Patient Care at Risk
at Tufts Medical Center
Boston, Massachusetts

A Report on the Dangerous and Deteriorating Patient Care Environment at Tufts Medical Center

April, 2011
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I. Introduction

“At Tufts Medical Center, our goal is to treat each patient and family as we would want our own families to be treated.”

Tufts Medical Center nurses should be commended for their commitment to the safety of their patients and for taking seriously the legal duties placed upon them by the Massachusetts Nurse Practice Act and their professional ethics to advocate for their patients. This patient care report is a representative summary of written unsafe staffing reports submitted by Tufts nurses over the last 18 months, as well as evidence of unsafe working conditions as identified by OSHA (Occupational Safety and Health Administration). The unsafe staffing report form is a tool for nurses to identify and track professional practice issues within the hospital where a nurse objects to an unsafe, or potentially unsafe, patient care assignment. These reports are signed by the nurse or nurses who file them and shared with the supervisor on duty. The forms are also shared with management on a regular basis in the hopes of using this evidence to address systemic problems that compromise the quality and safety of patient care.

Tufts nurses have been struggling to get resolution of unsafe working conditions, in particular dangerous staffing levels, which have resulted in the filing of more than 626 reports from September 2009 to February 2011 -- reports of unsafe situations where patient care was compromised. However, not every incident of short staffing or unsafe patient care is documented. Nurses fear retaliation and reprisal by supervisors or administrators for complaining about unsafe conditions; and the limitation on their time make the completion of reports difficult. Therefore, the number of actual unsafe situations is significantly higher. Nevertheless the numbers of unsafe staffing reports continues to grow, and as a result, the quality and safety of patient care at Tufts Medical Center continues to decline.

Tufts has become a “poster child” for deplorable nurse staffing practices. This growing national hospital industry problem has also become increasingly prevalent in the Commonwealth of Massachusetts. RN understaffing practices are dangerous and unacceptable. They contribute to the widely recognized failure to stem hospital morbidity, mortality and medical errors. They are outrageous from a patient safety standpoint and foolish from a cost-benefit business perspective. Extensive research studies exist which have documented for several years now that poor staffing and mandatory overtime contribute to millions of preventable complications for patients and causes thousands of preventable deaths each year.

Due to the Massachusetts legislature’s failure to address the issue of safe staffing in hospitals, nurses at Tufts are being forced to take new steps to protect their patients. Tufts Medical Center nurses are attempting to achieve safe patient limits through the collective bargaining process. Because there is no current Massachusetts legal requirement or state law
requiring hospitals to provide safe patient assignments for nurses, the only option for nurses may be to strike for patient safety. To ignore the situation is to fail our patients.

For well over a decade, the Massachusetts hospital industry has fought furiously to defeat any regulatory measure that would limit their ability to engage in unsafe staffing practices. Different versions of safe staffing legislation have reached both the Massachusetts House and Senate floors over the past 15 years. In 2006 the Massachusetts House passed legislation which would have protected patients. The legislation has never successfully passed through both chambers and so has never reached the Governor’s desk.

The nurses of Massachusetts, along with more than 125 leading health care and consumer groups who are part of the Coalition to Protect Massachusetts Patients, firmly believe that safe limits on nurses’ patient assignments, along with limits on forced overtime, will dramatically improve patient care and significantly reduce the turnover of nursing staff while at the same time improving the financial performance of hospitals. This is an issue of professionalism for nurses, who cannot continue to work in a setting where their own professional assessment is that they cannot provide proper care to all of the patients assigned to them. The analogy in aviation circles is that working with inadequate staffing is akin to flying a plane known to pilots to be dangerous. Just as we all hope our pilots would speak out, now is the time for our nurses to be heard.

