SUMMARY OF EXPRESS TERMS

This regulation amends 10 NYCRR sections 405.5, 405.12, 405.19, 405.21, 405.22, and 405.31.

The amended regulations implement requirements under Section 2805-t of the Public Health Law requiring every general hospital to create a clinical staffing committee made up of registered nurses, licensed practical nurses, ancillary staff members providing direct patient care, and hospital administrators, by January 1, 2022. The committee will be responsible for developing and overseeing the implementation of a clinical staffing plan that will include specific guidelines or ratios, matrices, or grids indicating how many patients are assigned to each nurse and the number of ancillary staff in each unit.

The amended regulations specifically provide factors for consideration in the development of the clinical staffing plans for intensive and critical care units. ICU and critical care unit clinical staffing plans must include a minimum standard of twelve (12) hours of registered nurse care per patient day.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2803 and 2805-t(5) of the Public Health Law, sections 405.5, 405.12, 405.19, 405.21, 405.22, and 405.31 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon filing a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (a) of section 405.5 of Title 10 is amended to read as follows:

(a) Organization and staffing.

(1) The hospital shall have a written nursing service plan of administrative authority and delineation of responsibilities. The director of the nursing service shall be a licensed registered professional nurse who is qualified by training and experience for such position. He or she shall be responsible for the operation of the service, including developing a clinical staffing plan to be approved by the hospital as provided in paragraph (8) of this subdivision for determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

* * *

(8) Hospitals must establish and maintain a clinical staffing committee as provided in section 2805-t of the Public Health Law. The clinical staffing committee shall develop and oversee the implementation of an annual clinical staffing plan. The clinical staffing plan shall delineate intensive care and critical care units of the hospital. The clinical staffing plan shall include specific staffing for each patient

care unit and work shift and shall be based on the needs of patients. Staffing plans shall include specific guidelines or ratios, matrices, or grids indicating how many patients are assigned to each registered nurse and the number of nurses and ancillary nursing personnel to be present on each unit and shift. Ancillary nursing personnel includes, but is not limited to, certified nurse assistants, patient care technicians, and other non-licensed members of the frontline team assisting with nursing tasks. Each hospital shall adopt and submit its first clinical staffing plan under this paragraph no later than July 1, 2022, and annually thereafter. Beginning January 1, 2023, and annually thereafter, each hospital shall implement the clinical staffing plan adopted by July 1 of the prior calendar year, and any subsequent amendments, and assign personnel to each patient care unit in accordance with the plan. Factors to be considered and incorporated in the development of the clinical staffing plan shall include, but are not limited to:

(i) census, including total numbers of patients on the unit on each shift and activity such as patient discharges, admissions, and transfers;

(ii) measures of acuity and intensity of all patients and nature of the care to be delivered on each unit and shift;

(iii) skill mix;

(iv) the availability, level of experience, and specialty certification or training of nursing personnel providing patient care, including charge nurses, on each unit and shift;

(v) the need for specialized or intensive equipment;

(vi) the architecture and geography of the patient care unit, including but not limited to placement of patient rooms, treatment areas, nursing stations, medication preparation areas, and equipment;

(vii) mechanisms and procedures to provide for one-to-one patient observation, when needed, for patients on psychiatric or other units as appropriate;

(viii) other special characteristics of the unit or community patient population, including age, cultural and linguistic diversity and needs, functional ability, communication skills, and other relevant social or socio-economic factors;

(ix) measures to increase worker and patient safety, which could include measures to improve patient throughput;

(x) staffing guidelines adopted or published by other states or local jurisdictions, national nursing professional associations, specialty nursing organizations, and other health professional organizations;

(xi) availability of other personnel supporting nursing services on the unit;

(xii) waiver of plan requirements in the case of unforeseeable emergency circumstances as defined in subdivision fourteen of section 2805-t of the Public Health Law;

(xiii) coverage to enable registered nurses, licensed practical nurses, and ancillary staff to take meal and rest breaks, planned time off, and unplanned absences that are reasonably foreseeable as required by law or

the terms of an applicable collective bargaining agreement, if any, between the general hospital and a representative of the nursing or ancillary staff;

(xiv) the nursing quality indicators required under section 400.25 of this Title;

(xv) general hospital finances and resources; and

(xvi) provisions for limited short-term adjustments made by appropriate general hospital personnel overseeing patient care operations to the staffing levels required by the plan, necessary to account for unexpected changes in circumstances that are to be of limited duration.

