



Non-Hospital Surgery in New York Ambulatory Surgery Centers and Office-Based Surgery Background

Executive Summary

The migration of medical and surgical care to ambulatory settings is undeniable. Ambulatory surgical care occurs in a variety of settings with various levels of oversight and regulation. Non-hospital surgery performed in ambulatory surgery centers (ASC) is highly regulated at both the state and federal level. In contrast, private practices of medicine are unregulated except those that perform invasive and/or surgical procedures that must become office-based surgery (OBS) accredited and report adverse events. Surgical care provided in non-hospital settings is generally considered safe and of sufficient quality. The cost of non-hospital surgery is lower than hospital-based surgery; with regulated facilities receiving higher reimbursements for the same procedures as offices—primarily due to receipt of a facility fee. Regulated facilities, including free-standing ambulatory surgery centers pay into the HCRA fund; office-based surgical practices do not.

There are a number of policy issues of relevance to the subject including: cost and appropriate site of care, sharing of space among regulated and unregulated entities as well as between OBS practices and unaffiliated physicians. Based on analysis of analysis of OBS adverse events and in response to the ever evolving landscape of healthcare, changes to the OBS statute are being pursued.

A review of the literature and state models revealed there are a variety of methods and models in place to oversee and regulate non-hospital surgery. A number of reform options for both ASCs and OBS practices are presented for your consideration.

Migration of Care to Outpatient Settings

The literature reports the migration of invasive and surgical procedures to ambulatory settings, including physician offices, noting the incentives to be: changes in population and health care prevention and surveillance recommendations, evolution of technology, payment schemes favoring outpatient procedures; physician control of schedules, staffing, policies, procedures, equipment, etc in private offices and physician owned ambulatory surgery centers (ASC); and patient convenience, comfort and choice based on infection control, privacy and other concerns.

Medicare periodically publishes a list of ambulatory surgery procedures that they will reimburse. The current list includes approximately 2000 procedures. Office-based surgery practices take this list into consideration when establishing the practices' scope of services. Though a number of factors are taken into consideration when scheduling a patient for a procedure in a one surgical care setting verses another, patient safety is primary. The risks and benefits of each procedure and associated sedation and/or anesthesia and each individual patient's medical history are evaluated. Based on this evaluation, the most setting most appropriate for the patient is selected.

A 2004 MedPac report to Congress reported that 60-70% of invasive and surgical procedures were being performed in an ambulatory setting (hospital outpatient department, freestanding ASCs and office-based surgery practices), with the expectation that these numbers would only increase. KNG Health Consulting, a health economics and policy firm, in 2009 published a report titled "An Analysis of Recent Growth in Ambulatory Surgery Centers" commissioned by the ASC Coalition revealed that 46% of the distribution of Medicare payments to ASCs in 2007 were for eye procedures (40% cataract related), 25% were for gastrointestinal procedures (17% colonoscopy & 8% upper GI), 10% were for pain management procedures and 7% were for orthopedic procedures. The report goes on to note that almost all Medicare growth in ambulatory surgery services from 2000-2007 was primarily due to growth in the number of services per beneficiary. KNG estimated that 70% of growth in service volume per beneficiary during this period could be attributed to migration of services from hospital outpatient departments to ambulatory surgery centers and other non-hospital surgical settings. For example, for colonoscopy and upper gastrointestinal procedures hospital outpatient department market share fell from 75% to less than 60% between 2000 and 2007, while physician' office share remained approximately 5% nationally.

Analysis of SPARCS data submitted by ASC can be analyzed to identify the procedures most frequently performed in ASCs – a request for analysis of this data is pending. Currently

there is minimal data available to the Department that identifies the procedures being performed in OBS practices. The Department is also exploring analysis of Medicaid data to gain additional information regarding procedures performed in OBS offices. Though not necessarily representative of all office-based surgery practices or procedures, OBS adverse event reports submitted to the Department in the time period 2010-2012 most frequently involved gastrointestinal procedures (All: 43%; colonoscopy 33% & upper GI 10%), followed by vascular procedures (All: 32%; access related 27% & other vascular 5%), and genitourinary procedures 11%. It is clear from OBS adverse event data that there is overlap between procedures being performed in OBS practices, ASCs and hospital outpatient departments.

