

## AN ACT RELATIVE TO PATIENT SAFETY

SECTION 1. Chapter 118G of the General laws, as appearing in the 2004 Official Edition, is hereby amended by adding the following new section:-

### Section 28:

- a. The division shall require hospitals, nursing homes, chronic care and rehabilitation hospitals, other specialty hospitals, clinics, including mental health clinics, all other health care institutions, organizations and corporations licensed or registered by the department of public health and health maintenance organizations as defined in chapter 176G to annually report appropriate data to the division. This data will be posted and made available to the general public via the internet and include but not be limited to:
  - i. measures which differentiate between severity of patient illness, readmission rates, length of stay, patient/family satisfaction with care, nurse satisfaction and nurse vacancy rates;
  - ii. indicators of the nature and amount of nursing care directly provided by licensed nurses including, but not limited to, the actual and the average ratio of registered nurses to patients or residents and the actual and the average skill mix ratio of licensed and supervised unlicensed personnel to patients or residents, and statistics as defined by the National Quality Forum (NQF) and/or the Center for Medicare and Medicaid Services (CMS) on the number of falls, number of incidents of failure to rescue, number of health care acquired infections, including sepsis and pneumonia, and number of medication errors.
  - iii. documentation of defined nursing interventions such as clinical assessment by a licensed provider, pain measurement and management, skin integrity management, patient education and discharge planning; and
  - iv. documentation of patient safety measures such as restraint checks, seizure precautions and suicidal precautions, to enable purchasers of group health insurance policies and health care services and for the public at large to make meaningful financial and quality of care comparisons.
- b. The division shall consult with interested parties, including but not limited to; the group insurance commission, the Massachusetts nurses association, the Massachusetts health data consortium, the Massachusetts hospital association, the public health council, Massachusetts senior action council, associated industries of Massachusetts, a large labor union, the division of medical assistance, the board of registration in nursing, the division of insurance, the Massachusetts association of health maintenance organizations, and a national council of quality assurance accreditation expert to develop methodologies for collecting and reporting data pursuant to this section and to plan for its use and dissemination to culturally diverse populations.
- c. Subject to the provisions of section 2(c) of chapter 66A, information collected by the division pursuant to this section shall be made available annually in the form of printed reports and through electronic medium derived from raw data and/or through computer-to-computer access. All personal data shall be maintained with the physical

safeguards enumerated in said chapter.

SECTION 2. Section 70E of Chapter 111 of the General Laws is hereby amended by striking out in line 89 the word “and”.

SECTION 3. Said section 70E of said Chapter 111, as so appearing, is hereby further amended by striking out in line 99 the word “foregoing.” and adding, the following words “foregoing; and”.

SECTION 4. Said section 70E of said Chapter 111, as so appearing, is hereby further amended by adding at the end thereof the following new subsection:—

(o) upon request, to receive from a duly authorized representative of the facility, disclosure of nursing sensitive outcome data as defined by NQF and/or CMS for statistics including but not limited to, the actual and the average ratio of registered nurses to patients or residents and the actual and the average skill mix ratio of licensed and supervised unlicensed personnel to patients or residents, the number of falls, the number of incidents of failure to rescue, the number of health care acquired infections, including sepsis and pneumonia, and the number of medication errors, and further, upon request, to receive from said duly authorized representative information regarding the educational preparation and length of employment of said facility’s nursing staff, as well as information on nurse satisfaction and nurse vacancy rates, and to receive a copy of the comparative nursing care data report as outlined in chapter 118G, section 24 subsection (a). The fee for said report shall be determined by the rate of reasonable copying expenses.

SECTION 5. Chapter 111 of the General Laws is hereby amended by adding the following 9 sections:—

Section 221. As used in sections 221 to 229, inclusive, the following words shall, unless the context clearly requires otherwise, have the following meanings:—

“Adjustment of standards”, the adjustment of nurse’s patient assignment standards in accordance with patient acuity according to, or in addition to, direct-care registered nurse staffing levels determined by the nurse manager, or his designee, using the patient acuity system developed by the department and any alternative patient acuity system utilized by hospitals, if said system is certified by the department.

