

ADDENDUM

STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

AGENDA

October 7, 2021

*Immediately following the Committee on Codes, Regulations and Legislation Meeting
(Codes scheduled to begin at 10:15 a.m.)*

Empire State Plaza, Concourse Level, Meeting Room 6, Albany

IV. REGULATION

Report of the Committee on Codes, Regulations and Legislation

Angel Gutiérrez, M.D., Chair of the Committee on Codes, Regulations
and Legislation

For Discussion

21-13 Addition of Section 415.34 to Title 10 NYCRR (Nursing Home Minimum Direct
Resident Care Spending)

21-17 Amendment of Part 405 of Title 10 (Clinical Staffing in General Hospitals)

21-20 Amendment to Sections 415.2 and 415.13 of Title 10 NYCRR (Minimum Staffing
Requirements for Nursing Homes)

Pursuant to the authority vested in the Commissioner of Health by Section 2828 of the Public Health Law, Part 415 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended by adding a new Section 415.34, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

415.34. Minimum Direct Resident Care Spending.

(a) Purpose. This Section sets forth the requirements of the minimum direct resident care spending law set forth in Section 2828 of the Public Health Law and applies to all residential health care facilities licensed pursuant to this Part, except as provided in subdivision (c) of this Section.

(b) Definitions. The definitions of this Section shall have the same meaning as those terms set forth in subdivision (2) of Section 2828 of the Public Health Law. Additionally, the following terms shall have the following meanings:

(1) “Contracted out” shall mean services provided by registered professional nurses, licensed practical nurses, or certified nurse aides who provide services in a residential health care facility through contractual or other employment agreement, whether such agreement is entered into by the individual practitioner or by an employment agency on behalf of the individual practitioner. Such agreement may be oral or in writing.

(2) “Direct resident care” shall mean the following cost centers in the residential health care facility cost report: (i) Nonrevenue Support Services - Plant Operation & Maintenance, Laundry and Linen, Housekeeping, Patient Food Service, Nursing Administration, Activities Program, Nonphysician Education, Medical Education, Medical Director's Office, Housing, Social

Service, Transportation; (ii) Ancillary Services - Laboratory Services, Electrocardiology, Electroencephalography, Radiology, Inhalation Therapy, Podiatry, Dental, Psychiatric, Physical Therapy, Occupational Therapy, Speech/Hearing Therapy, Pharmacy, Central Services Supply, Medical Staff Services provided by licensed or certified professionals including and without limitation Registered Nurses, Licensed Practical Nurses, and Certified Nursing Assistant; and (iii) Program Services - Residential Health Care Facility, Pediatric, Traumatic Brain Injury (TBI), Autoimmune Deficiency Syndrome (AIDS), Long Term Ventilator, Respite, Behavioral Intervention, Neurodegenerative, Adult Care Facility, Intermediate Care Facilities, Independent Living, Outpatient Clinics, Adult Day Health Care, Home Health Care, Meals on Wheels, Barber & Beauty Shop, and Other similar program services that directly address the physical conditions of residents. Direct resident care does not include, at a minimum and without limitation, administrative costs (other than nurse administration), capital costs, debt service, taxes (other than sales taxes or payroll taxes), capital depreciation, rent and leases, and fiscal services.

(3) "Resident-facing staffing" shall mean all staffing expenses in the ancillary and program services categories on Exhibit H of the residential health care facility cost reports.

(4) "Revenue" shall mean the total operating revenue from or on behalf of residents of the residential health care facility, government payers, or third-party payers, to pay for a resident's occupancy of the residential health care facility, resident care, and the operation of the residential health care facility as reported in the residential health care facility cost reports submitted to the Department; provided, however, that revenue shall exclude the average increase in the capital portion of the Medicaid reimbursement rate from the prior three years.

(c) Applicability.

(1) For the purposes of this Section, residential health care facilities shall not include:

(i) facilities that are authorized by the Department to primarily care for medically fragile children or young adults, people with HIV/AIDS, persons requiring behavioral intervention, or persons requiring neurodegenerative services. For the purposes of this subparagraph, a facility shall be considered to primarily care for such specialized populations if at least 51 percent of certified beds are designated for persons with such specialty health care needs; or

(ii) continuing care retirement communities licensed pursuant to Article 46 or 46-A of the Public Health Law.