KNG noted the significant growth in the number of ASC from 2000-2007 nationally. Growth of ASC in NYS, however, has been slower than in many other states and may have contributed to the growth in office-based provision of invasive and surgical services.

Oversight of Non-Hospital Surgery in NYS

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 (ASCs) and 2) office-based surgery practices (OBSP). This paper discusses each separately.

Ambulatory Surgery

Ambulatory surgery is defined in the regulations of Article 28 of the Public Health Law 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)¹

ASCs are of two types: hospital-based and freestanding. Hospital-based ASCs may be located at the same site as the hospital (on-site) or apart from the hospital (off-site). Non-hospital ASCs (i.e., those not owned, operated or sponsored by a hospital) are referred to as independent or freestanding ASCs. There are currently 114 freestanding ASCs operating in New York State, the majority of which are owned by physicians. Of these 116 facilities, 59 are single-specialty ASCs and 57 are multi-specialty ASCs (i.e., authorized to perform any ambulatory surgery procedure).

¹ Surgical procedures carried out in a procedure room, such as endoscopy, are also defined as ambulatory surgery for reporting purposes and must be reported as ambulatory surgery under Section 400.18. of the SPARCS regulations

Like hospitals, freestanding ASCs are subject to Certificate of Need (CON) review, for public need, financial feasibility and operator character and competence. Like other Article 28 facilities, they are also subject to review for compliance with the architectural and engineering requirements of Parts 711 and 715 of the State's medical facilities construction code. The Department also solicits comments from neighboring hospitals to evaluate whether a proposed ASC would have an adverse effect on the hospitals' surgical cases and revenues and on their community-oriented programs.

ASCs must comply with the staffing and other operational requirements set forth in Parts 405 and 755 of Article 28 regulations. In addition, NYS law and regulation require ASCs to submit adverse event to NYPORTS and to report procedure and payer information to SPARCS. Freestanding ASCs must become accredited by a national accrediting organization within two years of PHHPC approval. Closures of freestanding ASCs are rare, and virtually all ASCs renew their individual accreditation as required.

ASCs, whether freestanding or hospital-operated, are subject to the need methodology set forth in 10 NYCRR Section 709.5. This regulation states that need for an ASC is demonstrated through the ASC applicant's documentation that the capacity of the proposed ASC will be utilized sufficiently to be financially feasible, as demonstrated by a three-year analysis of projected costs and revenues associated with the program, based on expected demand and expected patient referral and use patterns. This definition is not based on demographic or epidemiological factors, projected trends in demand for surgery, utilization of existing surgical facilities or private practices or other measurable indicators. As a result, there is no estimate of the number of ASCs that would be necessary to satisfy public need for ASC services in New York State.

Ambulatory Surgery in Other States

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.

Office-Based Surgery

Office-based surgery in NYS is governed by PHL Article 2, Title 2-A, Section 230-d Office-based Surgery; Article 29-d, Title 2, Section 2998-d Reporting of Adverse Events in OBS and Education Law Article 131-A, Title 8, Section 6530 Definitions of Professional Misconduct Applicable to Physicians, Physician Assistants and Specialist Assistants. These laws resulted from the work of the second Committee on Quality Assurance (QA) in Office-based Surgery (OBS) that was commissioned in the fall of 2005 by the Commissioner of Health and Public Health Council to develop recommendations to ensure quality of care and patient safety in office-based surgical practices.

PHL 230-d, and related OBS legislation were signed into law in 2007 and require private physician practices performing invasive or surgical procedures involving more than minimal sedation (moderate sedation, deep sedation and general anesthesia) or liposuction of greater than 500 ml to become accredited and report select adverse events identified in the law. No OBS regulations have been written to date. NYS was an "early adopter" of meaningful OBS oversight based on the concern of the Department and the legislature about the increase in the number and complexity of procedures and sedation/anesthesia being performed in private physician practices as well as the occurrence of complications occurring in patients undergoing OBS.

As of June 2013 there are 997 accredited OBS practices. Office-based surgery practices are not required to demonstrate need and are not licensed by NYS. However, as noted above, what NY defines as OBS and refers to as an OBS practice is defined as ambulatory surgery and called an ASC in a number of other states. OBS adverse event data reveals that the types of procedures performed in OBS settings have some similarity to those performed in ambulatory ASC, but exact knowledge of procedures performed in this setting is not available at this time.