“Acuity”, the intensity of nursing care required to meet the needs of a patient; higher acuity usually requires longer and more frequent nurse visits and more supplies and equipment.

“Assignment”, the provision of care to a particular patient for which a direct-care registered nurse has responsibility within the scope of the nurse’s practice, notwithstanding any general or special law to the contrary.

“Assist”, patient care that a direct-care registered nurse may provide beyond his patient assignments if the tasks performed are specific and time-limited.

“Board”, the board of registration in nursing.

“Circulator”, a direct-care registered nurse devoted to tracking key activities in the operating room.

“Department”, the department of public health.

“Direct-care registered nurse”, a registered nurse who has accepted direct responsibility and accountability to carry out medical regimens, nursing or other bedside care for patients.

“Facility”, a hospital licensed under section 51, the teaching hospital of the University of Massachusetts medical school, any licensed private or state-owned and state-operated general acute care hospital, an acute psychiatric hospital, an acute care specialty hospital, or any acute care unit within a state-operated facility. As used in sections 221 to 229, inclusive, this definition shall not include rehabilitation facilities or long-term acute care facilities.

“Float nurse”, a direct-care registered nurse that has demonstrated competence in any clinical area that he may be requested to work and is not assigned to a particular unit in a facility.

“Health Care Workforce”, personnel that have an effect upon the delivery of quality care to patients, including but not limited to, licensed practical nurses, unlicensed assistive personnel and/or other service, maintenance, clerical, professional and/or technical workers and other health care workers.

“Mandatory overtime”, any employer request with respect to overtime, which, if refused or declined by the employee, may result in an adverse employment consequence to the employee. The term overtime with respect to an employee means any hours that exceed the predetermined number of hours that the employer and employee have agreed that the employee shall work during the shift or week involved.

“Nurse’s patient limit”, the maximum number of patients assigned to each direct-care registered nurse at one time on a particular unit.

“Monitor in moderate sedation cases”, a direct-care registered nurse devoted to continuously monitoring his patient’s vital statistics and other critical symptoms.

“Nurse manager”, the registered nurse, or his designee, whose tasks include, but are not limited to, assigning registered nurses to specific patients by evaluating the level of experience, training, and education of the direct-care nurse and the specific acuity levels of the patient.

“Nurse’s patient assignment standard”, the optimal number of patients to be assigned to each direct-care registered nurse at one time on a particular unit.

“Nursing care”, care which falls within the scope of practice as defined in section 80B of chapter 112 or is otherwise encompassed within recognized professional standards of nursing practice, including assessment, nursing diagnosis, planning, intervention, evaluation and patient advocacy.

“Overwhelming patient influx”, an unpredictable or unavoidable occurrence at unscheduled or unpredictable intervals that causes a substantial increase in the number of patients requiring emergent and immediate medical interventions and care, a declared national or state emergency, or the activation of the health care facility disaster diversion plan to protect the public health or safety.

“Patient acuity system”, a measurement system that is based on scientific data and compares the registered nurse staffing level in each nursing department or unit against actual patient nursing care requirements of each patient, taking into consideration the health care workforce on duty and available for work appropriate to their level of training or education, in order to predict registered nursing direct-care requirements for individual patients based on the severity of patient illness. Said system shall be both practical and effective in terms of hospital implementation.

“Teaching hospital”, a facility as defined in section 51 that meets the teaching facility definition of the American Association of Medical Colleges.

“Temporary nursing service agencies”, also known as the nursing pool as defined in section 72Y, and as regulated by the department.

“Unassigned registered nurse”, includes, but not limited to, any nurse administrator, nurse supervisor, nurse manager, or charge nurse that maintains his registered nurse licensing certification but is not assigned to a patient for direct care duties.

Section 222. The department shall reevaluate the numbers that comprise the nurse’s patient assignment standards and nurse’s patient limits and the patient acuity system in the evaluation period and then every 3 years thereafter, taking into consideration evolving technology or changing treatment protocols and care practices and other relevant clinical factors.