(iii) A facility may apply to the Commissioner for a waiver of applicability of this Section on the basis of providing specialty care services if such facility primarily provides care to a specialized population other than one listed in subparagraph (i) of this paragraph. Such application shall detail what specialty services the facility provides, the percentage of the resident population needing such specialty services, and whether any other residential health care facilities licensed by the Department provide such specialty services. The Commissioner shall have discretion to approve or reject applications submitted pursuant to this subparagraph, and shall provide the facility with the basis for the Commissioner's determination within a reasonable timeframe upon receipt of a complete application. Factors the Commissioner will assess in determining whether to grant or deny a waiver application based on provision of services to a specialty population include, but are not limited to, the following:

(a) the number of other residential health care facilities licensed by the Department that provide the services identified by the facility as specialized services;

(b) whether a majority of current facility residents have special health care needs as identified by the facility; and

(c) the unique training or licensing required of facility staff to provide services to the identified specialized population.

(iv) In the event a facility no longer provides care for a specialty population, as identified under subparagraphs (i) and (iii) of this paragraph, the facility shall comply with this Section by January first of the first year following the date on which the facility ceased operating as a specialty residential health care facility, as determined by the Commissioner.

(2) Additional Waivers. A facility may apply to the Commissioner for a waiver of applicability of this Section on the basis of unexpected or exceptional circumstances that prevented compliance. Such application shall detail the specific unexpected or exceptional circumstance experienced by the facility; when the facility first learned of such circumstances; why the facility could not have anticipated such circumstances arising; actions the facility took to address such circumstances; expenses incurred as a result of addressing such circumstances; when the facility expects such circumstances to be resolved; and what preventive steps the facility is taking to ensure that such circumstances do not unexpectedly arise in the future. The Commissioner shall have discretion to approve or reject applications submitted pursuant to this paragraph, and shall provide the facility with the basis for the Commissioner's determination within a reasonable timeframe upon receipt of a complete application. Factors the Commissioner will assess in determining whether to grant or deny a waiver application based on unexpected or exceptional circumstances include, but are not limited to, the following:

(i) whether the facility should have anticipated such events occurring;

- (ii) whether any other residential health care facilities licensed by the Department experienced similar circumstances but have not applied for a waiver under this paragraph;
- (iii) whether the facility has implemented sufficient policies and procedures to ensure such events do not recur.

(d) Minimum Spending Requirements. By January 1, 2022, residential health care facilities shall comply with the following minimum expenditures:

- (1) 70 percent of revenue shall be spent on direct resident care; and
- (2) 40 percent of revenue shall be spent on resident-facing staffing.

- (i) All amounts spent on resident-facing staffing shall be included as a part of amounts spent on direct resident care; and

- (ii) 15 percent of costs associated with resident-facing staffing that are contracted out by a facility for services provided by registered professional nurses, licensed practical nurses, or certified nurse aides shall be deducted from the calculation of the amount spent on resident-facing staffing and direct resident care.

(3) For the purposes of assessing whether a facility has met the minimum spending requirements, a facility may apply to the Commissioner to have certain revenues and expenses excluded from the calculation of the facility's total revenue and total expenditures, where the facility has satisfactorily demonstrated to the Commissioner that such revenues and expenses were incurred due to the following circumstances:

- (i) a natural disaster, where a federal, State, or local declaration of emergency has been issued; or

- (ii) the facility has received extraordinary, non-recurring revenue which, in the discretion of the Commissioner, does not accurately reflect operating revenue for the purposes of

this rule, including but not limited to revenue received through insurance or legal settlements.

(e) Recoupment.

(1) A residential health care facility shall be subject to recoupment for excessive total operating revenue if:

(i) the facility's total operating revenue exceeds total operating and non-operating expenses by more than five percent of total operating revenue; or

(ii) the facility fails to spend the minimum amount necessary to comply with the minimum spending standards for resident-facing staffing or direct resident care, as set forth in subdivision (d) of this Section, as calculated on an annual basis.

(2) Remission of excess revenue.

(i) The Department shall issue a notice of noncompliance to a facility subject to recoupment for excessive total operating revenue, which indicates the amount to be remitted based on the amount of excess revenue or the difference between the minimum spending requirement and the actual amount of spending on resident-facing staffing or direct care staffing, as applicable, as well as acceptable forms of payment.

(ii) Upon receipt of a notice of noncompliance pursuant to subparagraph (i), the facility shall remit the total amount indicated in the notice of noncompliance by November first in the year following the year in which the expenses are incurred.

