New York State Society of Plastic Surgeons

NYS Society of Plastic Surgeons, Inc.
Stuyvesant Station, PO Box 3728
Albany, New York 12203
Phone: 518-598-7755 Fax: 518-514-1424
E-Mail: nyssps@gmail.com Web: http://www.nyssps.org

November 15, 2018

Marcus Friedrich, MD, MBA, FACP
Chief Medical Officer
Office of Quality and Patient Safety
New York State Department of Health
Empire State Plaza, Corning Tower Suite 2001
Albany, NY 12237

Dear Dr. Friedrich:

On behalf of the New York State Society of Plastic Surgeons (NYSSPS), representing over 500 New York State plastic surgeons certified by the America Board of Plastic Surgery, our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety. As such, we acknowledge the intent of the proposed regulation is to help place in context how frequent or rare particular adverse events are occurring in office-based settings.

However, we write today with concerns regarding the vagueness of the regulations. As written, the proposed regulation does not meet the standards of rule making and lacks specificity in how, when and what the NYS DOH will require of practices, making the opportunity for plastic surgeons to provide meaningful comment as to the impact this will have on their practices null and void.

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.*

We are concerned that the term "licensee" could unintentionally be misconstrued to encompass physicians other than those who have accredited OBS practices, which is clearly not authorized by PHL § 230-d. To clarify, we believe the proposed regulation could be amended to state:

> Office-Based Surgery Reporting. A licensee~~s~~ practice in which office-based surgery is performed pursuant to Public Health Law § 230-d shall submit data ~~deemed necessary by the Department~~ for the interpretation of adverse events as set forth below~~. Data shall be submitted in a format specified by the Department. Such data shall include, but shall not be limited to:~~

Additionally, the intent of collecting the data is to enable the DOH to interpret adverse events. It appears outside of the scope of the request to ask for reporting on every procedure performed in an office setting. Therefore we suggest that the collection of adverse event reporting be specific to adverse events.

Section 1000-2.2 (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.*

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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.

NYSSPS encourages the State to continue promoting and developing programs and policies focused on improving health care quality and health care outcomes for New Yorkers. Unfortunately, even with the millions of dollars funded through the Health Care Efficiency and Affordability Law for New Yorkers Capital Grant Program and other state and federal programs, plastic surgeons operating in OBS settings have not had access to the funding mechanisms. The incentives to participate in implementing and maintaining qualified electronic health records have been funneled to larger institutions and to those physicians who primarily care for patients in the Medicare/Medicaid population. As a result, there has been slow adoption amongst the specialty and a minority has been able to make the significant investments in initial and ongoing costs of implementing these dynamically changing electronic health record systems.

Moreover, if the DOH intends to require information pertaining to CPT codes it should be noted that many OBS facilities provide services not covered by insurance and, therefore, do not use such codes.

> We recommend the DOH amend the language to adjust the reporting schedule to be once per year, provide detailed language on what data elements will be required, how the data shall be transmitted and cite when it will commence.

Section 1000-2.2 (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*

"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."

Seeing that, as described, information is currently being provided in adverse event reporting, we ask that the DOH further define the additional form and format as well as the specific data elements.

The language could be amended as follows:

> "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.

Section 1000-2.2 (c) *Reporting of additional data. Licensee practices shall report additional*

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data deemed necessary by the Department for the interpretation of adverse events, as specified by the Department.

This section is duplicative of Section 1000-2.2(a) and we ask that it be stricken.

> It should be noted that NYSSPS believes additional reporting is redundant of reports required by the accrediting agencies. We acknowledge the NYS Department of Health has cited reporting limitations, however, we encourage and recommend a pathway be developed for the accrediting entities to work with OBS practices and the NYS DOH to have information reported in this manner.

Section 1000-2.2 (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.*

New York law currently requires OBS facilities to be accredited by one of three nationally recognized entities that require strict standards of care on office-based practices. Because a significant percentage of plastic surgery procedures are performed on an ambulatory basis, we strongly support the standards of care monitored by these agencies. The accreditation process is rigorous and provides for a re-occurring review of the physicians practice. This is consistent with our professional standards, as the American Society of Plastic Surgeons (ASPS) requires its members to work only in certified facilities.

We acknowledge the interpretation of this data may help the Department further analyze and assess quality improvement in these settings.

> We recommend that the Department of Health work with the accrediting agencies and national medical specialty organizations to help develop and recommend areas for quality improvement and not bypass them as the proposed regulation is currently written.

NYSSPS appreciates the opportunity to continue to work with the New York State Department of Health in furthering quality improvement while protecting patients. However, as written, we do not support efforts by the DOH to grant itself broad discretion to define what information OBS practices must report, as well as the form, format and timing of such reports. We urge the DOH to re-publish a proposed regulation that provides the public with a meaningful opportunity to clearly understand the expectations of the department.

Respectfully,
David Greenspun
David Greenspun, MD
NYSSPS President

cc: Katherine Ceraolo, New York State Department of Health, Bureau of Program Counsel