The following pages explain the nature of Tufts Medical Center, the exceptional quality of nursing care at Tufts, the purposeful reduction in nurse staffing from their new staffing model and the resulting deterioration in Tufts’ patient care environment. The regulations in support of nurses’ objections to the current environment are included, as well as a partial listing of the extensive scientific research in support of the nurses’ demands. Our recommendations - indeed, our demands - for addressing this intolerable and unacceptable unsafe environment conclude this report.
II. An Overview of Tufts Medical Center

Tufts Medical Center (“Tufts,” formerly known as Tufts-New England Medical Center) distinguishes itself as a world class, first-rate quaternary care institution that treats the most difficult, complex patients to be found anywhere. In its own words:

Tufts Medical Center is a world-class academic medical center located in Boston. Our Medical Center is the principal teaching hospital for Tufts University School of Medicine. We offer outstanding patient care to both adults and children, teach generations of future physicians the most advanced medical science and break new ground with ongoing, innovative research.ii

Tufts describes itself further:

Tufts Medical Center, formerly Tufts-New England Medical Center (NEMC), is an academic medical center like no other. We offer the highest level of academic medicine and research, but we also do not forget that at the heart of every treatment, every research discovery and every visit is a patient and family needing support and care.

Tufts Medical Center holds the proud position of principal teaching hospital for Tufts University School of Medicine (TUSM), a premier, internationally respected medical school. All full-time physicians at Tufts Medical Center and Floating Hospital for Children hold faculty appointments at Tufts University School of Medicine.

Located in downtown Boston in Chinatown and the Theatre District, Tufts Medical Center is the oldest permanent medical facility in the country and was founded by early American patriots including Paul Revere and Samuel Adams.

Today, Tufts Medical Center is a 415-bed robust organization, providing comprehensive care from routine medical care to treating the most complex diseases affecting adults and children. Tufts Medical Center is also home to Floating Hospital for Children, a full-service children's hospital dedicated exclusively to all levels of pediatric care from the tiniest of newborns to maturing adolescents. From birth through adulthood, we are here for every member of the family.
Our focus is tertiary and quaternary care, providing the most advance treatments for the most complex and serious illnesses and injuries. We provide heart, kidney and bone marrow transplants, are a level II trauma center, provide comprehensive neurological and neurosurgical care, and offer cutting-edge cancer treatments.

Another vital component of Tufts Medical Center is our robust research program that includes groundbreaking bench research, clinical trials and developments in health policy. Our research activities are funded by the National Institutes of Health (NIH), private foundations, industry and private individuals. Tufts Medical Center ranks among the top 10 percent of the nation's independent hospitals to receive federal research funds. Our dual mission of advancing knowledge and training our experts to become future investigators drives forward with one goal in mind - quickly turning innovative research into pioneering care.

At Tufts Medical Center, our goal is to treat each patient and family as we would want our own families to be treated. We believe that the best medicine should be dispensed with the greatest compassion. Patients deserve nothing less. That is our philosophy. That's our opinion. That's what guides our doctors, nurses, researchers and staff every day. iii

And Tufts describes its mission as follows:

We strive to heal, to comfort, to teach, to learn, and to seek the knowledge to promote health and prevent disease. Our patients and their families are at the center of everything we do. We dedicate ourselves to furthering our rich tradition of health care innovation, leadership, charity and the highest standard of care and service to all in our community. iv

The significance of this is that Tufts is on par with other major Boston area teaching hospitals, such as Brigham & Women’s, Massachusetts General, and Beth Israel Deaconness in the depth and range of services it provides and patients that it cares for. The general acuity level of the patients that Tufts nurses care for is identical to that seen in other comparable institutions in like units. Similarly one would expect to see virtually the same proposed and actual staffing plans across hospitals.

This is not the case however. Tufts nurses are carrying significantly higher patient loads, which is an extremely dangerous situation putting both patients and nurses at risk.
In comparison to peer downtown university teaching hospitals, Tufts own planned staffing levels are far lower than expected given patient acuity levels. The Massachusetts Hospital Association’s (the Commonwealth’s hospital industry trade association) posts their member hospitals’ projected staffing plans on what they euphemistically named the “Patients First” website when it was launched in 2006. See http://patientcarelink.org, now known as the Patient Care Link. This website was created as an industry strategy to avoid regulation of safe staffing by hospitals. As an alternative to a legal requirement that they staff safely, hospitals have been permitted to publicly post their planned staffing, with no requirement that hospitals actually staff according to their promised levels. According to this self-reported source of projected staffing information, units at Tufts have the lowest nurse staffing levels of any similar-sized hospital in the city.