(3) Penalties.

(i) Failure to remit the total required fee by the due date may result in adverse action by the Department, including but not limited to: bringing suit in a court of competent

jurisdiction, taking deductions or offsets from payments made pursuant to the Medicaid program, and imposition of penalties pursuant to Section 12 of the Public Health Law.

(ii) Recouped funds shall be deposited by the Department into the Nursing Home Quality Pool, pursuant to Section 2808(2-c)(d) of the Public Health Law.

(f) Residential Health Care Facility Cost Reports.

(1) The Department shall, no less frequently than annually, audit the residential health care facilities' cost reports for compliance in accordance with this Section.

(2) If a facility did not report data in the 2019 residential health care facility cost report, they must promptly provide the Department with data on the facility's direct resident care and resident facing staffing expenses in accordance with this Section and Section 2828 of the Public Health Law. This data must be submitted with a written certification by the operator, officer, or public official responsible for the operation of the facility, in a form and format determined acceptable by the Department, attesting that all data reported by the facility is complete and accurate. If the data is not submitted within a reasonable timeframe, as determined by the Department, the Department shall use the previous available cost report data applicable to such facility.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under section 2828 of the Public Health Law (PHL), which directs the Department of Health (Department) to promulgate regulations governing the disposition of revenue in excess of expenses permitted under PHL § 2828 for residential health care facilities. Specifically, PHL § 2828 directs that, as of January 1, 2022, every residential health care facility shall spend a minimum of 70 percent of revenue on direct resident care and 40 percent of revenue on resident-facing staffing, wherein amounts spent on resident-facing staffing are included in the amount spent on direct resident care.

Legislative Objectives:

The legislative objective of PHL § 2828 is to ensure that residential health care facilities spend a majority of their revenue on direct resident care (70 percent), with 40 percent of such expenses focused on paying for resident-facing staffing. The goal of these minimum spending requirements is to help ensure a high quality of resident care.

Needs and Benefits:

These regulations are necessary to implement the statutory directive of PHL § 2828. Specifically, pursuant to the statute, the regulations (1) set forth how facilities that fail to meet the statutory minimum spending requirements must pay the State, (2) provide exceptions from the minimum spending requirements for residential health care facilities that serve certain specialized populations, (3) set forth factors the Department will use to determine whether to waive the spending requirements for facilities unable to comply due to “unexpected or exceptional circumstances that prevented compliance,” and (4) provide factors the Department

will use to determine whether to exclude extraordinary revenues and capital expenses from the calculations to determine whether a facility has met its minimum spending requirements.

Requiring nursing homes to spend an appropriate amount of revenue on the direct care of residents and resident-facing staffing will reduce errors, complications, and adverse resident care incidents. It will also improve the safety and quality of life for all long-term care residents in New York State.

COSTS:

Costs to Regulated Parties:

The purpose of this regulation is to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum spending requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum spending thresholds. While the Department anticipates that costs will be borne by residential health facilities, and that those costs may create financial challenges for some organizations, compliance with these minimum spending requirements is mandated by statute (PHL § 2828), and as such these regulatory amendments are necessary. Moreover, any recouped funds from residential health care facilities that fail to comply with PHL § 2828 will be deposited into the Nursing Home Quality Pool to benefit high-quality residential health care facilities, thereby helping to offset any costs for high-performing facilities while also encouraging the provision of quality resident care.

Costs to Local and State Governments:

This regulation will not impact local or State governments unless they operate a residential health care facility, in which case the costs will be the same as for privately-operated facilities. Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and 6 residential health care facilities operated by the State.

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health.

Paperwork:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit revenue and expense information through an annual cost report submitted to the Department, such costs reports are current required pursuant to PHL §§ 2805-e and 2808-b. If a facility has not submitted a cost report for 2019, the regulation requires the expense and revenue data to instead be submitted with a written certification by the operator, officer, or public official responsible for the operation of the facility, in a form and format determined acceptable by the Department, attesting that all data reported by the facility is complete and accurate. Although this data form would be a new requirement, because it is merely a temporary measure to substitute for a missing 2019 cost report, the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities subject to this new paperwork requirement.

Local Government Mandates:

Residential health care facilities operated by local governments will be affected and will be subject to the same requirements as any other residential health care facility licensed under PHL Article 28.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

These regulations are mandated pursuant to PHL § 2828. Accordingly, the alternative of not issuing these regulations was rejected.