Approximately 27 states currently regulate OBS through rules, regulations, statute, guidelines and/or policy as follows (See attached Table of OBS Oversight for details):

- 19 states require or encourage accreditation, registration/certification or licensure;
- 13 states require adverse event reporting by OBS practices;
- A number of the states that do not require accreditation have rules that mimic the OBS guidelines suggested by the Federation of State Medical Boards (FSMB) in a 2000 report; guidelines that are similar to accrediting agency requirements.

A number of other specialty medical societies and associations have recommended guidelines for OBS seeking to assure OBS quality and patient safety, notably the American College of Surgeons and the American Society of Anesthesiologists.

Quality and Safety

According to Agency for Healthcare Research and Quality (AHRQ) only about 10% of patient safety studies are conducted in outpatient settings. In addition, the research on the quality/safety of outpatient surgery is confusing. The terms ambulatory surgery, outpatient surgery, and office-based surgery are used interchangeably and findings for all settings are frequently lumped together or not clearly differentiated from each other. The lack of a standardized definition of terms illustrates the need to clarify taxonomy and definition of terms.

In 2011 the American Medical Association published, “Research in Ambulatory Patient Safety-A Ten Year Review” which reviewed patient safety data from 2000-2010 for all types of ambulatory care, including surgery. The authors concluded that “Even using relaxed criteria, the peer reviewed literature on ambulatory patient safety was often limited and publications of research on safety interventions were almost non-existent.” In the absence of such clarity, reliance upon these studies and the experiences of other states should be viewed with caution and focus on the actual experience of ASCs and OBS practices in New York State and analysis of NY data is, for now, our best option.

Ambulatory Surgery

NYS Department of Health longitudinal surveillance of freestanding ASC’s has not identified any undue occurrence of adverse events or poor outcomes for this category of provider. In addition, the NYPORTS system has not received reports in numbers that would indicate that freestanding ASCs pose any unusual risk for poor surgical outcomes or substandard quality of care. It should be noted, however, that incidents documented in NYPORTS may be subject to underreporting. Therefore, this favorable picture for ASCs may be biased.

The NYS experience is consistent with the research literature on ASCs that shows few differences in quality between freestanding ASCs and hospital-based ambulatory surgery services (Chukmaitov et al, 2008). Although critics often contend that freestanding ASCs select lower-risk patients (“cherry-picking”), resulting in favorable outcomes, studies adjusted for differences in co-morbidity have found no significant differences in outcomes between hospital-based and freestanding ASCs. Like other Article 28 providers, freestanding ASCs are required to implement quality assurance programs.

Office-Based Surgery

In 2011 the American Medical Association published, “Research in Ambulatory Patient Safety-A Ten Year Review” which reviewed patient safety data from 2000-2010 for all types of ambulatory care, including surgery. The authors concluded that “Though some very high-quality work on ambulatory safety took place between 2000 and 2010, research and initiatives in ambulatory safety were remarkably limited, both in quantity and in the ability to generalize from the studies that were reported...Even using relaxed criteria, the peer reviewed literature on ambulatory patient safety was often limited and publications of research on safety interventions were almost non-existent.”

The AMA 2011 report notes that overall the published research on office-based surgical safety has been characterized by small studies using varied methods, as well as other significant limitations. Lack of the availability of denominator data is generally identified as a challenge in carrying out studies of OBS safety. Most of the research referenced on office-based surgery has examined adverse events of plastics and dermatologic procedures.

Perhaps because of these limitations, different authors have arrived at different conclusions regarding the overall safety of OBS. Some investigators have concluded that office-based surgery is generally safe (Balkrishnan et al, 2003a; Venkat et al, 2004; Hancox et al, 2004a). Others have concluded that office-based surgery is safe only for certain procedures or if certain conditions are met (Hoefflin et al, 2001; Clayman et al, 2006; Coldiron et al, 2008). Others have concluded that office-based surgery or anesthesia may expose patients to additional risk (Cote et al, 2000; Vila et al, 2003; Fleisher et al, 2004). Still others have concluded that more information would be needed to establish the safety of office-based surgery (Balkrishnan et al, 2003b; Cao et al, 2010).

