Reform Options to Consider for Oversight of Non-Hospital Surgery

Executive Summary

The migration of medical and surgical care to the non-hospital setting is well documented. Under current New York State law, surgery performed in non-hospital settings is categorized and overseen according to the setting in which it occurs: 1) freestanding ambulatory surgery centers (ASC) and 2) office-based surgery practices (OBSP).

- Ambulatory surgery is defined in the regulations of Article 28 of Public Health Law (PHL) as: "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. These procedures do not include those outpatient surgical procedures which can be performed safely in a private physician's office or an outpatient treatment room." (10 NYCRR section 755.1)
- Office-based surgery (OBS) is defined in PHL 230-d as "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 twenty-eight of this chapter, excluding minor procedures and procedures requiring minimal sedation."

ASC are highly regulated and authorized to perform non-hospital surgery by both the Centers for Medicare and Medicaid Services (CMS) and Department of Health (DOH) regulations that require both CON and facility licensure. Physicians are authorized to practice medicine and surgery by their medical license and Education Law. Physicians seeking to provide office based surgery services are required by PHL 230-d to have their practices attain and maintain accreditation and file select adverse event reports. Although it is evident that there is some overlap in the types of procedures performed in freestanding ASC and OBSP, the lack of currently available data precludes an accurate comparison of procedure types, outcomes or complications occurring in these two settings.

Procedural and surgical care is generally considered to be safe and of sufficient quality in both ASCs and OBSP, with the acknowledgement that patients with significant co-morbidities and risk of complication(s) are generally directed to the hospital for their surgical/procedural care.

Development of options for reform of oversight of freestanding ASCs and OBS offered below were guided by findings, experiences and knowledge of NYS and other state practices, policies and outstanding issues, and efforts to ensure surgical care quality and patient safety.

Freestanding Ambulatory Surgery Centers

Options

1. Maintain current regulations and oversight.

Pros:

- Maintenance of a comparable regulatory footing for hospital-based and freestanding ASCs, since both are subject to Article 28 regulations governing operations, physical plant, surveillance, quality improvement and SPARCS reporting;
- Through CON review:
  - ⇒ Prevention of an undue proliferation of freestanding ASCs and possible over-utilization of surgical services;
  - ⇒ Assurance of operator character and competence, and of acceptable ownership and governance arrangements for freestanding ASCs.
- Maintenance of quality in freestanding ASC services through Article 28 monitoring and surveillance;
- Through HCRA contribution requirements, compensation for favorable case selection, whether intentional or unintentional, by freestanding ASCs vis-à-vis hospitals.
- Certification for CMS participation (Medicare and Medicaid) through DOH review process.
- Maintains required 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).
- Maintains required compliance with Statewide Policy Guidance for sharing of electronic patient health information.

Cons:

- None identified at this time.

State Models:

- Of the 37 states that operate CON programs (including the District of Columbia), 27 require CON review for ASCs. However, the review criteria vary considerably from state to state, as do the definitions of ASCs and of ambulatory surgery itself. Massachusetts, for example, subjects only those ASCs with costs of over $25 million to CON review. Maryland and Georgia define ASCs as non-hospital surgical venues with two or more operating rooms, while Illinois defines an ASC as any medical practice where more than 50 percent of the activity is surgical. A number of states define public need for ASCs in non-numerical terms, while others link it to utilization of existing OR's or to other measurable indicators. These inconsistencies make state-to-state comparisons difficult, especially since a number of states employ a broad definition of ambulatory surgery that encompasses what in New York State is considered office-based surgery. Few lessons can be drawn in comparing New York's State's experience with ASCs to that of other jurisdictions.

2. Deregulate/Revise/Eliminate CON and/or licensure requirements and maintain only current requirements for accreditation and compliance with Medicare Conditions of Participation.

Pros:

- None identified at this time.

Cons:

- Removal of comparable regulatory footing for freestanding ASCs and hospital-based ASCs;
- Proliferation of freestanding ASCs and possible over-utilization of surgical services;
- No review of operator character and competence or of ownership and governance arrangements;
- Loss of Article 28 monitoring and oversight for quality and safety;
- Loss of ASC payer and utilization data currently reported to SPARCS;
- Loss of contributions to HCRA pools;

- Need for separate process for Medicare and Medicaid participation;
- Loss of clinical data sharing mandate via RHIOs and SHIN-NY.

Office-Based Surgery

Options:

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 patient comfort performed in a private office practice setting; maintain requirements for accreditation and adverse event reporting for OBS.**

Pros:

- Added patient safety and consistency for all patients undergoing medical procedure(s), invasive or not, when receiving more than local and/or minimal sedation when treated in accredited settings. Currently there are procedures being performed with greater than minimal sedation in private practices that are not OBS accredited;
- Expansion of the law would address continuing evolution of health care toward less invasive procedures when accompanied by greater than minimal sedation or local/topical anesthesia.
- Clarifies the intent of legislation to include neuraxial and other methods of regional anesthesia as well as interpretation of procedures involving more than minimal sedation or local/topical anesthesia as "non-minor" procedures.

