

Disclosure of Quality and Surveillance Related Information

Effective date: 1/7/15

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2803 and 2805-t of the Public Health Law, a new Section 400.25 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Section 400.25 is added to read as follows:

Section 400.25 Disclosure of nursing quality indicators.

- (a) Definitions. For purposes of this section, the following terms shall have the following meanings:
- (1) Acuity means the nursing care requirements of patients or residents.
 - (2) Case mix means the differences in patients or residents within a population in terms of their physical and mental conditions, and the resources that are used in their care.
 - (3) Fall means:
 - (i) For general hospitals, an unplanned descent to the floor with or without injury to the patient including unassisted and assisted descents whether they result from physiological or environmental reasons.

- (ii) For nursing homes, an unintentional change in position coming to rest on the ground, floor or onto the next lower surface with or without injury to the resident including intercepted falls.
- (4) Fall injury level means:
 - (i) For general hospitals, the degree of injury resulting from a fall and designated as moderate, major or fatal. For purposes of this subparagraph: moderate injuries involve suturing, application of steri-strips/skin glue, splinting or muscle/joint strain; major injuries involve surgery, casting or traction, or require consultation to rule out neurological or internal injury or patients with coagulopathy that receive blood products as a result of the fall; and fatal falls involve injuries that cause the patient's death but do not include falls caused by physiologic events.
 - (ii) For nursing homes, the degree of injury resulting from a fall designated as major involves bone fractures, joint dislocations, closed head injuries with altered consciousness or subdural hematoma.
- (5) Healthcare setting associated infection means any localized or systemic patient condition that:
 - (i) resulted from the presence of an infectious agent or its toxin(s) as determined by clinical examination or by laboratory testing; and
 - (ii) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting.

- (6) Licensed Practical Nurse means a person who is licensed and currently registered as a Licensed Practical Nurse pursuant to Article 139 of the New York State Education Law.
- (7) Patient includes a resident of a nursing home.
- (8) Patient care staff means unit-based Registered Nurses, Licensed Practical Nurses and unlicensed personnel providing direct patient care greater than 50% of their shift.
- (9) Patient day is the average number of patients a unit has per shift during a 24 hour period.
- (10) Pressure ulcer means a localized injury to the skin and/or underlying tissue as a result of pressure or pressure in combination with shear acquired after admission to a healthcare facility.
- (11) Registered Nurse means a person who is licensed and currently registered as a Registered Professional Nurse pursuant to Article 139 of the New York State Education Law.
- (12) Shift means a 24 hour period of time as a whole or divided into parts as appropriate to the reporting facility.
- (13) Unit means a distinct location providing patient care in a general hospital or nursing home distinguished from other distinct locations by name, number or other patient-specific factors.
- (14) Unlicensed personnel means individuals trained to function in an assistive role to nurses in the provision of patient care, as assigned by and under the supervision of the Registered Nurse.

- (b) Nurse Staffing Indicators are:
- (1) The total number of productive hours of care provided by patient care staff per patient day for each unit, and the number and percentage of productive hours of care provided by Registered Nurses, Licensed Practical Nurses and unlicensed personnel each; and
 - (2) the average Registered Nurse and Licensed Practical Nurse to patient ratio for each unit and on each shift.
- (c) Nurse-sensitive patient outcome indicators for general hospitals are:
- (1) Falls with injury rate as indicated by the frequency in which falls result in a fall injury level of moderate, major or fatal per applicable unit calculated no less often than quarterly.
 - (2) Health care acquired pressure ulcers as indicated by the percentage of patients with facility-acquired pressure ulcer(s) of the skin that are determined to be stages II, III, IV, unstageable and suspected deep tissue injury per applicable unit calculated no less often than quarterly.
 - (3) Healthcare setting associated infection rates per applicable unit calculated no less often than quarterly for the following:
 - (i) Central line associated blood stream infection;
 - (ii) Catheter associated urinary tract infection; and
 - (iii) Ventilator associated (pneumonia) event.
- (d) Nurse-sensitive patient outcome indicators for nursing homes are:
- (1) Percent of long-stay residents who experienced one or more falls with major injury.