Federal Standards:

No federal standards apply.

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a residential health care facility. Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and 6 residential health care facilities operated by the State. Additionally, to date, 79 residential health care facilities in New York qualify as small businesses given that they have 100 or fewer employees.

Compliance Requirements:

This regulation seeks to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. In accordance with this statute, residential health care facilities will be required to meet these aforementioned minimum spending requirements, unless they meet certain exceptions as detailed in both PHL § 2828 and these regulations, including facilities that provide care to Commissioner-designated specialty populations and facilities that are unable to comply with the minimum spending requirements due to natural disaster or other “unexpected or exceptional circumstances that prevented compliance.”

Facilities that fail to meet the minimum spending requirements of PHL § 2828 and these regulations will be required to remit a penalty payment in the amount of the facility’s excessive total operating revenue, based on the amount of excess revenue or the difference between the minimum spending requirement and the actual amount of spending on resident-facing staffing or direct care staffing, as applicable.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

This regulation seeks to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum spending requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum spending thresholds. While the Department anticipates that costs will be borne by residential health facilities, and that those costs may create financial challenges for some organizations, compliance with these minimum spending requirements is mandated by statute (PHL § 2828), and as such these regulatory amendments are necessary. Moreover, any recouped funds from residential health care facilities that fail to comply with PHL § 2828 will be deposited into the Nursing Home Quality Pool to benefit high-quality residential health care facilities, thereby helping to offset any costs for high-performing facilities while also encouraging the provision of quality resident care.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL § 2828 and necessary to ensure that direct resident care is prioritized by setting forth minimum spending requirements for such care.

Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Small Business and Local Government Participation:

Health care provider organizations, individual institutions, local health departments and the public are invited to comment during the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). Interested parties and members of the general public will be notified and provided in advance of the PHHPC meeting the time and place of the meeting, the text of the regulation for their review and a chance to submit oral and written comments. All written comments will be sent to PHHPC members 72 hours in advance of the meeting.

Further, 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. Specifically, the Department will issue a *Dear Administrator Letter (DAL)* to each effected nursing home, either operated by a local government, or privately, which will outline the date such regulation will go into effect, the specific requirements outlined in the regulation and the penalties for non-compliance. Further, the Department will formally solicit questions from each effected party and will prepare a *Frequently Asked Questions, (FAQ)* which will be updated regularly and publicly posted on the Department's website for review and feedback.

Cure Period:

This regulation does not include a cure period given that compliance is required by January 1, 2022 per PHL § 2828.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by 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 of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the United States Census estimated county populations for 2010:

Albany County
Broome County
Dutchess County
Erie County

Monroe County
Niagara County
Oneida County
Onondaga County

Orange County
Saratoga County
Suffolk County

Licensed residential health care facilities are located in these identified rural areas.

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

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit revenue and expense information through an annual cost report submitted to the Department, such costs reports are currently required pursuant to PHL §§ 2805-e and 2808-b. If a facility has not submitted a cost report for 2019, the regulation requires the expense and revenue data to instead be submitted with a written certification by the operator, officer, or public official responsible for the operation of the facility, in a form and format determined acceptable by the Department, attesting that all data reported by the facility is complete and accurate. Although this data form would be a new requirement, because it is merely a temporary measure to substitute for a missing 2019 cost report, the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities subject to this new paperwork requirement.

Compliance Costs:

This regulation seeks to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum spending requirements, but rather may appropriately manage expenditures to balance overall expenditures

to meet the minimum spending thresholds. While the Department anticipates that costs will be borne by residential health facilities, and that those costs may create financial challenges for some organizations, compliance with these minimum spending requirements is mandated by statute (PHL § 2828), and as such these regulatory amendments are necessary. Moreover, any recouped funds from residential health care facilities that fail to comply with PHL § 2828 will be deposited into the Nursing Home Quality Pool to benefit high-quality residential health care facilities, thereby helping to offset any costs for high-performing facilities while also encouraging the provision of quality resident care.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL § 2828 and necessary to ensure that direct resident care is prioritized by setting forth minimum spending requirements for such care.

Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Rural Area Participation:

The Department will notify all residential health care facilities, including those located in rural areas, of the existence of these regulations and the opportunity to submit public comments or questions to the Department.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

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 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 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 sponsors of the Laws of 2021, Chapter 155, provided the following justification for the law.

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.

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.

The changes reflect the intent of the law 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.

