file adverse event reports.
- Require OBS/OBA practices to submit procedural and quality data determined by the Department to accrediting agencies.
- Add "observation of longer than 24 hours within 3 days of OBS" to list of reportable adverse events and extend reporting time to 3 days/72 hours.

Accrediting Agencies

- Require accrediting agencies to share the outcomes of survey and complaint/referral investigations and other requested data with the Department.
- Require accrediting agencies to collect procedural and quality data determined by the Department from OBS/OBA practices and share it with the DOH upon request.
- Require accrediting agencies to survey OBS/OBA practices and carry out complaint/incident investigations upon DOH request.
- Require accrediting agencies to utilize American Board of Medical Specialties (ABMS) certification, hospital privileges or other equivalent determination of competency in assessing credentialing of practitioners to perform procedures.

Statutory Amendments

- Existing statute, PHL 230-d, will need to be amended.

Non-Hospital Surgery Discussion

Advanced Medical Imaging Recommendations

Current Regulatory Environment

- All x-ray equipment is registered by NYS or NYC DOH.
- All x-ray equipment is routinely inspected by the registering agency every 1-4 years.
- Inspection and registration are focused on image quality assurance and radiation safety, not need assessment or clinical practice.

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

- 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.

Patient Safety and Quality

- Secure third party accreditation by a national accreditation organization approved by the Department.
  - If a 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.
  - DOH has proposed Part 16 amendments that will require accreditation of all CT operators. This recommendation will extend accreditation requirements to MRI and PET scans and other imaging services, as determined.

Patient Safety and Quality

- Require use of evidence-based practice guidelines to determine appropriateness of medical imaging options.
  - Facilities will 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.

Patient Safety and Quality

- Require documentation in every patient's electronic medical record of the CT scan (or other medical imaging study as determined by the Department) and a measure of the radiation dose if the equipment is capable of providing this information (verified through routine inspection).

Registration

- Require registration and data submission for all providers including existing providers that have advanced medical imaging equipment or new providers purchasing such equipment.
  - E.g. practice size, services, payer mix

- Approximately three years after registration/ data submission is begun and data is analyzed, evaluate if Certificate of Need is indicated.

Statutory and Regulatory Amendments

- Revise Title 10 regulations to define 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.
- The Department will revise or promulgate new regulations to require documentation in the EMR of the CT, or other medical imaging study as determined by the Department, and radiation dosage used.
- Revise regulations to require all advanced medical imaging providers, Article 28 and private physician practices, to register with the Department and submit specified data.

Advanced Medical Imaging Discussion

Radiation Therapy Recommendations

Current Regulatory Environment

- 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 or clinical practice.

Radiation Therapy: Regulatory Update

- Starting in May 2013 all facilities are required to pursue accreditation and become accredited by the end of 2015 by either ACR or ACRO. 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.

Radiation Therapy: Current CON Requirements

- CON not required for private physician offices

- CON required for Article 28 radiation therapy providers
  - An Article 28 CON review does not take into account the impact of physician-owned RT in the service area.

Radiation Therapy Recommendation

- Eliminate CON for Article 28 Radiation Therapy Providers
  - There is considerable current oversight of all RT providers by DOH Bureau of Radiation Protection (BERP) and federal Nuclear Regulatory Commission (NRC).
  - Recent DOH BERP Part 16 Regulations require all providers be accredited by organizations such as the ACR and ACRO.
  - There are very few applications for this specialized service.

Note:

The above recommendation does not impact the proton beam therapy (PBT) medical technology demonstration project.

Regulatory Amendment

- Through regulation, exempt CON requirements for radiation therapy.

Radiation Therapy Discussion

Upgraded D&TC Recommendations

Regulatory Amendments

- Revise Title 10, Section 752-2 of the regulations to remove UD&TCs.
  - There is no need for this model given the development of new models of care, including urgent care and hospital-based off-campus emergency departments.

Upgraded D&TC Discussion