See the three charts in Appendix A, “Patient Care Link (formerly “Patients First”) Staffing Ratios for Tufts,” “Comparable Downtown Boston Teaching Hospital’s” and “All Acute Care Hospitals in Massachusetts”. The first chart shows the units with maximum and minimum patient to RN staffing ratios for each teaching hospital in Boston. The second shows staffing ratios at Tufts compared to all Boston teaching hospitals and the third shows Tufts’ staffing compared to that of all acute care hospitals in the Commonwealth.

**Tufts staffing can be clearly seen as the worst of all teaching hospitals in Boston (Boston Medical Center, Brigham and Women’s Hospital, Beth Israel Deaconess Medical Center, Massachusetts General Hospital, New England Baptist Hospital and Tufts Medical Center).** Across all three shifts (days, eves, nights) on all 16 types of units for which staffing numbers are reported, Tufts’ nurses are responsible for the care of a significantly higher number of patients on 47 out of the 48 units for which the Massachusetts Hospital Association posts data.

**The dangerous staffing at Tufts holds when comparing Tufts to other hospitals across the Commonwealth.** Despite the fact that this measure includes smaller, far less acute community hospitals where patient acuity is much lower than for Tufts and other downtown teaching institutions, Tufts staffing still shows up as stretched dangerously thin. On the same 48 measures (16 units across three shifts), Tufts patients have less nursing time devoted to them on 42 of the 48 measures. This failure to provide their patients with the needed attention from nurses responsible for their lives is not only an embarrassment for Tufts but an indication that unless safe staffing is mandated for all hospitals, it clearly cannot be counted on to happen, even at a sophisticated teaching and research institution.

In the meantime, the 1,200 nurses at Tufts Medical Center are left in a precarious situation, as their license holds them personally accountable for the safety of their patients. They simply can’t afford to wait for legislative action, as lives are being placed in jeopardy every day on every shift. As responsible patient advocates, they are using the most effective tool at their disposal to protect their patients, which is to win safe patient limits through negotiation of their union contract.
III. Staffing Changes, 2009: The “New Model of Care”

Tufts Medical Center, which has a pediatric trauma and adult trauma center, cares for some of the sickest patients in the Commonwealth, which means that it requires a more intense level of nursing care to keep its patients safe. At current staffing levels, nurses find it a struggle to provide the level of care their patients require. Nearly two years ago (2009) the medical center began implementing staffing changes that increased the number of patients assigned to many Tufts nurses without adequately adjusting their level of nursing care based on “patient acuity,” which is the actual needs given the degree of illness of the patients. Management began pushing staff to move patients through the hospital faster and faster, without providing the resources to support this speed up in care delivery.

In the fall of 2009 continuing into 2010, the hospital engaged a high-priced consulting firm to develop a “new model” of care. The principal economic goal charged to the consultant was to reduce the amount of money spent by Tufts on patient care. Over the course of the fall, at least 80 Tufts administrators, nursing and other operations managers busied themselves with 24 “Priority Task Forces” designed to roll out “Quick Wins/First Steps.”

On January 6, 2010, in a four-hour presentation of their work, “Towards a New Care Delivery Model: Talking and Walking Together,” Tufts administrators unveiled to the staff their new nursing care model in a PowerPoint presentation. The focus was on work redesign and efficiency moves developed to eliminate $34 per patient day, or $3 million from the budget allotted for patient care.

The cuts were to be achieved by limiting the amount of care provided by registered nurses. For the past year, RNs have been forced to care for greater numbers of patients on almost every unit.