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 no additional costs associated with the implementation of these regulations for Local Governments.

Cost to State Government:

The annual costs to Department of Health operations for implementation of this bill is estimated at \$1.82 million. The bill 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 legislation would likely result in additional costs for contract Registered Nurse surveillance staff.

Local Government Mandates:

There are no local mandates in the amended regulations. However, 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:

There is no additional paperwork required under the amended regulations.

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.

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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:

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.

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.

JOB IMPACT STATEMENT

Nature of Impact:

The Department has determined that the amended regulations are likely to not have a substantial adverse impact on jobs and employment opportunities. The new clinical 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 regulations, it is likely that general hospitals would need to increase their count of clinical 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.

Categories and Numbers Affected:

Additional administrative support staff or professional staff may be hired on a short-term basis to meet the new requirements, but the numbers should be nominal.

Regions of Adverse Impact:

None.

Minimizing Adverse Impact:

Not applicable.

Self Employment Opportunities:

Not applicable.

Pursuant to the authority vested in the Commissioner of Health by sections 2803 and 2895-b of the Public Health Law, Sections 415.2 and 415.13 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon filing with the Secretary of State, to read as follows:

Subdivision (h) of Section 415.2 is amended to read as follows:

(h) Nurse aide (see section [415.13(c)(1)] 415.13(d)(1) of this Part).

Section 415.13, and the title thereof, are amended to read as follows:

Section 415.13 Nursing Services and Minimum Nursing Staff Requirements.

(a) Staffing standards. The facility shall have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care. The facility shall further assure that staffing levels enable each resident to receive[s] treatments, medications, diets and other health services in accordance with individual care plans. At a minimum, the facility shall ensure its daily nursing staff levels comply with paragraph (2) of subdivision (b) of this Section; provided, however, that compliance with paragraph (2) of subdivision (b) of this Section shall not serve as a defense where the facility has failed to provide sufficient nursing care to residents in accordance with their resident assessment and individual plans of care, or the facility failed to ensure residents received ordered treatments, medications, diets or other health services consistent with the residents' individual plans of care and in accordance with federal and State law and regulations.

[(a)] (b) Sufficient staff.

(1) The facility shall provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

- (i) registered professional nurses or licensed practical nurses;
- (ii) certified nurse aides, meaning any person included in the nursing home nurse aide registry pursuant to Section 2803-j of the Public Health Law; and
- (iii) other nursing personnel.

(2) Minimum Nursing Staff Requirements. At a minimum, the facility shall employ certified nurse aides, registered professional nurses, licensed practical nurses, or nurse aides sufficient to maintain the following daily staffing hours per resident:

(i) From January first, two thousand twenty-two through December thirty-first, two thousand twenty-two, the facility shall maintain daily average staffing hours equal to 3.5 hours of care per resident per day by a certified nurse aide, registered professional nurse, licensed practical nurse, or nurse aide. Out of such 3.5 hours, no less than 2.2 hours of care per resident per day shall be provided by a certified nurse aide or a nurse aide, and no less than 1.1 hours of care per resident per day shall be provided by a registered professional nurse or licensed practical nurses.

(ii) Beginning January first, two thousand twenty-three and thereafter, every nursing home shall maintain daily average staffing hours equal to 3.5 hours of care per resident per day by a certified nurse aide, registered professional nurse, or licensed practical nurse. Out of such 3.5 hours, no less than 2.2 hours of care per resident per day shall be provided by a certified nurse aide, and no less than 1.1 hours of care per resident per day shall be provided by a registered professional nurse or licensed practical nurse.

[(2)] (3) The facility shall designate a registered professional nurse or licensed practical nurse to serve as a charge nurse on each tour of duty who is responsible for the supervision of total nursing activities in the facility. Alternatively, as necessitated by resident care needs, the facility may designate one charge nurse for each tour of duty on each resident care unit or on proximate nursing care units in the facility provided that each nursing care unit in the facility is under the supervision of a charge nurse.

[(b)] (c) Registered professional nurse.

(1) The facility shall use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week, or more often as necessary to comply with the minimum staffing requirements set forth in paragraph (2) of subdivision (b) of this Section.

* * *

[(c)] (d) Nurse aide.