Section 223. (a) The department shall develop nurse's patient assignment standards which shall be an ideal number of patients assigned to a direct-care registered nurse that will promote equal, high-quality, and safe patient care at all facilities. The standards shall form the basis of nurse staffing plans set forth in section 225. The department shall use, at a minimum, the following information to develop nurse's patient assignment standards for all facilities: (1) Massachusetts specific data, including, but not limited to, the role of registered nurses in the commonwealth by type of unit, the current staffing plans of facilities, the relative experience and education of registered nurses, the variability of facilities, and the needs of the patient population; (2) fluctuating patient acuity levels; (3) variations among facilities and patient care units; (4) scientific data related to patient outcomes, a rigorous analysis of clinical data related to patient outcomes and valid nationally recognized scientific evidence on patient care, facility medical error rates, and health care quality measures; (5) availability of technology; (6) treatment modalities within behavioral health facilities; and (7) public testimony from both the public and experts within the field.

(b) The nurse's patient assignment standards may be adjustable and flexible, as determined by the department, to consider factors, including but not limited to; varying patient acuity, time of day, and registered nurse experience. The number of patients assigned to each direct-care registered nurse may not be averaged. The nurse's patient assignment standards may not refer to a total number of patients and a total number of direct-care registered nurses on a unit and shall not be factored over a period of time.

(c) The department shall develop nurse's patient limits which represent the maximum number of patients to be safely assigned to each direct-care registered nurse at one time on a particular unit. The number of patients assigned to each direct-care registered nurse shall not be averaged and each limit shall pertain to only one direct-care registered nurse. Nurse's patient limits shall not refer to a total number of patients and a total number of direct-care registered nurses on a unit and shall not be factored over a period of time. A facility's failure to adhere to these nurse's patient limits shall result in non-compliance with this section and the facility shall be subject to the enforcement procedures herein and section 228.

(d) If the commissioner finds that, for any unit, the department cannot arrive at a rationally based limit using available scientific data, the commissioner shall report to: (1) the clerks of the house of representatives and the senate who shall forward the same to the speaker of the house of representatives, the president of the senate, the chairs of the joint committee on public health, and the joint committee on state administration and regulatory oversight; (2) the commissioner of the division of health care financing and policy; and (3) the nursing advisory board as defined in section 16H of chapter 6A, the reasons for the department's failure to arrive at a rationally based limit and the data necessary for the department to determine a limit by the next review period.

(e) The setting of nurse's patient assignment standards and nurse's patient limits for registered nurses shall not result in the understaffing or reductions in staffing levels of the health care workforce. The availability of the health care workforce enables registered nurses to focus on the nursing care functions that only registered nurses, by law, are permitted to perform and thereby helps to ensure adequate staffing levels.

(f) Nurse's patient assignment standards and nurse's patient limits shall be determined for the following departments, units or types of nursing care:— intensive care units, (a) critical patient(s) (b) critical unstable patient(s); critical care units, (a) critical patient(s) (b) critical unstable patient(s); neo-natal intensive care (a) critical patient(s) (b) critical unstable patient(s); burn units (a) critical patient(s) (b) critical unstable patient(s); step-down/intermediate care; operating rooms, (a) not to include a registered nurse working as a circulator (b) to be determined for registered nurse working as a monitor in moderate sedation cases; post anesthesia care with the patient remaining under anesthesia; post-anesthesia care with

the patient in a post-anesthesia state; emergency department overall; emergency critical care, provided that the triage, radio or other specialty registered nurse is not included; emergency trauma; labor and delivery with separate standards for (i) a patient in active labor, (ii) patients, or couplets, in immediate postpartum, and (iii) patients, or couplets, in postpartum; intermediate care nurseries; well-baby nurseries; pediatric units; psychiatric units; medical and surgical; telemetry; observational/out-patient treatment; transitional care; acute inpatient rehabilitation; specialty care unit; and any other units or types of care determined necessary by the department.

(g) The department shall jointly, with the department of mental health, develop nurse's patient assignment standards and nurse's patient limits in acute psychiatric care units. These standards and limits shall not interfere with the licensing standards of the department of mental health.

(h) Nothing in this section shall exempt a facility that identifies a unit by a name or term other than those used in this section, from complying with the nurse's patient assignment standards and nurse's patient limits and other provisions established in this section for care specific to the types of units listed.

