

December 10, 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

RE: Amendment of Part 1000 of Title 10 NYCRR

Dear Dr. Friedrich:

I am writing on behalf of the American Society of Plastic Surgeons (ASPS) regarding the proposed changes to Part 1000 of Title 10 NYCRR. ASPS is the largest association of plastic surgeons in the world, representing more than 7,000 members and 93 percent of all board-certified plastic surgeons in the United States – including 601 board-certified plastic surgeons in New York. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

As proposed, the amendment of Part 1000 of Title 10 NYCRR is not consistent with rulemaking standards under New York law. The regulation does not include information on how, when, or what the New York State Department of Health (NYS DOH) will require office-based surgery (OBS) practices to report. Rather than circumventing the input of providers and other interested stakeholders, DOH should instead be seeking out insight and experience from knowledgeable parties during a change like this.

Section 1000-2.2 pertains to office-based surgery reporting by “licensees,” which could be interpreted to include physicians who do not have accredited OBS practices. PHL § 230-d does not authorize this type of data collection expansion. Therefore, Section 1000-2.2 should be amended to read:

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:

Furthermore, in this case, it is outside of DOH's purview to collect data that is not for the purpose of interpreting adverse events. Accordingly, adverse event reporting data should be restricted to adverse events – not every procedure performed in an office-based setting.

Section 1000-2.2 (a) attempts to lay out the data reporting schedule and the type of data that OBS practices will be required to report. While ASPS appreciates the attempt to implement a data collection program that would improve the quality of care for New Yorkers, we are concerned with the manner in which NYS DOH is attempting to give itself broad latitude to define what information OBS practices will be required to report – including the form, format, and timing of those reports. NYS DOH has overlooked the impact that this regulation will have on OBS practices, many of which are small businesses, in its regulatory impact statement. The regulatory impact statement says, “In such case, the flexibility afforded by the regulations

is expected to minimize any costs of compliance as described below.”¹ As NYS DOH is aware, many of the incentives to participate in transitioning to qualified EHR systems are geared toward larger entities and physicians whose care focuses on the Medicare/Medicaid population. Unless NYS DOH is suggesting that OBS practices will have the flexibility not to report on all procedures that are performed, the cost of integrating electronic health record (EHR) systems that are fully-compatible with NYS DOH – both in terms of time and capital – would be extremely burdensome.

Moreover, the requirement that OBS practices report on information relating to Current Procedural Terminology (CPT) codes demonstrates a lack of understanding of how OBS practices work. Many OBS facilities provide services that are not subject to insurance coverage, thus they do not use CPT codes. Given the aforementioned factors, Section 1000-2.2 (a) should be amended to limit the reporting schedule to once per year, clarify language regarding the data elements that will be required, and further alleviate the burden on OBS practices. Therefore, we recommend the following edits:

Practice and procedural information reporting. A licensee practice in which office-based surgery is performed pursuant to Public Health Law § 230-d practices shall report the following 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. The data reporting schedule, not to exceed once per year, shall be made available to licensee practices and commence no earlier than [month] [day], 2019.

As previously stated, ASPS is also concerned with creating redundancies in reporting of adverse events. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has been collecting data on adverse events in New York since June 2008.² Therefore, NYS DOH should work with OBS practices and their accrediting agencies to streamline the reporting process.

Section 1000-2.2 (b) uses similarly problematic vague language. As NYS DOH already requires adverse event reporting, this section needs further clarification as to the additional form, its format, and the data points that will be required. If the agency deems this section necessary, it should be amended to read:

“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.

Like much of this proposal, Section 1000-2.2 (c) is duplicative and would seemingly enable NYS DOH further unchecked discretion to expand future reporting requirements. As is the theme in much of the regulation, it is also ambiguous and does not provide adequate direction for current or future OBS reporting requirements. Therefore, it should be removed.

¹ <https://docs.dos.ny.gov/info/register/2018/October24/rulemaking.pdf>

² https://www.jointcommission.org/assets/1/18/S3_JCP06_08.pdf

Section 1000-2.2 (d) relates to the use of data gathered under this part to develop and implement guidelines for quality improvement. While we understand that the interpretation of this data may help NYS DOH analyze quality improvement in OBS settings, 1000-2.2 (d) would bypass the work that is already being done by accrediting agencies. OBS facilities are required by New York law to be accredited by one of three nationally-recognized accrediting organizations that require strict standards of care in office-based practices. A large number of our members perform plastic surgery procedures on an ambulatory basis; therefore, we support the standards of care monitored by these agencies. Moreover, per our organizational bylaws, we require our members to work only in certified surgical facilities. ASPS members then reaffirm their commitment to working in certified surgical facilities through renewing of annual organizational dues. NYS DOH should work with the state-recognized accrediting agencies and the national specialty organizations to establish areas where quality improvement can happen, rather than cut them out of the process.

ASPS is grateful of your consideration of our recommendations and we appreciate the opportunity to work with NYS DOH to protect New Yorkers. However, we cannot support the regulation as it is currently written. Therefore, we suggest that NYS DOH withdraw the proposal and instead work with all interested stakeholders to craft a more comprehensive proposal. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions.

Sincerely,

A handwritten signature in blue ink that reads "Alan Matarasso, MD". The signature is written in a cursive style and is positioned above a light blue horizontal line.

Alan Matarasso, MD, FACS
President, American Society of Plastic Surgeons

cc. Katherine Ceroalo