Paragraph (1) of subdivision (a) of section 405.12 of Title 10 is amended to read as follows:

(1) The operating room shall be supervised by a registered professional nurse or physician who the hospital finds qualified by training and experience for this role.

(i) Nursing personnel shall be on duty in sufficient number for the surgical suite in accordance with the needs of patients and the complexity of services they are to receive and in accordance with the annual clinical staffing plan established under paragraph (8) of subdivision (a) of section 405.5 of this Title.

* * *

Paragraph (2) of subdivision (d) of section 405.19 of Title 10 is amended to read as follows:

(2) Nursing services shall be in accordance with the annual clinical staffing plan established under paragraph (8) of subdivision (a) of section 405.5 of this Title. In addition:

* * *

Subparagraph (iv) of paragraph (2) of subdivision (d) of section 405.21 is amended to read as follows:

(iv) Level II, Level III and RPC perinatal care services shall maintain a nursing staff in accordance with the annual clinical staffing plan established under paragraph (8) of subdivision (a) of section 405.5 of this Title that is appropriately trained and adequate in size to provide specialized care to distressed mothers and infants. The number of patient care staff on duty during any shift shall reflect the volume and nature of patient services being provided during that shift.

Subdivisions (b), (c), and (d) of section 405.22 of Title 10 are amended to read as follows:

(b) Intensive Care Unit (ICU) and critical care unit clinical staffing plans. ICU and critical care unit clinical staffing plans, as established under paragraph (8) of subdivision (a) of section 405.5 of this Title, shall include a minimum standard of twelve (12) hours of registered nurse care per patient day.

(c) Pediatric Intensive Care Unit (PICU) Services.

(1) Definitions.

(i) PICU. A PICU is a physically separate unit that provides intensive care to pediatric patients (infants, children and adolescents) who are critically ill

or injured. A PICU must be staffed by qualified practitioners competent to care for critically ill or injured pediatric patients.

(ii) Qualified practitioner. Qualified practitioner as referred to in this section shall mean a practitioner functioning within his or her scope of practice according to State Education Law who meets the hospital's criteria for competence, credentialing and privileging practitioners in the management of critically ill or injured pediatric patients.

(2) General.

(i) A PICU must be approved by the Department. The governing body of a hospital that provides PICU services must develop written policies and procedures for operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients. The PICU shall:

(*a*) Provide multidisciplinary definitive care for a wide range of complex, progressive, and rapidly changing medical, surgical, and traumatic disorders occurring in pediatric patients;

(*b*) Have a minimum average annual pediatric patient number of 200/year;

(*c*) Have age and size appropriate equipment available in the unit; and

(*d*) Provide medical oversight for interhospital transfers of critically ill or injured patients during transfer to the receiving PICU.

(ii) Organization and Direction. The PICU shall be directed by a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who shall be responsible for the organization and delivery of PICU care and has specialized training and demonstrated competence in pediatric critical care. Such physician in conjunction with the nursing leadership responsible for the PICU shall participate in administrative aspects of the PICU. Such responsibilities shall include development and annual review of PICU policies and procedures, oversight of patient care, quality improvement activities, and staff training and development.

(*a*) All hospitals with PICUs must have a physician, notwithstanding emergency department staffing, in-house 24 hours per day who is available to provide bedside care to patients in the PICU. Such physician shall be at least a post graduate year three in pediatrics or anesthesiology. This physician must be skilled in and be credentialed by the hospital to provide emergency care to critically ill or injured children.

(*b*) The PICU shall have, at a minimum, a physician at the level of post graduate year two or above and/or physician assistant and/or nurse practitioner with specialized training in pediatric critical/intensive care assigned to the unit 24 hours/day, 7 days/week with an attending pediatric, medical, surgical or anesthesiology critical care/intensivist available within 60 minutes.

(*c*) An attending pediatric medical, surgical, or anesthesiology critical care/intensivist physician shall be responsible for the oversight of patient care at all times.

(*d*) The PICU shall provide registered professional nursing staffing sufficient to meet critically ill or injured pediatric patient needs, ensure patient safety and provide quality care, and that meets the ICU clinical staffing plan requirements in subdivision (b) of this section.