Section 224. (a) The department shall develop a patient acuity system, as defined in section 221. The department may also certify patient acuity systems developed or utilized by facilities. Patient acuity systems shall include standardized criteria determined by the department. The patient acuity system shall be used by facilities to: (1) assess the acuity of individual patients and assign a value, within a numerical scale, to each individual patient; (2) establish a methodology for aggregating patient acuity; (3) monitor and address the fluctuating level of acuity of each patient; (4) supplement the nurse's patient assignments and indicate the need for adjustment of direct-care registered nurse staffing as patient acuity changes; and (5) assess the need for health care workforce staff to ensure nurses' focus on the delivery of patient care.

(b) The patient acuity system designed by the department or other patient acuity system used by a facility and certified by the department shall be used in determining adjustments in the number of direct-care registered nurses due to the following factors: (1) the need for specialized equipment and technology; (2) the intensity of nursing interventions required and the complexity of clinical nursing judgment needed to design, implement and evaluate the patient's nursing care plan consistent with professional standards of care; (3) the amount of nursing care needed, both in number of direct-care registered nurses and skill mix of members of the health care workforce necessary to the delivery of quality patient care required on a daily basis for each patient in a nursing department or unit, the proximity of patients, the proximity and availability of other resources, and facility design; (4) appropriate terms and language that are readily used and understood by direct-care registered nurses; and (5) patient care services provided by registered nurses and the health care workforce.

(c) The patient acuity system shall include a method by which facilities may adjust a nurse's patient assignments within the limits determined by the department as follows: (1) a nurse manager or designee shall adjust the patient assignments according to the patient acuity system whenever practicable as determined by need; (2) a nurse manager or designee shall adjust the patient assignments when the department-developed or certified patient acuity system indicates a change in acuity of any particular patient to the extent that it triggers an alert mechanism tied to the aggregate patient acuity; (3) a nurse manager or designee shall be responsible for reassigning patients to comply with the patient acuity system, provided that the nurse manager may rearrange patient assignments within the direct-care registered nurses already under management and may also utilize an available float nurse; (4) at any time, any registered nurse may assess the accuracy of the patient acuity system as applied to a patient in the registered nurse's care. Nothing in this section shall supersede or replace any

requirements otherwise mandated by law, regulation or collective bargaining contract so long as the facility meets the requirements determined by the department.

Section 225. As a condition of licensing by the department, each facility shall submit annually to the department a prospective staffing plan with a written certification that the staffing plan is sufficient to provide adequate and appropriate delivery of health care services to patients for the ensuing year. A staffing plan shall: (1) incorporate information regarding the number of licensed beds and amount of critical technical equipment associated with each bed in the entire facility; (2) adhere to the nurse's patient assignment standards; (3) employ the department -developed or facility-developed or any alternative patient acuity system developed or utilized by a facility and certified by the department when addressing fluctuations in patient acuity levels that may require adjustments in registered nurse staffing levels as determined by the department; (4) provide for orientation of registered nursing staff to assigned clinical practice areas, including temporary assignments; (5) include other unit or department activity such as discharges, transfers and admissions, and administrative and support tasks that are expected to be done by direct-care registered nurses in addition to direct nursing care; (6) include written reports of the facility's patient aggregate outcome data; (7) incorporate the assessment criteria used to validate the acuity system relied upon in the plan; and (8) include services provided by the health care workforce necessary to the delivery of quality patient care. As a condition of licensing, each facility shall submit annually to the department an audit of the preceding year's staffing plan. The audit shall compare the staffing plan with measurements of actual staffing, as well as measurements of actual acuity for all units within the facility assessed through the patient acuity system.

Section 226. (a) A direct-care registered nurse at the beginning of the nurse's shift will be assigned to a certain patient or patients by the nurse manager, who shall use professional judgment in so assigning, provided that the number of patients so assigned shall not exceed the nurse's patient limit associated with the unit.

(b) An unassigned registered nurse may be included in the counting of the nurse to patient assignment standards only when that unassigned registered nurse is providing direct care. When an unassigned registered nurse is engaged in activities other than direct patient care, that nurse shall not be included in the counting of the nurse to patient assignments. Only an unassigned registered nurse, who has demonstrated current competence to the facility to provide the level of care specific to the unit to which the patient is admitted, may relieve a direct-care registered nurse from said unit during breaks, meals, and other routine and expected absences.

