Ambulatory Services: Non-Hospital Surgery

Ambulatory Surgery Centers & Office-Based Surgery Practices

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*Ambulatory Surgery Defined

*Those surgical procedures which need to be performed for safety reasons in an operating room on anesthetized patients requiring a stay of less than 24 hours' duration. (10 NYCRR Section 755.1)

*Why Discuss Ambulatory Surgery?

*Fully regulated under Article 28

*May have elements applicable to other modes of ambulatory care.

* Freestanding

* Hospital-based
  * On-site
  * Off-site (extension clinic)

* **Ambulatory Surgery Centers (ASCs)**

* Not owned or operated by a hospital

* Diagnostic and Treatment Center (D&TC) certified for ambulatory surgery

* **Freestanding ASCs**

Freestanding ASCs – How Many?

- 116 with Operating Certificates
  - 57 Multi-Specialty
  - 59 Single Specialty
- Most are owned by physicians

*Freestanding ASCs - Regulatory Requirements

*CON Review Required

*Article 28 Operational Oversight Requirements governing operations, physical plant, surveillance, SPARCS reporting, etc.

*Accreditation Required

Freestanding ASCs – Regulatory Requirements

- Contribute to HCRA Pools
  - 9.63% charge on payments from commercial insurers, Blues, self-insured plans, HMOs
  - 7.04% charge on Medicaid payments (State share portion)

Freestanding ASCs – Regulatory Requirements

* CON Review
  - Public Need
  - Financial Feasibility
  - Character and Competence

ASC CON Need Methodology

- Demonstrate feasibility based on expected demand and patient referral and use patterns.
- Expand access to care, including for underserved groups.
- Not based on population criteria, utilization standards or epidemiological factors.

*Office-Based Surgery Defined

*Any surgical or other invasive procedure, requiring general anesthesia, moderate sedation, or deep sedation, and any liposuction procedure, where such surgical or other invasive procedure or liposuction is performed by a licensee in a location other than a hospital, as such term is defined in Article 28, excluding minor procedures and procedures requiring minimal sedation. (PHL 230-d)

*Office-Based Surgery Authority & Oversight

- *Authority to practice medicine established in Education Law
- *Authority to perform OBS limited by PHL 230-d to accredited medical practices
- *Oversight of professional medical practice carried out by (OPMC), the Office of Professional Medical Conduct

Office-Based Surgery Statute

- PHL Article 230-d:
  - Defined Office-based Surgery (OBS)
  - Identified that the statute applied only to specific licensees (physicians, PAs & SAs)
  - Identified minor procedures performed with local anesthesia or minimal sedation as exempt
  - Identified that practices performing OBS must attain and maintain accreditation
  - Required adverse event reporting

Office-Based Surgery Related Statutes

* Made performance of OBS in an unaccredited office unprofessional conduct

* Made failure to file an OBS adverse event report professional misconduct

*Office-Based Surgery

- *OBS practices do not require CON
- *OBS practices have no operational oversight, commonly referred to as licensure, in the traditional sense
- *OBS practices do not contribute to the HCRA pool.

*Non-Hospital Surgery Summary

Ambulatory Surgery* Centers

* Oversight established in PHL Article 28 and via the Medicare CoP
* ASC are facilities primarily owned and operated by physicians
* CON required
* Operational oversight authorized via Article 28 PHL (generally referred to as licensure)
* Accreditation required
* Currently 116 open and operating ASC.

Office-Based Surgery* Practices

* Oversight established in PHL 230-d & Article 131 Ed. Law
* OBS practices are private physician office practices in which OBS is performed
* CON not required
* DOH has no operational oversight over OBS practices
* Accreditation required
* As of June 2013 there were 997 open and accredited OBS practices.

*Freestanding ASCs – Option 1

Maintain Current Regulations and Oversight

- *Pros:
  - *Maintenance of comparable regulatory footing for hospital-based and freestanding ASCs;
  - *CON Review prevents undue proliferation of ASCs and possible over-utilization of surgical services;
  - *CON Review for character and competence and acceptable ownership and governance.

*Freestanding ASCs – Option 1

Maintain Current Regulations and Oversight

- *Pros (cont'd.):
  - *Maintenance of quality through Article 28 monitoring and surveillance;
  - *Through HCRA contribution requirements, compensation for favorable case selection;
  - *Certification for CMS participation (Medicare and Medicaid);
  - *Required utilization of EHRs and SHIN-NY and RHIO participation

*Freestanding ASCs – Option 1

Maintain Current Regulations and Oversight

*Cons:

*None identified

*Freestanding ASCs - Option 2

Accreditation Only and Medicare CoP

*Pros:

*None identified

*Freestanding ASCs - Option 2

Accreditation Only and Medicare CoP

*Cons:

- *Removal of comparable regulatory footing between freestanding and hospital-based ASCs
- *Proliferation of ASCs and possible over-utilization of surgery;
- *No review of character and competence or ownership and governance.

*Freestanding ASCs - Option 2

Accreditation Only and Medicare CoP

*Cons (cont'd.):

- *Loss of Article 28 monitoring and oversight
- *Loss of SPARCS reporting
- *Loss of contributions to HCRA pools
- *Need for separate process for Medicare and Medicaid participation
- *Loss of EHR and clinical data-sharing through RHIOs and SHIN-NY.