Factors identified in the literature as being important to patient safety such as patient selection, co-morbidity, nature and complexity of procedure, and peri-operative management have been identified as issues of concern when reviewing OBS Adverse Event Reports received by the DOH Patient Safety Center.

Reimbursement and HCRA

Ambulatory Surgery Centers

Freestanding ASCs, like hospitals, receive a “facility fee” from public and private payers to reflect their more elaborate operations, staffing and physical plant compared to office-based settings. However, in 2008 Medicare undertook a phased in alignment of ASC reimbursement rates with the ambulatory payment classification (APC) groups used for

hospital outpatient departments, which resulted in an overall decrease in reimbursement rates for ASCs compared to hospitals.

Physicians performing procedures in freestanding ASCs and hospital settings are reimbursed a professional fee that is lower than they would receive for the same procedures performed in an office setting (site of service differential). Physicians performing procedures in ASC in which they have full or partial ownership also receive some component of the facility fees paid to the facility in addition to a professional fee.

The 2009 KNG report notes that almost 60% of growth in Medicare spending for ASCs between 2000 and 2007 was due to cataract surgeries, colonoscopies and upper gastrointestinal procedures. This report also notes an absolute increase in the number of pain management procedures performed and paid for by Medicare.

As noted above, the majority of freestanding ASCs in New York State are owned by physicians and are operated on a proprietary basis. The proportion of Medicaid and self-pay clients treated by freestanding ASCs is lower than that of hospital-based ASCs. However, HCRA imposes a charge of 9.63% on payments to freestanding ASCs from commercial insurers, Blue Cross, HMOs, self-insured plans and other non-governmental payers to support the HCRA pools, which aid hospitals in providing safety net services. A charge of 7.04% is also assessed on the ASCs' Medicaid revenues (State share portion). In 2012, these combined assessments on the revenues of freestanding ASCs resulted in payments of \$3.3 million to the HCRA pools.

Office-Based Surgery

Physicians performing procedures in private OBS office practices do not routinely receive a facility fee, though this is a matter of negotiation between the physician and private payers. Neither Medicare nor Medicaid pays a facility fee to OBS practices. Public and private payers routinely reimburse private practice physicians professional fees for covered procedures performed in OBS offices. Professional fees paid for procedures performed in this setting are generally higher than what the physician receives for performing the same procedure in a regulated setting, such as a freestanding or hospital-based ASC. Overall, the cost of surgical care in non-hospital settings is less costly than that delivered in hospital settings primarily due to reduced or non-payment of facility fees to outpatient and office settings, coupled with reduced professional fees for services rendered.

Each payer decides what they will pay for, how much they will pay and in what settings they will reimburse performance of procedures and other medical care. Medicare, Medicaid and private payers reimburse OBS practices for covered procedures, e.g. gastrointestinal,

genitourinary, pain management, etc. Medicare is the primary payer of end stage renal disease vascular access related care. OBS surgeons performing elective cosmetic/plastic surgery procedures report their primary payers as the patients themselves.

Medicare payments to physicians for OBS are based on current procedural terminology (CPT) codes and reimbursed at approximately 60% of the Medicare approved amounts. As noted above, the KNG report notes that for the period of 2000-2007 approximately 5% of reimbursed ambulatory surgery services were provided to private physician offices.

Medicare reimbursement for ambulatory surgery services to New York OBS physicians is unknown at this time. Similar to Medicare, the amount of care that private OBS practices provide to Medicaid and uninsured patients in New York State is unknown, though many of the invasive and surgical services they provide are reimbursed by both Medicaid fee for service and managed care plans.

OBS practices do not pay into the HCRA pool, no matter their size or service provision.

Issues with Policy Relevance to Non-Hospital Surgery

Ambulatory Surgery

Freestanding ASC's have a long history of regulation by the federal government and New York State. Freestanding ASCs are subject to federal Conditions of Participation, CON review and to Article 28 regulations governing physical plant, staffing, operations and surveillance, and reporting to SPARCS; and are required to contribute to the HCRA pools. DOH review of the staffing and operations of freestanding ASCs reflects CMS standards for ASC participation in the Medicare and Medicaid programs. While the Committee could consider amending or repealing New York's regulation applicable to freestanding ASCs, the movement of the health care system towards greater reliance on ambulatory modes of care and the likely continued growth of surgery outside of the traditional hospital setting would seem to reaffirm the need for the current regulation of freestanding ASCs, which has the following benefits:

- 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, intentional or unintentional, by freestanding ASCs vis-à-vis hospitals.