In addition to the increase in patient assignments, nurses have been inappropriately and unsafely floated to units that they are unfamiliar with, to provide care for patients whose specialty nursing needs are unfamiliar. Nurses who are untrained, unfamiliar and not oriented or educated in the particular needs of patients cannot safely provide care to those patients. Just as Tufts would not float its Chief Financial Office to cover for the Director of Nursing (or perhaps they have!), or expect its Director of Engineering to handle Food Service operations for a day, nurses cannot safely deliver care to patients whose needs are not ones they are trained to meet.

The new model of care has also included an increase in mandatory overtime as a staffing model with a dramatic reduction in staff morale. These actions compromise nurses’ ability to deliver the exceptional care they have always taken pride in delivering.
The consultants used by Tufts are typical of consultants used during the 1990s to redesign how nursing care was delivered, with disastrous results. At that time, there was not a shred of research to support such changes in staffing. Now there are more than 40 studies that provide overwhelming scientific evidence demonstrating that implementing changes such as those proposed at Tufts would dramatically increase the risk of patient injury, complications, the length of hospital stays, and could even lead to preventable deaths.\cite{vi}

In a letter to management signed by nearly all the nurses on a busy cardiac floor, the nurses wrote: “With both the current and newly proposed staffing models ... opportunities for critical observation and patient advocacy will effectively disappear ... higher nurse-patient ratios will lead to increased mortality and poor patient outcomes.”

In creating the new staffing model, the hospital ignored the nurses’ union contract, which mandates a process for the union and management to work together to address staffing concerns. Tufts management ignored that process and utilized the consultant to engage in a process, common for such redesign schemes, where committees are formed and elaborate processes are implemented to give staff the illusion that they have helped develop the new model of care.

Tufts administrators knew from the beginning what cuts they wanted to make and what model they would end up with. The committees were used to co-opt the employees and to make them believe they were responsible for creating the very changes that would later undermine their ability to deliver safe patient care. In fact staffing ratios and cuts were never a topic of discussion in these meetings, but became the end result.

The nurses at Tufts were not fooled by the process. More than 30 nurses who participated in the planning committee for the new model signed a letter stating their opposition to the changes and to the fact that their actual suggestions to improve care at the hospital were ignored.

In a January 26, 2010 letter to staff, Tufts Chief Executive Officer (CEO) Ellen Zane, engaged in a highly public battle with a major insurer demanding higher payments for the care of Tufts patients, stated that Tufts had the “highest case mix index for a full service hospital in the state.” In other words, Tufts nurses and physicians care for the most acutely ill patients in the state. However, instead of investing those resources in better patient care, Tufts has cut the level of care provided to the public and in doing so is endangering patients’ lives.
IV. Tufts: Current Patient Care Problems

Since Tufts began implementing the nursing care delivery model in 2009, changes in the RN staffing grids (schedules) and increased patient assignments began. The proposed increase in ancillary support to accommodate these changes has never fully materialized.

Since that time, nurses have submitted over 626 unsafe staffing forms. These depict scenarios in which nurses at Tufts medical center are overwhelmed, unsupported by their administration and unable to practice effectively. The number of complaints exceeds the number of days since the nurses started documenting the situation, essentially now an everyday-plus occurrence. Most important of all, nearly every single complaint or form represents a situation where patient health and safety was knowingly placed in jeopardy by Tufts.

The current care model is dangerous. It does not allow for the standard of care that patients deserve nor that which the patient acuity at Tufts dictates.

The outcome of the far greater patient assignment loads include delays in nursing assessment, in the administration of tests and medications, significant changes in patients’ hemodynamic status which go unnoticed, poor patient outcomes, patient falls due to lack of available assistance with ambulation, and patients left in soiled beds until staff can address these basic human needs—sometimes hours after they should be taken care of.

Nurses have had to work with scarce resources due to Tufts administration’s failure to provide RNs, techs and ancillary services when needed. Transport services have been removed, as have the “runner” and IV Team services for evening and night shifts, short staffing is repeatedly demonstrated with “holes” in the staffing schedules on a daily basis. There is no backup for nurses who call in when they are ill or for nurses on leaves of absence (LOAs). Administrators have taken advantage of their ability to refuse work for “Flex Nurses” and then replace qualified staff with nurses floated from other units, and mandatory overtime has been used to patch the gaps in the new staffing plan.