(*e*) PICU physician and nursing staff shall have successfully completed a course and be current in pediatric advanced life support (PALS) or have current equivalent training and/or experience to PALS.

(iii) Quality Performance. The hospital shall have an organized quality assessment performance improvement (QAPI) program for PICU services. Such program shall require participation by all clinical members of the PICU team and include: monitoring of volume and outcomes, morbidity and all case mortality review, regular multidisciplinary conferences including all health professionals involved in the care of PICU patients.

(iv) Closure. Failure to meet one or more regulatory requirements or inactivity in a program for a period of 12 months or more may result in actions, including, but not limited to, the Department's withdrawal of approval for the hospital to serve as a PICU.

(v) Voluntary closure. The hospital must give written notification, including a closure plan acceptable to the department, at least 90 days prior to planned discontinuance of PICU services. No PICU shall discontinue operation without first obtaining written approval from the department.

(vi) Notification of significant changes. A hospital must notify the department in writing within 7 days of any significant changes in its PICU services, including, but not limited to: (a) any temporary or permanent suspension of services or (b) difficulty meeting staffing or workload requirements.

[(c) Reserved.]

(d) Burn unit/center.

(1) Personnel and staffing.

(i) A burn unit/center shall designate a director who is a board-certified or board-admissible general or plastic surgeon with one additional year of specialized training in burn therapy or equivalent experience in burn patient care.

(ii) Staff for the burn unit/center shall <u>be in accordance with the annual clinical staffing plan established under paragraph (8) of subdivision (a) of section 405.5 of this Title and shall</u> include:

(*a*) a head nurse of the facility who is a registered professional nurse, with two years intensive care unit or equivalent training and a minimum of six months burn experience;

(*b*) one registered professional nurse for every two intensive care patients at all times;

(*c*) one registered professional nurse for every three nonintensive care patients at all times;

(*d*) on staff, or through formal arrangement, a physical therapist and occupational therapist with a minimum of three months training or six months experience in burn treatment available as needed;

(*e*) staff or through formal arrangement a registered dietician available as needed;

(*f*) on staff, or through formal arrangement, a medical social worker responsible for referral and follow-up care and individual and group counseling available as needed; and

(*g*) a psychologist and/or psychiatrist available as needed.

(iii) The burn unit/center shall be responsible for training facility staff and other personnel within the service area on emergency treatment procedures, assessment of total body surface area affected, and the classification of burns and triage protocols.

(2) Operation and service delivery.

(i) Each burn unit/center shall have a minimum of six beds.

(ii) Each burn unit/center shall treat a minimum of 50 patients with major burn injury to moderate uncomplicated burn injury per year.

(iii) The burn unit/center shall refer patients for whom there are no available beds to another burn unit/center which can provide the care needed.

(iv) Each burn unit/center shall have available, either through direct control or through a network of clearly identified relationships, a system of land and/or air transport which will bring severe burn victims to the unit/center.

(v) Each burn unit/center shall have a designated area for providing specialized intensive care and an operating room easily accessible within the hospital.

(vi) Reviews of each patient with major burn injury or moderate uncomplicated burn injury shall be undertaken on a weekly basis by the burn care team.

Paragraph (5) of subdivision (p) of section 405.31 of Title 10 is amended to read as follows:

(5) Nursing Minimum Staffing Requirements. Nurse staffing shall be in accordance with the annual clinical staffing plan established under paragraph (8) of subdivision (a) of section 405.5 of this Title. In addition:

(i) Nursing staff shall have ongoing education and training in live donor liver transplantation nursing care (donor and recipient). This shall include education in the pain management issues particular to the donor. The registered professional nursing ratio shall be at least one registered professional nurse for every two

patients (1:2) in the ICU/PACU level setting, increased as appropriate for the acuity level of the patients.

(ii) After the donor is transferred from the ICU/PACU, the registered professional nursing ratio shall be at least 1:4 on all shifts, increased as appropriate for the acuity level of the patients

(iii) The same registered professional nurse shall not take care of both the donor and the recipient.

(iv) The nursing service shall verify that the potential donor received appropriate pre-surgical information.

(v) The names and contact numbers of the transplant team shall be posted on all units receiving transplant donors.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2803(2)(a) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (Commissioner), to implement PHL Article 28 and establish minimum standards for health care facilities.

