Pursuant to the authority vested in the Commissioner of Health by section 230-d(5) of the Public Health Law, Chapter IX of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The title of Chapter IX is amended to read as follows:

Chapter IX [Physician Profiling] Private Practice Reporting

The title of Part 1000 is amended to read as follows:

Part 1000 [Physician Profiles] Private Practice Reports

A new title Subpart 1000-1 is added and the section numbers of the sections in the existing Part 1000 are amended to read as follows:

Subpart 1000-1 Physician Profiles

Sec.

[1000.1]1000-1.1 Definitions.

[1000.2]1000-1.2 Criminal convictions.

[1000.3]1000-1.3 Malpractice awards, judgments and settlements.

[1000.4]1000-1.4 Collection of initial profile information.

[1000.5]1000-1.5 Updating self-reported information.

Paragraph (4) of subdivision (a) of section 1000-1.3 is amended to read as follows:

(4) place(s) of each award, judgment or settlement as specified by the department in accordance with section [1000.1(f)] 1000-1.1(f) of this [Part] Subpart; and

Clause (*b*) of subparagraph (ii) of paragraph (2) of subdivision (b) of section 1000-1.3 is amended to read as follows:

(b) Additional clinical information provided by a physician must be received by the department postmarked within 30 days of the date of the letter transmitting the physician's medical malpractice review copy as specified in section [1000.4(c)] 1000-1.4(c) of this [Part] Subpart. Requests for an extension of the 30-day period will be considered only if they: …

Subdivision (c) of section 1000-1.4 is amended to read as follows:

(c) Subsequent to receiving the physician's review copy, if returned within the time frame required by subdivision (b) of this section, the department will provide to the physician a copy of any medical malpractice information in the form to be used for public dissemination, hereafter referred to as the medical malpractice review copy. Physicians shall correct any factual inaccuracies on the medical malpractice review copy and return it to the department postmarked within 10 days of the date of the letter transmitting the medical malpractice review copy to the physician, or, in the instance where the physician has two or fewer medical malpractice settlements over the most recent 10-year period and opts to access the panel review process, shall provide additional factual clinical information pursuant to section [1000.3(b)(2)(ii)] 1000-1.3(b)(2)(ii) of this [Part] Subpart. If the physician does not respond in accordance with the timeframes set forth in this subdivision, the department will publicly disseminate the physician's medical malpractice information provided on the medical malpractice review copy.

A new Subpart 1000-2 and new sections 1000-2.1 and 1000-2.2 are added to read as follows:

Subpart 1000-2 Office-Based Surgery Practice Reports

Section 1000-2.1 Definitions. Words or phrases defined in Public Health Law §230-d shall have the same meanings in this Subpart.

Section 1000-2.2 Office-Based Surgery Reporting. Licensees shall submit data deemed necessary by the Department for the interpretation of adverse events. Data shall be submitted in a format specified by the Department. Such data shall include, but shall not be limited to:

(a) Practice and procedural information reporting. Licensee practices shall report practice and procedural information data for the interpretation of adverse events in a form and format specified by the Department and on a schedule determined by the Department. The data reporting schedule, not to exceed twice per year, shall be made available to licensee practices. The data to be reported shall include, but shall not be limited to: practice identifiers, types of procedures, and number of each type of procedure performed in office-based surgery practices.

(b) Adverse event reporting. Licensee practices shall report adverse events as required by Public Health Law §230-d. Adverse event reports shall be submitted to the Department in a form and format specified by Department. The data to be reported shall include, but shall not be limited to: when the event occurred, where the event occurred, the nature of the event, and the identity of the individuals involved in the event.

(c) Reporting of additional data. Licensee practices shall report additional data deemed necessary by the Department for the interpretation of adverse events, as specified by the Department.

(d) The Department may use the data gathered under this part to develop and implement guidelines and criteria for quality improvement pursuant to section 2998-e of the Public Health Law.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 230-d(4)(b) of the Public Health Law (PHL) authorizes the New York State Department of Health (Department) to require licensees who perform office-based surgery (OBS) to report data, such as procedural information as needed for the interpretation of adverse events.

Section 230-d(5) of the Public Health Law authorizes the Commissioner of Health to adopt rules and regulations to effectuate the purposes of section 230-d, under which the Department oversees OBS practices.

Legislative Objectives:

The Legislature's objective in enacting PHL §230-d(4)(b) was to provide the Department with more information about the number and types of procedures, complications sustained and other quality indicators occurring in OBS practices other than that derived from reported adverse event data, in order to provide context to the adverse event reports and to permit the Department to better assess the quality of care provided in OBS practices.

Current Requirements:

Pursuant to PHL §§ 230-d and §2998-e, OBS practices must report adverse events and suspected health care disease transmission originating in their practices. OBS practices are not currently required to report general practice and procedure information. Guidance on current reporting requirements for OBS practices is provided on the Department's website but currently there are no applicable regulations.

Needs and Benefits:

PHL § 230-d(4)(a) requires Office Based Surgery (OBS) practices to report adverse events to the Department within three business days of such adverse event, and PHL § 230-d(4)(b) authorizes the Department to require licensees to report additional data such as procedural information as needed for the interpretation of adverse events. The Department is currently lacking a framework for understanding the quality of the care that is being provided in OBS practices, because the only data currently reported to the Department are adverse events.