The extreme budgetary constraints leveled on the nursing department have led to the abusive and illegal practice of reassigning nurses without proper orientation and the increased use of transient or inexperienced staff. Rather than function as a “support system” these floated, transient or inexperienced staff are in reality being used as core staff. This has necessitated the more experienced nurses taking on heavier and heavier assignment loads. The floated or support staff simply do not have the level of experience to deal with the sickest patients or to care for patients with very specific specialty needs.
Less experienced staff state they feel as though they have been “thrown to the wolves” – a common description. They are overwhelmed, discouraged, and unable to anticipate changes in patients’ status or needs, which can result in poor patient outcomes.

For example one nurse was told to give chemotherapy although she was not certified nor had she been given proper training. Her manager told her to “give it [anyway], that she didn’t have a Clinical Educator to hold [her] hand through everything.”

Not only does this clearly risk patients’ lives, but it violates regulations, it is illegal and it puts the nurse at risk of losing her license or being sued should a lawsuit be brought. It also places the nurse manager at legal liability since nurse managers also have a mandatory duty under the Massachusetts Nurse Practice Act to see that safe patient care is provided. Finally it also threatens the institution’s image, respect in the medical community, and financial condition.

These very serious issues have been brought to the attention of the institution at numerous staff nursing advisory meetings, at joint labor management meetings and most recently at the negotiating table. Tufts’ nursing administration has continued to ignore or minimize this crisis. They have done little or nothing to support, correct or improve the inadequacies that exist throughout the hospital.

In examining reports filed from July 2010 through February 13, 2011, 298 unsafe staffing reports were filed by Tufts nurses in that 219 day period.

The pattern of staffing problems demonstrated in these reports is as follows:

- 81% of the unsafe staffing complaints demonstrate that the hospital chose to run with fewer staff than the “grid”, or what they themselves had dictated for staffing levels per their model of care guidelines.

- 71% of the reports show existing ‘holes’ in the schedules.

- In addition to the short staffing due to poor scheduling and holes in the staffing, 17% of the time nursing care was unsafe or unsatisfactory due to the flexing up of beds/patients without increasing the numbers of nursing staff to handle the increase in patients.

- 68% of the reports involve lack of staffing to meet the increased acuity leading to long delays in care for less acute patients and a tripling of ICU patients. This often resulted in patients being placed in critically dangerous situations.

41% of the unsafe reports filled out in very recent months involve situations where Tufts managers refused to utilize available, scheduled nurses to meet patient acuity – and instead chose to save money by flexing staff down, pressing nurses to use vacation time, threatening to float nurses, or forced the floating of nurses to other units that were short staffed where they
might not be competent to provide appropriate care. To emphasize, this situation is NOT one where there is an insufficiency or shortage of qualified nurses. The nurses are available. They are on the staff of Tufts Medical Center, able and willing to work but Tufts has chosen in many cases to send them home or to refuse to schedule them to work.

Further issues reported on the unsafe staffing forms involve mandatory overtime. 26% of the unsafe reports filed last year reported a nurse was mandated to stay overtime. Most of these were nurses who had worked the evening shift and then were asked to stay for the night shift but there were also even worse cases of night shift nurses being forced to stay to work days. Typically this means that nurses are working on their 24th plus hour without sleep.

The research is clear that this is an unsafe practice, not only for patients and for nurses’ ability to protect their own nursing license, but for the personal safety of nurses (and others on the road) in driving home as well. Drowsy Driving Legislation research shows that sleep deprivation dulls senses and reactions, and that someone who has been awake for 24 hours straight suffers the same impairment as someone with a blood alcohol level of .10, which is above the legal limit. This is not safe practice.

Tufts nurses have correlated their staffing levels with Press Ganey scores. The clear pattern is that when the numbers of unsafe staffing reports were lower than usual, the Patient Experience measures reported by Press Ganey were better or higher than when staffing levels fell.