PHL § 2805-t(5) requires the Commissioner to promulgate regulations relating to nurse staffing in intensive care and critical care units of general hospitals. Such regulations must consider the factors set forth in PHL § 2805-t(4)(b), standards in place in neighboring states, and a minimum standard of 12 hours of registered nurse care per patient day.

In addition, PHL § 2805-t(5) states that a clinical staffing plan shall comply with "[r]egulations made by the department on burn unit staffing, liver transplant staffing, and operating room circulating nurse staffing."

Legislative Objectives:

The objective of Chapter 155of the Laws of 2021 is to establish clinical staffing committees and staffing plans for nursing and unlicensed direct care staff in hospitals to help ensure that these facilities operate in a manner that guarantees the public safety and the delivery of quality health care services.

Needs and Benefits:

Rulemaking was necessitated by the addition of Section 2805-t to the Public Health Law under Chapter 155 of the Laws of 2021. These regulations are needed to incorporate the statutory

clinical staffing committee requirements and factors for consideration regarding staffing of the intensive and critical care units into the general hospital operational standards regulations.

Having safe and appropriate levels of nurse and ancillary member staffing has been shown to reduce avoidable and adverse patient outcomes. Research has demonstrated that hospitals with lower nurse staffing levels have higher rates of pneumonia, shock, cardiac arrest, urinary tract infections and upper gastrointestinal bleeds; all leading to higher costs and mortality from hospital-acquired complications. The improved outcomes reduce medical malpractice and other penalties resulting from avoidable occurrences and poor patient satisfaction. In addition, assuring sufficient staffing of hospital personnel protects patients and supports greater retention of nurses and promotes safer working conditions.

Allowing each hospital to collaboratively develop these clinical staffing plans with the nurses and other staff will allow for the best staffing outcomes at these hospitals. With a hospital-by-hospital approach, they will be able to balance what is best for the patient and workforce while taking into account the varying needs of each individual hospital.

Establishing these clinical staffing committees and staffing plans for nursing and unlicensed direct care staff in hospitals will help ensure that these facilities operate in a manner that guarantees the public safety and the delivery of quality health care services.

Costs:

Nominal costs are associated with the implementation of these regulations, as further outlined below.

Costs to Private Regulated Parties:

Nominal costs may be incurred by a general hospital operator to adhere to these regulations. This cost will be incurred by the current operator of the facility and would relate to the convening of a clinical staffing committee and production of the clinical staffing plan developed, including staff time to discuss, agree upon, produce and disseminate the clinical staffing plan.

Costs to Local Governments:

There are 14 hospitals owned by the counties and municipalities which will be affected by this regulation and the costs associated with it.

Cost to State Government:

The annual costs to Department of Health operations for implementation of this regulation is estimated at $1.82 million. The regulation is anticipated to require 75 additional on-site hospital surveys per year, or the equivalent of one survey per hospital over a three-year period. The Department would require 2 teams, each consisting of 3 surveillance staff, to perform on-site inspection and enforcement activities. An additional 6 staff would be required for establishment of a Hospital Complaint Intake program and to meet other administrative and reporting requirements.

The Department currently contracts with IPRO for a portion of hospital surveillance activities, including managing postings on the NYS Hospital Profiles website. Without the establishment of a State staff-only hospital staffing enforcement program, this regulation would likely result in additional costs for contract Registered Nurse surveillance staff.

Local Government Mandates:

General hospitals that fall under the jurisdiction of local government will be affected and be subject to the same requirements as any other general hospital established under PHL Article 28.

Paperwork:

Each hospital will be required, at least annually to file their clinical staffing plan to the Department, starting by July 31, 2022, in a matter and form to be determined by the Department.

Duplication:

These proposed regulatory amendments do not duplicate State or federal rules.

Alternatives:

The amended regulations implement the statutory requirements for the development of clinical staffing plans and the form they shall take. The Department considered current standards employed in all states regarding staffing requirements for direct care staff. The Department also considered the impact of implementation of an absolute threshold or fixed ratio for staffing decisions on patient safety, consistent with the provision of a high level of care, staffing availability and data availability. To promote the general quality of care rendered by a general hospital through improved staffing, the Department's regulatory framework requires consideration of the combination of factors staffing committees would find relevant to assessing quality of care and patient safety in the general hospital. The Department also included additional factors to consider in the development of staffing requirements for critical and intensive care units.