Cons:

- Potential opposition among currently exempted MD groups;
- Cost of accreditation for currently unaccredited office practices;
- Maintains potential inequities that currently exist (OBSP not paying into HCRA fund; having to negotiate with payers for fees, both professional and facility)

State Models:

- Many states regulate/guide practice of OBS/OBA by describing different levels of procedures and/or sedation/anesthesia, including all medical procedures (whether invasive or not) in their definitions. (See attached state summary)

2. **Require OBS/OBA practices to register with DOH and submit specific information related to services provided, payer mix and quality and safety indicators appropriate to population served; maintain accreditation and adverse event reporting; with or without expansion of law as describe in number 1 above.**

Pros:

- Same as above, plus:
- Gives DOH authority to collect data
- Create more of a level playing field between ASCs and OBS
- Provides DOH with information related to practices that may be made available to the public, may help in planning, will increase DOH knowledge of OBS/OBA practices to assist in Department understanding, data analysis, etc.
- Maintains required 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).
- Maintains required compliance with Statewide Policy Guidance for sharing of electronic patient health information.

Cons:

- Potential opposition to increased administrative and reporting requirements for OBS providers;
- Increased demand for practices to register and collect and submit data/information.

State Models – See attached table:

- Approximately ¼ of the states require submission of adverse event data;
- A number of states that require licensure/registration, and submission of information regarding services/procedures provided;
- Tennessee requires submission of claims data quarterly.

3. **Require operational oversight similar to Article 28 (licensure) of OBS/OBA practices (as defined above) who provide services such that 4 or more patients rendered incapable of self-preservation at one time.**

Pros:

- Operational oversight gives DOH the authority to:
  - Require compliance with regulations, e.g. physical plant, patient selection by ASA class and/or anesthesia type, procedural and post-procedure recovery time, etc.;
  - 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 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.
  - Survey and inspect;
- Playing field would be more even between ASC and OBS/OBA practices.
- Providers of this service would welcome assurance of payment of the facility fee in addition to professional fee payments;

Cons:

- May exceed DOH authority by "regulating the practice of medicine"—unless the operational oversight model chosen is that of the existing ASC model;
- Increased increase the cost of health care if practices routinely receive a facility fee;
- Increase in processes and costs required of practices to become licensed.

State Models:

- Multiple states place limits on the types of procedures and/or anesthesia/sedation that can be performed on patients with significant co-morbidities, e.g. ASA 3

patients must get clearance prior to procedures; ASA 4 & 5 patients cannot have a procedure requiring general anesthesia in an office.

- One state prevents OBS procedures on children < 2 years old and limits what procedures can be performed on children 2-14 years old in private offices.

4. Require operational oversight similar to Article 28 (licensure) of OBS practices performing level 2 and level 3 cosmetic/plastic surgeries.

Pros:

- Same as first and third arrow in option 3 above;
- Plastic or cosmetic surgery cases involving complications often make the news and provoke questions about quality of care and DOH oversight; theoretically, requiring licensure would reduce some of those questions and provide patients with increased comfort regarding safety.
- Some plastic/cosmetic cases are long and involve prolonged post-procedure time; licensure could limit post-procedure time and standardize care requirements.

Cons:

- Physician providers may not support an increase in state oversight of their practices;
- Other than length of procedure/anesthesia time and need for a longer post-op recovery in some of these cases, these patients are no different than most other OBS patients. State would be treating one group of surgical providers differently than others.

State Models:

- Many states' rules/guidelines contain a special focus on plastic/cosmetic procedures—specifically liposuction (limiting the amount of fat that can be removed and doses of lidocaine that can be given in tumescent anesthesia);
- Some states limit procedural time and recovery/time to discharge;
- NJ is currently contemplating disallowing liposuction in non-licensed or non-accredited settings.

5. Standardize/differentiate naming/terminology used to describe non-inpatient surgical services in all sites of care: ASCs, OBS and Hospital OPDs, other venues.

Pros:

- Standardizing naming would help reduce confusion among the public and health care providers;
- Would promote differentiation between provider types and clarify distribution of services across the state;
- Would help to establish a baseline with which to assist in evaluation of data and provider types across jurisdictions/states.

Cons:

- Would require inter-agency collaboration;
- Practices may need to change names which would include legal and other costs.
- May be seen as added and unnecessary bureaucratic intervention with minimal added benefit for providers or consumers.

State Models:

- States vary in if and how they differentiate between office-based and ambulatory surgery.