*Office-Based Surgery Option 1

Broaden premise of the law to include any medical procedure requiring greater than minimal sedation and/or local/topical anesthesia to perform the procedure and/or attain/maintain adequate patient comfort performed in a private office practice.

- *Maintain current requirements for accreditation and adverse event reporting;
- *AKA Office-Based Anesthesia (OBA)

*Office-Based Surgery Option 1

Pros:

* Clarifies intent to include neuraxial and upper and lower extremity major conduction blocks;
* Assures one standard of care for patients undergoing procedures (invasive and non-invasive) in private medical offices with greater than minimal sedation via requirements for accreditation and adverse event reporting;
* Responsive to continuing evolution of health care toward non and minimally invasive procedures
* Consistent with other states that do not limit procedures to invasive but rather oversee based on levels of sedation/ anesthesia provided.

*Office-Based Surgery Option 1

Cons:

* Potential opposition from currently unaffected practitioners;
* Cost of accreditation for currently unaccredited office practices;
* Maintains payment inequities between regulated ASCs and accredited practices.

*Office-Based Surgery Option 2

Require OBS/OBA practices to register with DOH and submit specific information, e.g. services provided, service specific quality and safety indicators, payer mix.

- *With or with out expansion of law as described in number 1;
- *Maintain current requirements for accreditation and adverse event reporting.

*Office-Based Surgery Option 2

Pros:

* Same as in Option 1;
* Gives DOH the authority to collect data and require participation in RHIOs, etc.;
* Maintains compliance with Statewide Policy Guidance for sharing of electronic health information;
* Provides information to the DOH that is currently not available that could be made available to the public, be used in planning, identify collaborative quality improvement opportunities, etc.

Office-Based Surgery Option 2

Cons:

* Same as in Option 1
* Increased demands on practices to register and collect and submit data.

*Office-Based Surgery Option 3

Require operational oversight, similar to that of Article 28 (commonly referred to as licensure), of OBS/OBA practices who provide services such that 4 or more patients are rendered incapable of self preservation at one time.

Pros:

* Operational oversight gives DOH the authority to:
  * Require compliance with regulation, e.g. physical plant, patient selection by ASA class and/or anesthesia type, procedural and post-procedure recovery, etc.;

*Office-Based Surgery Option 3

Pros, cont.:

* Operational oversight gives DOH the authority to:
  * Require submission of data, e.g. services provided, safety and quality indicators, payer mix, etc.;
  * Require participation in the Medicaid Program;
  * Require payment into the HCRA fund;
  * Require utilization of certified EHR connected to the Statewide Health Information Network (SHIN-NY) and Regional Health Information Networks (RHIOs);
  * Survey and inspect

*Office-Based Surgery Option 3

Pros, cont'd:

* Playing field is more even between ASCs and OBS/OBA practices;
* Goal of OBS/OBA practices of receiving a facility fee would be accomplished.

*Office-Based Surgery Option 3

Cons:

* May exceed DOH authority by “regulating the practice of medicine” --unless the operational oversight model chosen is that of existing ASC model;
* May increase the cost of health care if practices begin to routinely receive a facility fee for services.
* Would increase the work and the likely cost of practices required to attain this more regulated model of oversight.

*Office-Based Surgery Option 4

Require operational oversight similar to Article 28 (commonly referred to as licensure) of OBS practices performing level 2 and level 3 plastic and cosmetic procedures.

Pros:

* There are higher risks of complications associated with longer surgical and anesthesia times and use of general anesthesia (GA); some of the plastic/cosmetic surgery procedures performed in OBS are quite long using GA—longer than other procedure times associated with other specialties reported via adverse event reports.

*Office-Based Surgery Option 4

Pros, cont'd:

* Complications associated with plastics/cosmetic cases performed in offices often make the news and provoke questions about quality of care and raise questions about lack of DOH oversight.
* Operational oversight is viewed by the public as an assurance of quality and safety.
* Require compliance with regulation, e.g. physical plant, patient selection by ASA class and/or anesthesia type, procedural and post-procedure recovery, etc.;
* Same as those identified above in Option 3 related to authority granted to DOH

*Office-Based Surgery Option 4

Cons:

* All plastic/cosmetic surgeons may not welcome increased oversight of their practices
* Cost of care may increase due to eligibility for receipt of facility.
* Disparate requirements for plastic/cosmetic surgeons/procedures.

*Office-Based Surgery Option 5

Standardize/differentiate name/terminology used in describing non-inpatient surgical services in all sites, e.g. ASCs, OBS, Hospital OPDs, other venues.

Pros:

* Standardizing naming convention would decrease confusion among public and health care providers;
* Promote differentiation between provider types and clarify distribution of services across the state;
* Assist in establishing a baseline with which to assist in evaluation of data and provider types across jurisdictions.

*Office-Based Surgery Option 5

Cons:

* Would require inter-agency, and potentially state and federal, collaboration;
* Some practices may need to change their names—which would legal and other costs;
* Maybe seen as an added unnecessary bureaucratic intervention with minimal added benefit for providers or the public.