Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law section 2803, sections 405.4 and 405.6 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (4) of subdivision (b) of Section 405.4 is amended to read as follows:

The hospital shall have an organized medical staff that operates under bylaws approved by the governing body.

* * *

(b) Organization.

* * *

(4) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with the provisions of this Part and the New York State Public Health Law. Following the initial appointment of medical staff members, the medical staff shall conduct periodic reappraisals of its members, on at least[,] a [biennial] triennial basis.

Subparagraph (i) of paragraph (7) of subdivision (b) of Section 405.6 is amended to read as follows:

(b) The activities of the quality assurance committee shall involve all patient care services and shall include, as a minimum:

* * *

- (7) the committee shall oversee and coordinate the following:
- (i) the establishment of a medical, dental and podiatric staff privileges review procedure through which credentials, physical and mental capacity, and competence in delivering health care services are reviewed at least [biennially] triennially as part of an evaluation of staff privileges and in accordance with section 405.4 of this Part. These procedures shall include the collection of the following information from a physician, dentist or podiatrist prior to granting or renewing professional privileges or association in any capacity with the hospital:

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities, including hospitals.

Legislative Objectives:

PHL Article 28 assures the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. Specifically, PHL section 2800 specifies that "hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Needs and Benefits:

The proposed regulations will benefit Article 28 general hospitals by lengthening the requirement to review the credentials of medical staff from every two years to every three years, which will reduce administrative burdens and provide consistency by aligning with a recent revision by The Joint Commission to its credentialing and privileging standards applied to its Advanced Diagnostic Imaging, Ambulatory Surgical Center, Critical Access Hospital, and Hospital accreditation programs.

Costs for Regulated Entities:

There are no anticipated costs to regulated parties (PHL Article 28 general hospitals), insofar as the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Cost to State and Local Government:

There are no anticipated costs to regulated parties, including general hospitals owned and operated by State or Local governments, insofar as the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Cost to the Department of Health:

There are no anticipated costs to the Department of Health.

Local Government Mandates:

This regulation does not impose a local government mandate.

Paperwork:

Regulated entities will be required to maintain documentation that they have satisfied the minimum recredentialing review of medical staff as articulated in the proposed regulations.

However, the proposed regulations do not require new or additional paperwork requirements, insofar as existing regulations at 10 NYCRR sections 405.4 and 405.6 currently require Article 28 general hospitals to maintain records relating to their review of medical staff qualifications; the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Duplication:

The proposed regulation does not duplicate any federal, state, or local law.

Alternatives:

Alternatives include not amending the regulations or requiring a recredentialing period of a length other than every three years (triennially). However, the Department finds that neither alternative is viable. The proposed regulations align with a recent change by The Joint Commission to revise its credentialing and privileging standards applied to its Advanced Diagnostic Imaging, Ambulatory Surgical Center, Critical Access Hospital, and Hospital accreditation programs. Therefore, the Department finds that the triennial recredentialing timeframe proposed in these regulations—as opposed to the current (biannual) or an alternative timeframe—will provide consistency to regulated facilities, as it will align with standards applied by this national hospital accreditation organization to many of the Article 28 general hospitals in New York State.

Federal Requirements:

Federal Conditions of Participation at 42 CFR 482.22(a)(1) require medical staff to "periodically conduct appraisals of its members." The federal Centers for Medicare & Medicaid Services (CMS) has stated in a letter to The Joint Commission that "[p]eriodic review would be

consistent with local laws or national practice." Therefore, the proposed regulatory requirement for triennial reviews is consistent with existing federal regulation.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person: Ms. Katherine E. Ceroalo

NYS Department of Health

Bureau of Program Counsel, Regulatory Affairs Unit

Corning Tower Building, Room 2438

Empire State Plaza Albany, NY 12237 (518) 473-7488

(518) 473-2019 –FAX REGSQNA@health.ny.gov

STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

No Regulatory Flexibility Analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, nor does it require any new reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or new, significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

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. It is apparent, from the nature of the proposed amendments, that it
will not have an adverse impact on jobs and employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The Department received comments from health care providers and associations representing hospitals and physicians. All of the comments were in support of this regulation. Commenters noted that this regulation aligns with recent recommendations from The Joint Commission to extend medical staff credential review from a two-year cycle to a three-year cycle. While some commenters seemed to conflate hospital review of medical staff credentials with medical staff license registration renewal, the Department emphasizes that this regulation does not impact or change any requirements set forth by the State Education Department (SED) that medical staff renew their license registration with SED on a two-year or three-year cycle depending on license type. Rather, this regulation addresses the frequency with which a hospital must review the credentials of medical staff.

Comment: One commenter suggested modifying section 405.6(b)(7)(iv) to state that hospitals are required to obtain information from any newly affiliated hospital starting from the time of the initial application for staff privileges or triennial credentialing, and not the full preceding five years.

Response: The purpose of this regulation was solely to extend medical staff credential review from a two-year cycle to a three-year cycle. No changes to this regulation have been made in response to this comment.