Federal Standards:

The amended regulations do not exceed any minimum standards of the federal government.

Compliance Schedule:

The amended regulations will take effect January 1, 2022.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Local governments and small businesses will not be affected by this rule, unless they operate a general hospital. Where a local government or small business operates a general hospital, they will be similarly affected as any other regulated entity under the rule. There are 15 general hospitals owned by municipalities and local governments. The Department does not anticipate an increase in general hospital establishment applications by such applicants as a result of the proposed regulation.

Compliance Requirements:

Regulated parties are expected to be in compliance with the amended regulations as of January 1, 2022. The amended regulations will define new, statutory requirements for general hospitals to create a clinical staffing committee made up of registered nurses, licensed practical nurses, ancillary staff members providing direct patient care, and hospital administrators. The committee will be responsible for developing and overseeing the implementation of a clinical staffing plan, which must take into account several factors. Clinical staffing plans are required to be completed and submitted to the Department by July 1 each year, and they must specifically address intensive and critical care unit staffing, requiring at least 12 hours of registered nurse care per patient day.

Professional Services:

These regulations are not expected to require any additional use of professional services.

Compliance Costs:

Nominal costs may be incurred by a general hospital operator to adhere to these regulations. This cost will be incurred by the current operator of the facility and would relate to the convening of a clinical staffing committee and production of the clinical staffing plan developed, including staff time to discuss, agree upon, produce and disseminate the clinical staffing plan.

Economic and Technological Feasibility:

There are no economic or technological impediments to the proposed regulatory amendments.

Minimizing Adverse Impact:

Minimal flexibility exists to minimize impact since these new requirements are statutory and apply to all general hospital operators. Operators will convene their own clinical staffing committee to determine the appropriate staffing levels, with inclusion of factors that consider the unique operating situation of each general hospital.

Small Business and Local Government Participation:

The Department has already taken several steps to notify the hospital industry on the effects of this regulation and has provided the opportunity for public comment. On October 7, 2021, at the Public Health and Health Planning Council (PHHPC), the Department presented this regulation for information and discussion purposes. At that meeting the regulation was reviewed and discussed by PHHPC members. In addition, the public, including the effected parties to this regulation, were afforded and opportunity to ask questions and provide comments.

In addition, there were conference calls made to the various associations representing the nursing home industry to inform them of the regulation and to provide an opportunity to ask questions.

Further, the regulation will be filed in the State Register, providing another opportunity for public comments and review. Once completed, the regulation will again go to PHHPC where there will be another opportunity for public comment.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Number of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas, for the purpose of this Rural Area Flexibility Analysis (RAFA), are defined under Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein." The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

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	

Reporting, recordkeeping, and other compliance requirements; and professional services:

General hospital operators are expected to be in compliance with the amended regulations as of January 1, 2022. There are several general hospitals in rural areas. The amended regulations will define new, statutory requirements for general hospitals to create a clinical staffing committee made up of registered nurses, licensed practical nurses, ancillary staff members providing direct patient care, and hospital administrators. The committee will be responsible for developing and overseeing the implementation of a clinical staffing plan, which must take into account several factors. Clinical staffing plans are required to be completed and submitted to the Department by July 1 each year, and specifically address intensive and critical care unit staffing requiring at least 12 hours of registered nurse care per patient day. Record keeping will be related to general hospital operators having to provide their staffing plan to the Department July 1 of each year. No additional professional staff are expected to be needed as a result of the amended regulations.

Costs:

Per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

Minimizing Adverse Impact:

The amended regulations do not create any adverse effect on regulated parties.

Rural Area Participation:

Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting. The Department will engage in active discussions and dialogue with all interested parties, including industry associations directly impacted by this regulation, to inform them of their need to comply, to answer questions and listen to comments they may have on this regulation.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

The Department has determined that the amended regulations are likely to not have a substantial adverse impact on jobs and employment opportunities. The new clincial staffing plan provisions codifies standard industry considerations in the apportionment of clinical staffing in a general hospital. Such a staffing plan will be developed and executed by existing staff resources. If there is to be any impact on jobs under the regulaitons, it is likely that general hospitals would need to increase their count of clincial staffing positions, if a general hospital determines under their plan that such additional staff is necessary for compliance. The amended regulations should not cause a change to the workload for the establishment a clinical staffing plan and is most likely to not increase nor decrease jobs and employment opportunities.