Clearly Tufts RN to patient staffing ratios compare very unfavorably to those of other Boston hospitals. No other institutions in the city post 3:1 ICU ratios (3 ICU patents per nurse) or 7+ patient assignments on other units. See Appendix A. Despite having the “highest quality of care with the highest case mix index for a full service hospital in the state,” Tufts has chosen to risk patient safety, nurses’ lives and licenses to practice and their own reputation and financial viability through such shameful management practices.

Nurses have been unable to convince their own institution of the dangers they are posing for the community despite trying for well over a year.

Background:

By April 2010, Tufts nurses were reporting that under the new model of care, patients had been placed in jeopardy 74% of the days studied. The Massachusetts Nurses Association negotiating committee at Tufts had begun to campaign heavily to reverse the staffing practices being forced on nurses.
April 19, 2010: While the new model of care went into effect officially on Jan. 25, 2010, on a number of units, the changes to the staffing grids occurred in September, 2009, which is why the time frame of September 11, 2009 to March 9, 2010 was chosen for the first analysis of staffing complaints. The findings from these reports were shocking, and reports included a number of harrowing incidents that resulted in serious harm to patients.

The data and anecdotes gathered were shared with Tufts Board of Trustees. In the absence of any demonstration of concern or attempts to remedy the situation, and as these practices are tantamount to nursing malpractice perpetrated by our nursing leadership, it is time to share the situation with the community at large.

Key findings April 2010 (September 11, 2009- March 9, 2010 study)

Review of all unsafe staffing reports filed from Sept. 11, 2009 to March 9, 2010 revealed a total of 132 reports over 179 days. This averaged out to 74 percent of days in this time frame reported to be unsafe by nursing staff.

Of the 132 reports only 31 of them (or 23 percent) proved to be “at” minimum staffing quotas as set by administration. The other 99 reports (or 76 percent) showed the unit to be running “below” minimum staffing quotas at the time of the unsafe event.

In these reports acuity was recorded as well as staffing levels. 57 percent of the reports showed acuity on the floor at the time was higher than average for the floor (minimum staffing grids do not allow increases in staffing numbers for acuity).

Of the 132 reports, 69 (55 percent) detailed an existing hole in the schedule as an underlying cause.

Only nine reports (7 percent) showed that ill calls contributed to the staffing problem.

The most common theme throughout many of these reports was the mandating of admissions or flexing up of beds, where nurses are forced to accept additional patients beyond what they are staffed for because of increased census. Flexing up was noted in 34 reports (26 percent) of the unsafe events recorded. 33 percent of the reports cited mandatory overtime, where nurses were forced to work double shifts.
It should be noted that the Tufts nurses who took the time to fill out unsafe staffing reports should be recognized for their dedication to patient safety and their courage in speaking out. These nurses felt the obligation to report conditions that prevent them from delivering the care their patients need to be safe. Documenting the reality of this crisis is viewed by nurses as essential to remediing this situation.

**The situation worsened (September 2009-September 2010 study)**

A study was conducted by the MNA negotiating committee to examine what individual Tufts nurses were experiencing and reporting as increasingly deplorable patient care conditions for nurses and of course their patients during the 12 months (September 2009 – September 2010) following the introduction of a new model of care. That model, as has been explained, increased nurses’ patient assignments, while failing to provide ancillary support staff as promised under this dangerous and misguided plan.

The findings from the study indicated an unacceptable and unsafe situation and include a number of harrowing incidents that have resulted in serious harm to our patients and nurses alike.

Review of all unsafe staffing reports filed from Sept. 1, 2009 through Sept. 1, 2010 revealed a total of 328 reports filed over the 365 days studied. This averages out to 90% of the days in this time frame reported as being unsafe by nursing staff working under the new model of care.

An examination of the reports by quarter shows that the number of reports more than doubled for each three month period, i.e, there were 19 reports of unsafe staffing in Quarter 1; 49 in Quarter 2; 102 in Quarter 3; and an astounding 153 reports in the final three months studied. The situation had escalated.