The proposed regulations would require OBS practices to report the number and types of procedures that are performed by OBS practices. This will assist the Department in determining whether quality of care issues exist in certain OBS practices, or with specific types of procedures. This information is important to provide context to the adverse event reports and allow comparison of adverse event report rates to national benchmarks and rates from other settings. For example, ambulatory surgery centers and other health care facilities licensed under PHL Article 28. In addition, this information will assist with the accomplishment of the Department's responsibilities related to ensuring patient safety. For example, the Department will be able to better assess the quality of an OBS practice if the Department knows the total number of procedures performed by the practice. The Department can currently ascertain the number of adverse events (numerator), but the Department needs to know the total number of procedures (denominator) to assess overall quality of care.

Additionally, the proposed changes would allow the Department to request additional information as needed to interpret adverse events. In the event the Department identifies a trend or opportunities for quality improvement through the collection of data,

the proposed regulations would allow the Department to develop and implement guidelines and/or criteria for quality improvement related to the issues identified.

COSTS:

Costs to Private Regulated Parties:

The proposed regulation will result in minimal costs to OBS practices. Costs may include: maintaining a database to be able to report procedural information (if a database is not already maintained by the practice); staff time for completing practice reports; and the purchase of reference materials for determining applicable procedure codes to be reported to the Department, though no-cost reference materials are available on the internet.

Costs to Local Government:

The Department is not aware of any OBS practices operated by local governments.

Costs to the Department of Health:

The proposed regulations will require the Department to facilitate additional data collection, to maintain additional datasets and to perform additional data analyses. The Department intends to perform these functions with existing staff.

Costs to Other State Agencies:

There are no OBS practices operated by other State agencies.

Local Government Mandate:

The proposed regulations impose no new mandates on any county, city, town or village government.

Paperwork:

The proposed regulations will require OBS practices to report additional data to the Department under PHL §230-d(4)(b) as described above. The reporting will be electronic; no paper reports will be required.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

An alternative considered by the Department was to continue without adopting regulations that mandate OBS practice reporting of practice and procedural information. However, this would hinder the Department's ability to enforce PHL § 230-d, which obligates the Department to collect information about the scope of adverse events in the context of all procedures performed in OBS settings. The Department recognizes the importance of ensuring patient safety and quality of care and it has determined that regulations are necessary to implement section 230-d.

Federal Standards:

The proposed regulation does not exceed any minimum standards of the Federal government.

Compliance Schedule:

The proposed regulation will take effect upon a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulations will apply to all Office Based Surgery (OBS) practices in New York State. This proposal will not impact local governments or small business unless they operate such OBS practices. Although the Department doesn't track the size of OBS practices, the agency understands that many will be small businesses under the definition of the State Administrative Procedure Act (SAPA). In such case, the flexibility afforded by the regulations is expected to minimize any costs of compliance as described below.

Compliance Requirements:

This regulatory amendment would require OBS practices to report the number and types of office based surgical procedures performed by such practices.

Professional Services:

This proposal is not expected to require any additional use of professional services.

Compliance Costs:

The proposed regulation will result in minimal costs to OBS practices that are small businesses. Costs may include: maintaining a database to be able to report procedural information (if a database is not already maintained by the practice); staff time for completing practice reports; and the purchase of reference materials for determining

applicable procedure codes to be reported to the Department, though no-cost reference materials are available on the internet.

Economic and Technological Feasibility:

This proposal is economically and technically feasible. The costs associated with reporting procedural information not more than twice per year will not place an undue burden on OBS practices and many practices already maintain databases containing the information required by this regulation.

Minimizing Adverse Impact:

The impact of this proposal is expected to be minimal. This proposal will require minimal staff time to report procedural information as the proposal requires a reporting frequency of no more than twice per year, many practices have established methods of collecting and maintaining the information requested by the proposal, and the required information will be submitted using the Department's pre-existing Health Commerce System available to all prescribing providers in NYS at no cost.

Small Business and Local Government Participation:

The Department engaged the following entities prior to and during the development of this proposed regulation: The Medical Society of the State of New York (MSSNY), The New York State Society of Plastic Surgeons, the New York Chapter of the American College of Physicians and the OBS Advisory Committee, which is comprised of clinicians actively involved in OBS practices.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov). Approximately 22.4% of Office Based Surgery (OBS) practices are located in rural areas.

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

There are 206 OBS practices in rural areas.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

Any impact is minimal, as this proposal can be incorporated into existing processes, and is not expected to substantially increase administrative burden or require additional use of professional services upon OBS practices as many practices already maintain the information requested by the proposed regulations in existing databases.

Costs:

The proposed regulation will result in minimal costs to OBS practices in rural areas. Costs may include: maintaining a database to be able to report procedural information (if a database is not already maintained by the practice); staff time for completing practice reports; and the purchase of reference materials for determining applicable procedure codes to be reported to the Department, though no-cost reference materials are available on the internet.

Minimizing Adverse Impact:

The impact of this proposal is expected to be minimal. This proposal will require minimal staff time to report procedural information as the proposal requires a reporting frequency of no more than twice per year, many practices have established methods of collecting and maintaining the information requested by the proposal, and the required information will be submitted using the Department's pre-existing Health Commerce System available to all prescribing providers in NYS at no cost.

Rural Area Participation:

The proposed regulation will have a 60-day public comment period.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.