This experience in regulating freestanding ASCs may suggest interventions to govern other modes of current and emergent forms of ambulatory care.

Office-Based Surgery

Payment of Facility Fee to OBS Practices

The foci of the OBS laws are assurance of patient safety and quality of care. Accreditation and adverse event reporting are the methods used to achieve these objectives. Reimbursement of services provided in this setting has not historically been regulated by the Department, other than in Medicaid, in the same manner as the reimbursement of hospitals. Since OBS practices do not meet the criteria of a “facility” as defined in NYS law, neither Medicare nor Medicaid pay a facility fee to OBS practices.

Payment for OBS services, specifically receipt of the facility fee, is a very significant issue of concern to physician providers of OBS. The Department of Health has taken the position that payment for OBS services is a matter between the practice and the payers to negotiate. The private payer community is split but OBS physicians report that most payers, even those that previously paid them a facility fee, now do not pay one. Though the number of OBS practices has stayed stable, generally between 970 and 990 for the past 2 years (997 as of 06/2013), the DOH understands from physician OBS providers that it is increasingly fiscally impossible to make ends meet and closure of the practice or transition of the practice to an ambulatory surgery center is/may be necessary if this does not change.

Review of the literature and other states oversight of OBS identifies that payment, in most cases lack of payment of a facility fee, is an issue of concern for private physician office-based surgical practices in other states as well as NYS. A small number of states have language in their rules/guidelines that specify that OBS practices are not facilities; some going so far as to state that they don’t qualify for receipt of a facility fee.

Sharing Space

“Sharing space” has been a long standing issue among physicians, attorneys and regulators and has been the topic of increased interest of late due to the dislocation of physicians by Hurricane Sandy.

As noted above, PHL 230-d defines OBS as any surgical or other invasive procedure requiring, more than local or topical anesthesia or minimal sedation, or liposuction of greater than 500 ml, performed by a physician, physician assistant or specialist assistant in a location other than a hospital, as defined in Article twenty-eight. PHL 230-d also requires that physician practices performing OBS attain and maintain accreditation.

Multiple aspects of a medical practice seeking to provide office-based surgery are evaluated and surveyed as part of the accreditation process including, but not limited to, the following: the legal structure of the practice; the education, training and licensure of physicians and other health care practitioners providing care to patients of the practice; policies, procedures and protocols used to guide selection and care of patients and operations of the practice; physical plant and equipment used in the care of practice patients, etc. All office locations of the OBS practice must be so accredited and any/all new locations where OBS will be performed must be accredited before any OBS procedures are performed.

Only those practitioners who are part of the practice or who are providing services to the patients of the practice, as defined below, may perform procedures or provide anesthesia services in an accredited OBS office.

State Education Law prohibiting the corporate practice of the professions in NYS only allows private physician practices to be legally structured as one of the following: a sole practitioner; professional corporation (all of the shareholders, officers and directors must be physicians); professional limited liability company (all of the members and managers must be physicians); or university faculty practice corporation (all of the officers and directors must be physicians); general partnership (all of the partners must be physicians); registered limited liability partnership (all of the partners must be physicians).

An accredited OBS practice may not allow physicians or non-physician licensed health care practitioners who are not part of the practice in a manner noted above, or affiliated with the practice as employees of the OBS practice performing services within the scope of their employment or working under a contractual arrangement with the OBS practice, to perform procedural and/or sedation/anesthesia services, as applicable, for the OBS practice.

Physicians/licensed practitioners who are not part of or affiliated with an accredited OBS practice may not perform procedures or provide anesthesia services in an accredited setting on their own behalf simply because they have entered into arrangements such as leases that allow them to use space in an accredited OBS setting.