(1) For the purpose of this section and section 415.26(d) of this Part, nurse aide shall mean any person [who provides direct personal resident care and services including, but not limited to, safety, comfort, personal hygiene or resident protection services, for compensation, under the supervision of a registered professional nurse or licensed practical nurse in the facility] who is included in the nurse aide hour component of the federal Centers for Medicare and Medicaid Services payroll based journal for long-term care facilities but has not yet been certified as a certified nurse aide, including individuals who are in the first four months of employment and who are receiving training in a Department-approved nurse aide training and competency evaluation program and are providing nursing or nursing-related services for which they have been trained and are under the supervision of a licensed or registered nurse, or individuals, other than a licensed professional, who have been approved by the Department to

administer medications to residents. For the purposes of this section and section 415.26(d) of this Part, a nurse aide does not include volunteers or [except for] those individuals who furnish services to residents only as feeding assistants as defined in Section [415.13(d)] 415.13(e) of this Part. Certification of such nurse aide shall be in accordance with the provisions of section 415.26(d) of this Part.

* * *

[(d)] (e) Feeding Assistant.

* * *

(f) Non-Compliance with Staffing Standards.

(1) Compliance with the minimum nursing staff requirements set forth in paragraph (2) of subdivision (b) of this Section shall be determined on a quarterly basis, as determined by the Department, by comparing the daily average of the number of hours provided per resident, per day, using the most recent data available from the federal Centers for Medicare and Medicaid Services payroll based journal and the facility's average daily census on a daily basis.

(i) The Department shall initially determine whether a facility is compliant or non-compliant with the minimum nursing staff requirements by conducting the following three assessments:

(a) Assessing whether the total daily staffing hours provided per resident by nurse aides (only from January first, two thousand twenty-two through December thirty-first, two thousand twenty-two), certified nurse aides, licensed practical nurses, or registered nurses fell below 3.5 hours of care per resident on average over the course of the quarter; and

(b) Assessing whether at least 2.2 hours of care per resident per day was provided by a certified nurse aide or a nurse aide (only from January first, two thousand twenty-two through December thirty-first, two thousand twenty-two) on average over the course of the quarter; and

(c) Assessing whether at least 1.1 hours of care per resident per day was provided by a registered professional nurse or licensed practical nurse on average over the course of the quarter.

(ii) A facility that, on average over the course of the quarter, fell below the hourly requirements set forth in clauses (a) through (c) of subparagraph (i) will be considered non-compliant for the purposes of this Section. Any facility that the Department finds non-compliant shall have progressive penalties assessed based upon the number of days per quarter in which the daily staffing hours provided per resident fell below the minimum hourly requirements set forth in paragraph (2) of subdivision (b) of this Section.

(iii) For the purposes of determining compliance, an individual shall not be counted while performing administrative services, as defined in the Centers for Medicare and Medicaid Services payroll based journal for long-term care facilities. Further, individuals who are attending training, either onsite or offsite, and are not available to perform their primary job duties shall not be counted for purposes of determining compliance with the minimum daily staffing hours.

(2) Penalties.

(i) The Department shall impose a penalty of up to two thousand (2,000) dollars per day for each day in a quarter that a facility fails to comply with the minimum nursing staff requirements set forth in paragraph (2) of subdivision (b) of this Section, unless mitigating or aggravating factors exist.

(ii) Mitigating Factors. The Department may reduce penalties, to an amount no lower than three hundred (300) dollars per day in a quarter that a facility is non-compliant, if the Department determines, in its sole discretion, that any of the following mitigating circumstances existed during the period of non-compliance:

(a) Extraordinary circumstances faced the facility. For the purposes of this clause, extraordinary circumstances shall mean that the facility experienced a natural disaster; a national emergency affecting the facility has been officially declared; a State or municipal emergency affecting the facility has been declared pursuant to Article 2-B of the Executive Law; or the facility experienced a catastrophic event that caused physical damage to the facility or impaired the ability of facility personnel to access the facility. Provided, however, that the facility must first demonstrate, to the satisfaction of the Department, that such extraordinary circumstances could not have been prevented or mitigated through effective implementation of the facility's pandemic emergency plan, prepared pursuant to Section 2803(12) of the Public Health Law, and that the facility complied with the disaster and emergency preparedness requirements set forth in Section 415.26(f) of this Part; or

(b) An acute labor supply shortage of nurse aides, certified nurse aides, licensed practical nurses, or registered nurses exists in the Metropolitan and Nonmetropolitan Area in which the facility is located, as such areas are defined by the federal Bureau of Labor Statistics.