- (2) Percentage of short-stay residents who have medical conditions that predispose them to developing a facility-acquired pressure ulcer with new or worsening pressure ulcers Stage II-IV.
 - (3) Percentage of long-stay residents with urinary tract health care setting associated infections.
- (e) Within 30 days of a written request, general hospitals and nursing homes shall provide to the requester in hard copy or an electronic copy such as a portable document format (pdf) file, the following information for a three to twelve month period of time that is not more than one year prior to the date of the request:
- (1) nurse staffing indicators and nurse-sensitive patient outcome indicators specified in this section;
 - (2) the procedures and processes used for determining and adjusting staffing levels based on patient case mix and acuity;
 - (3) the final conclusions of any complaint investigations filed with any state or federal regulatory agency or accrediting agency and any citations resulting from surveys; and
 - (4) the sources and dates for data disclosed.
- (f) Facilities shall have policies and procedures for documentation and management of requests and responses to requests under this section. Documentation of requests and responses to requests under this section shall be kept for a period of no less than two years from the date the request for information was received.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of this regulation is contained in Public Health Law (PHL) Sections 2803 and 2805-t.

PHL Section 2803 outlines the powers and duties of the Commissioner. It also authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Section 2805-t authorizes the Commissioner to promulgate regulations on the disclosure of nursing quality indicators including: (1) the number of hours of total direct nursing care per patient; (2) the percentage of such nursing care provided by Registered Nurses, Licensed Practical Nurses and unlicensed personnel; (3) the ratio of patients per Registered Nurse providing direct care; (4) the incidence of select adverse patient care occurrences; (5) the procedures and processes used to determine staffing based on patient or resident case mix and/or acuity and the facility's compliance with these methods; and (6) outcomes of complaint investigation(s) filed with any state or federal regulatory agency or accrediting agency and survey(s) resulting in citation(s), including but not limited to significant medication errors.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost. The objective of PHL Section 2805-t is to provide the public with information regarding nursing staffing levels and nursing-sensitive patient outcome indicators.

Needs and Benefits:

The Nursing Care Quality Protection Act (Chapter 422 of the Laws of 2009), effective March 15, 2010, added PHL Section 2805-t and requires Article 28 facilities to disclose identified nursing quality indicator information upon request to any member of the public, and to the Commissioner of any State agency responsible for licensing the facility or responsible for overseeing the delivery of services by the facility, or any organization accrediting the facility. PHL Section 2805-t authorizes the Commissioner to promulgate regulations regarding disclosure of nursing quality indicators to such requesters. This regulation is to provide, consistent with PHL Section 2805-t, standards for the collection and disclosure of data regarding nursing staffing levels and nursing-sensitive patient outcome indicators. These regulations require the use of established, standardized definitions and measurement criteria that are, to the extent possible, already being collected by facilities.

COSTS:

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The Nursing Care Quality Protection Act (Chapter 422 of the Laws of 2009), became effective March 15, 2010, 180 days after it was signed into law. Initial compliance was facilitated by guidance documents developed collaboratively with stakeholders and communicated to facilities via Dear Administrator letters. At this point, facilities have been complying with the requirements of the Nursing Care Quality Protection Act for over three years. In addition: (1) CMS utilizes and makes information regarding a number of these indicators available to the public on the Nursing Home Compare website as measures of quality; (2) prior to this law becoming effective over 50% of hospitals already participated in the National Database for Nursing Quality Indicators (NDNQI) which requires measurement and reporting of the nursing quality indicators included in this regulation; and (3) a CMS hospital requirement recently became effective that requires measurement and reporting of a number of these same indicators. Costs associated with collecting and maintaining data have already been borne. Ongoing costs of implementation will be small but variable, relative to the number and complexity of requests for information received. It is estimated that an average size facility would expend \$5.00 per request to make 5, 10-page reports available per year, for a total annual cost of \$25.00.

Costs to Local and State Government:

Article 28 facilities that fall under the jurisdiction of local or state government such as county nursing homes, clinics, or hospitals are affected and incur costs the same as any other

Article 28 facilities. Ongoing costs of implementation will be small but variable, relative to the number and complexity of requests for information received.

Costs to the Department of Health:

There will be no additional costs to the Department of Health in enforcing this regulation. Implementation and surveillance of these provisions will be accomplished utilizing existing staff.