Title 10 NYCRR Section 600.8 provides detail regarding when a private practice must become licensed as an Article 28 health care facility. If a practice is “sharing” their accredited space with a physician or other licensed practitioner that is not affiliated with the practice in one of the ways noted above, then the practice may be subject to enforcement action as a scofflaw Article 28 facility

Questions regarding this issue are raised frequently by OBS practices because physicians would like to “share” their space with other physicians whose relationship with the accredited practice does not include any of the roles or relationships noted above. The questions generally revolve around “guest” or “renting” physicians who would be using the accredited practices space but providing services to his or her own patients.

Both Ambulatory Surgery Centers and OBS Practices

Appropriateness of Site and Cost of Care

June 1, 2013 the New York Times published an article, “The \$2.7 Trillion Medical Bill; Colonoscopies Explain Why U.S. Leads the World in Health Expenditures.” The article notes that colonoscopies were largely an office procedure when widespread screening was first recommended and have “moved to surgery centers....a lucrative step down from doctors’ examining rooms—which are billed like a quasi-operation.” It identifies colonoscopies as the most expensive screening test that healthy Americans routinely undergo and the average cost of a colonoscopy in the U.S. as \$1,185.00, much more expensive than in other developed countries.

The Times reported their findings as:

- In 2011, Medicare paid gastroenterologists an average of \$531.00 for a colonoscopy—this did not include payments for a facility fee or anesthesiologist care.
- A Long Island woman underwent 2 colonoscopies, one in a hospital outpatient surgery department-- billed as \$ 9, 142.84 (\$5,742.67 reimbursed including a facility fee) and a second in a doctor’s office—billed as \$ with \$5,322. 76 with \$2,922.63 reimbursed.
- Also on Long Island, a woman underwent a colonoscopy in an ambulatory surgery center. She was billed \$6,385 including \$1075 for the

gastroenterologist, \$2,400 for the anesthesiologist and \$2,910 for the facility fee.

The Times, and many other authors, raise questions about the differences in charges and reimbursements, why the same tests are billed, and reimbursed, at such different amounts per setting, if hospital and ambulatory surgery center care (and costs) are needed for certain, in most instances, low risk procedures, if “anesthesia services” are required for routine procedures that can be performed using different (non-anesthetic) medications or practitioners to administer them, etc.

Changes to OBS Statute Supported by the OBS Advisory Group

As more and more health care, including invasive and surgical care, migrated to the non-hospital setting the NYS DOH, and then Public Health Council, established the first Committee on Quality Assurance in Office-based Surgery in late 1997. In December 2000, the Department of Health published and the PHC endorsed the work of the committee in the form of Clinical Guidelines for Office-based Surgery. The Committee was re-commissioned in the fall of 2005 due to ongoing quality and safety concerns regarding OBS and in January 2007 the Department published the report of the committee. The report recommended that DOH seek to require private physician practices performing invasive and surgical procedures involving more than minimal sedation or local/topical anesthesia, or liposuction of over 500 ml in non-Article 28 settings to attain and maintain accreditation and report select adverse events to the Patient Safety Center (PSC). The OBS law requiring accreditation and adverse event reporting, PHL 230-d, was passed in the fall of 2007. The adverse event reporting requirement became effective in January 2008; the accreditation requirement became effective in July 2009.

Members of the original committee, new committee members and consulting physician specialists continue to work with PSC staff reviewing adverse events, adverse event data and advising on clinical and policy issues. Guided by a number of years of adverse event data and knowledge of the evolution of health care the OBS Advisory Group support a number of changes to the OBS laws:

1. Broaden premise of the law to include office-based sedation/anesthesia (OBA) greater than minimal sedation or local anesthesia when accompanying any medical or surgical procedure performed to diagnose or treat patients.
2. Broaden licensees included in the law to podiatrists, potentially dentists, and others whose scope of practice includes or evolves to include OBS or OBA.
3. Limit expected procedural and post-anesthesia care time to six hours.

4. Lengthen time to report adverse events from 24 hours to 72 hours.
5. Expand list of reportable adverse events to capture “observation” admissions to the hospital of greater than 24 hours and discharge of patients to the emergency department.
6. Require accrediting agencies to share specific information with DOH upon request, including:
 - a. Findings of survey(s) and complaint investigations
 - b. Available quality data
7. Require accredited OBS practices to respond to requests for information and data when requested.

DOH staff are in the early stages of pursuing these changes to the statute.