(c) Nothing in this section shall prohibit a direct-care registered nurse from assisting with specific tasks within the scope of the nurse's practice for a patient assigned to another nurse.

(d) Each facility shall plan for routine fluctuations in patient census. In the event of an overwhelming patient influx, said facility shall demonstrate that prompt efforts were made to maintain required staffing levels during the influx and that mandated limits were reestablished as soon as possible, and no longer than a total of 48 hours after termination of the event, unless approved by the department.

(e) For the purposes of complying with the requirements set forth in this section, except in cases of federal or state government declared public emergencies, or a facility-wide emergency, no facility may employ mandatory overtime.

Section 227. (a) No facility shall directly assign any unlicensed personnel to perform non-delegable licensed nurse functions to replace care delivered by a licensed registered nurse. Unlicensed personnel are prohibited from performing functions which require the clinical assessment, judgment and skill of a licensed registered nurse. Such functions shall include, but

not be limited to: (1) nursing activities which require nursing assessment and judgment during implementation; (2) physical, psychological, and social assessment which requires nursing judgment, intervention, referral or follow-up; (3) formulation of the plan of nursing care and evaluation of the patient's response to the care provided; (4) administration of medications; and (5) health teaching and health counseling. (b) For purposes of compliance with this section, no registered nurse shall be assigned to a unit or a clinical area within a facility unless the registered nurse has an appropriate orientation in the clinical area sufficient to provide competent nursing care and has demonstrated current competency levels through accredited institutions and other continuing education providers.

Section 228. (A) If a facility can reasonably demonstrate to the department, with sufficient documentation as determined by the appropriate entity, the attorney general or the division of health care finance and policy, extreme financial hardship as a consequence of meeting the requirements set forth in sections 221 to 229, inclusive, then the facility may apply to the department for a waiver of up to 9 months.

(B) As a condition of licensing, a facility required to have a staffing plan under this section shall make available daily on each unit the written nurse staffing plan to reflect the nurse's patient assignment standard and the nurse's patient limit as a means of consumer information and protection.

(C) The department shall enforce paragraphs (1) to (6), inclusive, as follows: (1) If the department determines that there is an apparent pattern of failure by a facility to maintain or adhere to nurse's patient limits in accordance with sections 221 to 228, inclusive, the facility may be subject to an inquiry by the department to determine the causes of the apparent pattern. If, after such inquiry, the department determines that an official investigation is appropriate and after issuance of written notification to the facility, the department may conduct an investigation. Upon completion of the investigation and a finding of noncompliance, the department shall give written notification to the facility as to the manner in which the facility failed to comply with sections 221 to 228, inclusive. Facilities shall be granted due process during the investigation, which shall include the following: (a) notice shall be granted to facilities that are noncompliant with sections 221 to 228, inclusive; (b) facilities shall be afforded the opportunity to submit to the department, through written clarification, justifications for failure to comply with sections 221 to 228, inclusive, if so determined by said department, including, but not limited to, patient outcome data and other resources and personnel available to support the registered nurse and patients in the unit, provided however, that facilities shall bear the burden of proof for any and all justifications submitted to the department; (c) based upon such justifications, the department may determine any corrective measures to be taken, if any. Such measures may include: (i) an official notice of failure to comply; (ii) the imposition of additional reporting and monitoring requirements; (iii) revocation of said facility's license or registration; and (iv) the closing of the particular unit that is noncompliant. (2) Failure to comply with limited nurse staffing requirements shall be evidence of noncompliance with this section. (3) Failure to comply with the provisions of this section is actionable. (4) If the department issues an official notice of failure to comply, as set forth in paragraph (1) of subsection (C) and subclause (i) of clause (c) of said paragraph (1) following submission to and adjudication by the department of justifications for failure to comply submitted by a facility pursuant to clause (b) of paragraph (1) of said subsection (C) to a facility found in noncompliance with limits, the facility shall prominently post its notice within each noncompliant unit. Copies of the notice shall be posted by the facility immediately upon receipt and maintained for 14 consecutive days in conspicuous places including all places where notices to employees are customarily posted. The department shall post the notices on its website immediately after a finding of noncompliance. The notice shall remain on the department's website for 14 consecutive days or until such noncompliance

is rectified, whichever is longer. (5) If a facility is repeatedly found in noncompliance based on a pattern of failure to comply as determined by the department, the commissioner may fine the facility not more than \$3,000 for each finding of noncompliance. (6) Any facility may appeal any measure or fine sought to be enforced by the department hereunder to the division of administrative law appeals and any such measure or fine shall not be enforced by the department until final adjudication by the division. (7) The department may promulgate rules and regulations necessary to enforce this section.