Article 28 facilities operated by the Department of Health (Helen Hayes Hospital and Four Veterans' Nursing Homes) are affected and incur costs the same as any other Article 28 facilities. Ongoing costs of implementation will be small but variable, relative to the number and complexity of requests for information received.

Local Government Mandates:

Article 28 facilities that fall under the jurisdiction of local government such as county nursing homes or general hospitals will be affected and be subject to the same requirements as any other Article 28 facilities.

Paperwork:

New paperwork associated with this regulation is minimal. Tracking and measurement of staffing data for payroll purposes is routine in all Article 28 facilities. One hundred fifty-one (151) hospitals currently measure staffing and nursing-sensitive patient outcome indicators in the manner required by these regulations as a result of their voluntary participation in the National Database for Nursing Quality Indicators (NDNQI). In addition, many other hospitals measure and track these indicators without formal participation in NDNQI in order to benchmark their nursing quality against other facilities. Nursing homes currently report nursing quality indicator

measures/information through Minimum Data Set (MDS) submissions, so a substantial amount of new paperwork is also not expected for these providers. Maintenance of requests for nursing quality indicator information for the required two year period of time will be new but should not create considerable paperwork for Article 28 providers.

Duplication:

This proposal does not duplicate any New York State regulation. In an effort to avoid duplication of work for regulated facilities, when appropriate, efforts have been made to define nursing staffing and patient outcome indicator measurement and calculation in the same way as defined by the Center for Medicaid and Medicare Services (CMS), Centers for Disease Control and Prevention (CDC), New York State Department of Health (NYSDOH), National Quality Forum (NQF) and/or the National Database of Nursing Quality Indicators (NDNQI)—entities where these indicators are either already required for submission or, a submission plan is under development or, in the case of NDNQI, have been elected voluntarily for submission by NYS hospitals and/or LTC facilities.

There is a CMS initiative requiring hospitals to participate in a nursing registry and submit nursing quality indicators consistent with this proposed regulation. The planned acknowledgement of submission of 2012 structural measures data was April 1, 2013 through May 15, 2013.

Alternative Approaches:

These regulations are authorized by PHL Section 2805-t. Efforts have been made to minimize any adverse impact by requiring standardized indicators that in many cases are already being collected by the facilities. Acceptable methods of disclosure include facility report cards, website displays, information included in patient information materials, and tailored reports based on submitted requests for this information.

Federal Requirements:

CMS Hospital Inpatient Quality Reporting (IQR) Program requires that certain measures are reported that assess the characteristics and capacity of the provider to deliver quality healthcare. This includes Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. A hospital's Annual Payment Update is affected when the hospital does not answer all required questions indicating participation or non-participation in a registry. For FFY 2014 dates for acknowledging collection of IQR data were April 1, 2013, through May 15, 2013.

The Centers for Medicare & Medicaid Services (CMS) began a national Nursing Home Quality Initiative (NHQI) in 2002. The nursing home quality measures come from resident assessment data that nursing homes routinely collect on the residents at specified intervals during their stay. These measures assess the resident's physical and clinical conditions and abilities, as well as preferences and life care wishes. These assessment data are converted to develop quality measures that show how well nursing homes are caring for their residents' physical and clinical needs. The Minimum Data Set (MDS) is currently in use to collect resident assessment data.

Compliance Schedule:

This regulation will take effect upon publication of a Notice of Adoption in the New York *State Register*.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

The provisions of this regulation will apply to hospital and nursing homes authorized to operate pursuant to Public Health Law Article 28. Such facilities include: 228 general hospitals, and 635 nursing homes. Three general hospitals and 84 nursing homes are considered small businesses. Local governments operate 18 hospitals and 40 nursing homes.

Compliance Requirements:

General hospitals and nursing homes will be required to disclose identified nursing quality indicators, including information associated with complaint investigations and surveys, and methods used to determine and adjust staffing levels upon request. Records of requests and facility response must be kept for a period of no less than two years in order for organizations to be able to track and show evidence of their compliance with requests for this information.