(l) For the purposes of determining whether a facility was located in an area experiencing an acute labor supply shortage during the period of non-compliance, the Commissioner shall issue a determination on a quarterly basis as to whether an acute labor supply shortage of nurse aides, certified nurse aides, licensed practical nurses, or registered nurses exists in any Metropolitan or Nonmetropolitan Area of New York State. Such determination shall be made in consultation with the New York State Department of Labor and shall take into account job availability metrics developed by the New York State Department of Labor, which may include but is not limited to the list of job openings in New York State.

(2) The fact that the facility is located in an area experiencing an acute labor supply shortage pursuant to this clause shall not serve as a mitigating factor unless the facility has demonstrated, to the satisfaction of the Department, reasonable attempts to procure sufficient staffing during the period of non-compliance, notwithstanding the acute labor supply shortage. Reasonable attempts may include, but not be limited to, incentivizing new personnel through increased wage and benefit offers and searching for personnel outside of the Metropolitan and Nonmetropolitan Area in which the facility is located;

(3) The fact that the facility is located in an area experiencing an acute labor supply shortage pursuant to this clause shall not serve as a mitigating factor unless the facility has demonstrated, to the satisfaction of the Department, that it has taken steps over the course of the quarter to ensure resident health and safety notwithstanding any labor supply shortage, including but not limited to discontinuing admissions, closing units, or transferring residents to another appropriate facility; or

(c) A verifiable union dispute exists between the facility and nurse aides, certified nurse aides, licensed practical nurses, or registered nurses employed or contracted by such facility, resulting in a labor shortage at the facility.

(g) Eligibility for Funding to Comply with Minimum Nursing Staff Requirements.

The Department shall determine which nursing homes are anticipated to be in compliance with Section 2828 of the Public Health Law based on the most current, available Residential Health Care Facility cost report data, or such other source of cost information as the Department shall identify. Pursuant to methodology set forth in the current Medicaid State Plan Amendment, the Department shall determine whether such nursing homes must expend additional funds to comply with this Section, beyond any costs necessary to comply with Section 2828 of the Public

Health Law. Any such nursing home that the Department finds will be required to expend additional funds to comply with this Section shall be eligible to receive from the Department additional funds, subject to availability from the New York State Division of the Budget, to hire nursing staff necessary to achieve the minimum nursing staff requirements set forth in paragraph (2) of subdivision (b) of this Section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under sections 2803 and 2895-b of the Public Health Law, which provides that the Commissioner of Health enact regulations establishing standard nursing home staffing levels.

Legislative Objectives:

The legislative objective of PHL section 2895-b is to ensure safe and appropriate levels of nurse staffing in nursing homes in order to improve the care for residents of nursing homes. Research has demonstrated that as nurse turnover increases in nursing homes, the quality of resident care declines. Therefore, having adequate nurse staffing levels provides residents with the highest quality of care. Requiring these facilities to meet this minimum level of staffing will help ensure patient safety and improve the quality of care received by the residents of the nursing home.

Needs and Benefits:

These regulations are necessary to implement the statutory directive of PHL section 2895-b. Specifically, pursuant to the statute, the regulations: (1) set forth minimum nurse staffing standards; (2) provide for the imposition of penalties for failure to meet minimum staffing standards; (3) provide for mitigating factors for failure to meet the minimum staffing requirements; and (4) set forth a process for the Department to determine facilities that are in need of assistance to meet the staffing requirements.

Costs:**Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:**

This regulation seeks to implementing standard minimum nursing home staffing levels. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum staffing requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum staffing thresholds. In any event, if costs are borne by residential health care facilities, compliance with these minimum staffing requirements is mandated by Public Health Law section 2895-b, and as such these regulatory amendments are necessary.

Costs to State and Local Governments:

This regulation will not impact local or State governments unless they operate a residential health care facility, in which case the costs will be the same as for privately-operated facilities. Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and 6 residential health care facilities operated by the State.

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health.

Local Government Mandates:

Residential health care facilities operated by local governments will be affected and will be subject to the same requirements as any other residential health care facility licensed under PHL Article 28.

Paperwork:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit staffing and care information through the facility's average daily census on a daily basis, such reporting is already required. Therefore, the submission of this data does not create a new requirement, and the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

These regulations are mandated pursuant to PHL section 2895-b. Accordingly, the alternative of not issuing these regulations was rejected. The Department considered different alternatives for the imposition of civil penalties and determined that penalties need to be high enough to prevent facilities from simply paying the penalty as a cost of doing business rather than complying with the law.