Section 229. The department of public health shall provide for (1) an accessible and confidential system to report any failure to comply with requirements of sections 221 to 228, inclusive, and (2) public access to information regarding reports of inspections, results, deficiencies and corrections under said sections 221 to 228, inclusive, unless such information is restricted by law or regulation. Any person who makes such a report shall identify themselves and substantiate the basis for the report; provided, however, that the identity of said person shall be kept confidential by the department.

SECTION 6. The department of public health shall include in its regulations pertaining to temporary nursing service agencies, or nursing pools, as defined in section 72Y of chapter 111 of the General Laws, and as regulated by the department, parameters in which the department shall deny registration and operation of said agencies only if the agency attempts to increase costs to facilities by at least 10 per cent.

SECTION 7. Section 7 is hereby repealed.

SECTION 8. The department of public health shall submit 2 written reports on its progress in carrying out this act. Said department shall report to the general court the results of its 2 written reports to the clerks of the house of representatives and the senate who shall forward the same to the president of the senate, the speaker of the house of representatives, the chairs of the joint committee on public health. The first report shall be filed on or before March 1, 2012 and the second report shall be filed on or before December 1, 2013.

SECTION 9. The department of public health shall initially evaluate the numbers that comprise the nurse's patient assignment standards and nurse's patient limits set forth in sections 221 to 228, inclusive of chapter 111 of the General Laws on or before January 1, 2015.

SECTION 10. The department of public health, shall develop a comprehensive statewide plan to promote the nursing profession in collaboration with: the executive office of housing and economic development, the board of education, the board of higher education, the board of registration in nursing, the Massachusetts Nurses Association, 1199SEIU, the Massachusetts Hospital Association, Inc., the Massachusetts Organization of Nurse Executives Inc., and any other entity deemed relevant by the department. The plan shall include specific recommendations to increase interest in the nursing profession and increase the supply of registered nurses in the workforce, including recommendations that may be carried out by state agencies. The plan shall be filed with the clerks of the house of representatives and the senate, who shall forward the same to the president of the senate and the speaker of the house of representatives on or before April 15, 2012.

SECTION 11. Teaching hospitals, as defined in section 221 of chapter 111 of the General Laws, shall meet the applicable requirements of sections 221 to 229, inclusive of said chapter 111 of the General Laws on or before October 1, 2012. All other facilities, as defined in section 221 of

chapter 111 of the General Laws, shall meet the applicable requirements of sections 221 to 229, inclusive of said chapter 111 of the General Laws no later than October 1, 2012.

SECTION 12. Section 8 shall take effect on December 1, 2016.

SECTION 13. The department of public health shall, on or before January 1, 2012, promulgate regulations defining criteria and proscribing the process for establishing or certifying by the department a standardized patient acuity system, as defined in section 221 of chapter 111 of the General Laws, developed or utilized by a facility as defined in said section 221 of said chapter 111.

SECTION 14. The department of public health shall, on or before March 1, 2012, develop a standardized patient acuity system or certify a facility developed or utilized patient acuity systems, as defined in section 221 of chapter 111 of the General Laws, to be utilized by all facilities to monitor the number of direct-care registered nurses needed to meet patient acuity level.

SECTION 15. The department of public health shall, on or before June 1, 2012, establish, but not before the development or certification of standardized patient acuity systems, nurse's patient assignment standards and nurse's patient limits as defined in section 221 of chapter 111 of the General Laws.

SECTION 16. The department of public health shall, on or before June 1, 2012, promulgate regulations to implement the requirements of section 229 of chapter 111 of the General Laws.