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 the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

At this point, facilities have been complying with the requirements of the Nursing Care Quality Protection Act for over three years. Ongoing costs of implementation will be small but variable, relative to the number and complexity of requests for information received.

Economic and Technological Feasibility:

It is economically and technologically feasible for small businesses and local governments to comply with these regulations.

Minimizing Adverse Impact:

The regulations will require standardized measurement of nursing quality indicators and limit indicators to those that have been established as valid and reliable. The Department will not require hospitals and nursing homes to create additional reports to comply with these provisions. In order to minimize any adverse impact, the Department will allow facilities to use as acceptable methods of disclosure: facility report cards, website displays, information included in patient information materials, and tailored reports based on submitted requests for this information.

Small Business and Local Government Participation:

Outreach to the affected parties was and continues to be conducted. Affected parties were given the opportunity to contribute to the pre-publication development of the content and processes involved in implementation of this regulation. Organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Number of Rural Areas:

The proposed amendment will apply Statewide, including the 43 rural counties with less than 200,000 inhabitants, and the 10 urban counties with a population density of 150 per square mile or less.

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

This proposal specifies that “facilities shall have policies and procedures for documentation and management of requests and responses to requests under this section. Records must be kept for a period of no less than two years from the date the information was received.” At this point, facilities have been complying with the requirements of the Nursing Care Quality Protection Act for over three years. Ongoing costs of implementation will be small but variable, relative to the number and complexity of requests for information received.

Minimizing Adverse Impact:

The regulations will require standardized measurement of nursing quality indicators and limit indicators to those that have been established as valid and reliable. The Department will not require hospitals and nursing homes to create additional reports to comply with these provisions. In order to minimize any adverse impact, the Department will allow facilities to use as acceptable methods of disclosure: facility report cards, website displays, information included in patient information materials, and tailored reports based on submitted requests for this information.

Rural Area Participation:

Outreach to the affected parties, including those in rural areas is being conducted. Organizations that represent the affected parties have been given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

JOB IMPACT STATEMENT

Pursuant to the State Administrative Procedure Act (SAPA) Section 201-a(2)(a), a Job Impact Statement for this amendment is not required because it is apparent from the nature and purposes of the proposed rules that they will not have a substantial adverse impact on jobs and employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The comment period ended on February 24, 2014, and the Department received one comment from the New York State Nurses Association (NYSNA).

Comment:

The NYSNA expressed opposition to the regulations as proposed. NYSNA's letter identified opposition to the proposal due to concerns that the proposed regulations were not written to apply to all Article 28 facility types, that the proposed form and timeliness of data disclosure was not consistent with the statute and allowed for the possibility of misrepresentation of true staffing and inclusion of non-direct care nursing staff hours in staffing indicator counts.

Response:

In response, the Department notes that the nursing quality indicators included in the proposed regulations have been determined to be valid and reliable in hospitals and nursing homes only and that Public Health Law § 2805-t only requires reporting of data "as specified by the commissioner by rule or regulation." See also, L. 2009, ch. 422, Governor's Approval Memo No. 18 ("The bill entrusts the Commissioner of Health with ample authority and responsibility to appropriately tailor its application. . . . For example, if the Commissioner, in consultation with relevant stakeholders, determines that certain measures are not appropriate for assessing nursing care quality in diagnostic and treatment centers that offer primary care, the Commissioner may exempt or limit their disclosure in regulation. I have confirmed with the sponsors that this is their understanding of the legislation [emphasis supplied]"). The Department will propose regulations to amend section 400.25, if necessary, if it identifies additional indicators it determines to be valid and reliable for Article 28 facilities.

In regards to NYSNA's concerns about the timeliness and form of data disclosure, the Department responds that the proposed regulations were based upon the standardized definitions, measurement and reporting of National Database of Nursing Quality Indicators (NDNQI) for hospitals and the Centers for Medicare and Medicaid Services (CMS) for nursing homes allowing for comparison of nurse sensitive indicators across facilities.

Although "productive hours" is not defined in the proposed regulations, the Department intends to include the definition of this term in an update to previously published implementation guidelines for PHL section 2805-t. The definition of productive hours is derived from that used by NDNQI and is consistent with NYSNA's desire to include only those hours devoted to direct patient care in the counting of nursing hours and staff.