Federal Standards:

No federal standards apply.

Compliance Schedule:

The regulations incorporate the compliance dates contained in the Public Health Law section 2895-b, which requires a certain level of staffing by January 1, 2022, and a certain level by January 1, 2023.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

This regulation implements PHL Section 2895-b, which provides the Commissioner of Health authority to establish minimum staffing standards for nursing homes and impose civil penalties for nursing homes that fail to adhere to the minimum standards. These minimum standards, which take effect January 1, 2022, require every nursing home to maintain daily staffing hours equal to 3.5 hours of care per resident per day by a certified nurse aide (CNA), licensed practical nurse, or registered nurse with at least 2.2 hours of care per resident per day being provided by a CNA and at least 1.1 hours of care per resident per day provided by a licensed nurse. The nursing home must post information regarding nurse staffing at the facility. Penalties may not be assessed against nursing homes until April 1, 2022, and the Commissioner may take into consideration several mitigating factors when issuing penalties including declared disaster emergencies, the frequency of non-compliance, and regional labor supply shortages.

Compliance Requirements:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit staffing and care information through the facility's average daily census on a daily basis, such reporting is already required. Therefore, the submission of this data does not create any new requirement, and the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

This regulation seeks to implementing standard minimum nursing home staffing levels. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum staffing requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum staffing thresholds. In any event, if costs are borne by residential health care facilities, compliance with these minimum staffing requirements is mandated by Public Health Law section 2895-b, and as such these regulatory amendments are necessary.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL section 2895-b and necessary to ensure that direct resident care is prioritized by setting forth minimum staffing requirements for such care. Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Additionally, regulations provide that the Department shall determine whether nursing homes must expend additional funds to comply, and nursing homes that the Department finds will be required to expend additional funds to comply may be eligible to receive from the

Department additional funds, subject to availability from the New York State Division of the Budget, to hire nursing staff necessary to achieve the minimum nursing staff requirements.

Further, regulations establishing the civil penalties include mitigating factors to account for: (1) extraordinary circumstances facing the facility such as officially declared emergencies or natural disasters; (2) the frequency of the violations of the facility; and (3) the existence of a nurse labor shortage in the area of the nursing home

Small Business and Local Government Participation:

The Department will notify such entities of the existence of these regulations and the opportunity to submit comments or questions to the Department. 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.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

The governing statute directs the Commissioner of Health to establish civil penalties for those facilities that fail to comply with the minimum staffing requirements. However, there are several mitigating factors set forth in the regulation to potentially reduce the fine amount; additionally, the regulation provides for a progressive system of penalties depending on the number of days per quarter the facility was out of compliance with the minimum staffing requirements.

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 (<https://www.census.gov/quickfacts/>).

Approximately 17% of small health care facilities 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	

Licensed residential health care facilities are located in these identified rural areas.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit staffing and care information through the facility's average daily census on a daily basis, such reporting is already required. Therefore, the submission of this data does not form any new requirement, and the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities.

Costs:

This regulation seeks to implementing standard minimum nursing home staffing levels. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum staffing requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum staffing thresholds. In any event, if costs are borne by residential health care facilities, compliance with these minimum staffing requirements is mandated by Public Health Law section 2895-b, and as such these regulatory amendments are necessary.

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL section 2895-b and necessary to ensure that direct resident care is prioritized by setting forth minimum staffing requirements for such care. Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Additionally, regulations provide that the Department shall determine whether nursing homes must expend additional funds to comply, and nursing home that the Department finds will be required to expend additional funds to comply may be eligible to receive from the Department additional funds, subject to availability from the New York State Division of the Budget, to hire nursing staff necessary to achieve the minimum nursing staff requirements.

Further, regulations establishing the civil penalties include mitigating factors to account for: (1) extraordinary circumstances facing the facility such as officially declared emergencies or natural disasters; (2) the frequency of the violations of the facility; and (3) the existence of a nurse labor shortage in the area of the nursing home

Rural Area Participation:

The Department will notify all residential health care facilities, including those located in rural areas, of the existence of these regulations and the opportunity to submit public comments or questions to the Department. 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

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities. To the contrary, given the minimum requirements for nursing staff, including nurse aides, certified nurse aides, licensed practical nurses, and registered nurses, the Department anticipates that these regulations will have a positive impact on nursing jobs throughout the State, to the extent these regulations will help incentivize hiring in these professions.