Put simply, things have continued to get worse as time passes.

Of the 328 reports only 19% showed staffing levels to be at the minimum staff quotas set by Tufts Administration itself, while 81% of the reports showed the unit to be running “below” minimum staffing quotas at the time of the unsafe event.

In these reports acuity is recorded as well as staffing levels. More than 68% of the reports showed acuity on the floor was higher than the average for the floor (minimum staffing grids do not allow for increases in staffing based on acuity).

Nearly half of the reports, 46%, detailed an existing hole in the schedule as an underlying cause, and only 5% showed that sick calls contributed to the staffing problem.
While the increase in patient loads in the new model of care was supposed to be offset by an increase in ancillary staff, a shortage of ancillary staff was cited in 74% of the reports filed, including a lack of patient care technicians, unit coordinators or sitters.

When nurses are assigned to a floor or shift, many of them are not prepared to take those assignments. In 35% of the reports filed in the last quarter, nurses reported having insufficient training in the area, with the patient case type or with the equipment required for care delivery.

In addition to being assigned too many patients on a typical shift, these reports show that the hospital forced nurses to accept additional patients by flexing up beds, which was reported in 22% of the unsafe staffing reports filed over this period. Telemetry and medical-surgical nurses are experiencing assignments of 7 – 8 patients each and ICU nurses are being forced to care for three patients at a time. These nurse to patient ratios are extremely dangerous for patients as research over the past decade has fully documented.

Summary

As has been described above, dangerous understaffing of RNS (unsafe RN to patient ratios), mandatory overtime, failure to anticipate staffing needs, the cynical use of flexing and floating have continued unabated and if anything have gotten worse in recent months. This is an intolerable situation that must end. Tufts nurses’ proposed solutions are at the end of this report.

See Appendix C for specific examples of Tufts Unsafe Staffing Situations filed by Tufts RNs in recent months.
V. OSHA Workplace Violations by Tufts

On April 29, 2010, Tufts made news headlines with the announcement that the management of the medical center had been forced by the Occupational Health and Safety Administration (OSHA) to pay a $5,000 fine for its failure to address workplace safety issues repeatedly brought to its attention by Tufts nursing staff.

In addition to the fine, Tufts was also required to post a public notice detailing the numerous lapses in its efforts to track injuries to nurses, including a significant number of needle stick injuries, which could have exposed nurses to life threatening pathogens, including HIV and Hepatitis C.

As part of the settlement agreement with the Occupational Health and Safety Administration in the past year, OSHA issued a letter detailing a number of instances where the hospital failed to document and track injuries to staff. Under federal law all workplace injuries are required to be tracked on what are commonly known as "OSHA 300 logs." The logs are a vital tool used to monitor the type and frequency of workplace injuries, and for identifying ongoing workplace safety issues that may need to be addressed. The investigation by OSHA resulted from a complaint filed by the nurses' union, the Massachusetts Nurses Association, which discovered the lack of proper injury tracking while doing its own investigation of unreported incidents of workplace violence at the facility in 2009.

According to the OSHA investigation, Tufts Medical Center failed to comply with a number of important safety regulations:

- They failed to document sharp and needle stick injuries and illnesses. These lapses were documented as happening 67 times in 2007, 90 times in 2008 and 59 times in 2009).
- They took longer than the 7 days allowed to record employee injuries and illnesses. This happened 166 times in 2007, 169 times in 2008 and 105 times in 2009.
- They did not prepare an annual Summary of Work-Related Injuries and Illnesses (OSHA 300A) for the years 2007 or 2008.
- They failed to track the days employees were unable to work due to injuries (even in the very serious case of an employee who was absent due to injury for over 180 days).
- They failed to keep employee names private as is mandated by law.

Needle stick injuries are a very serious concern for health care workers. Such injuries can expose nurses to blood borne pathogens, like HIV and Hepatitis C which can be, and often are, life-threatening. It is vitally important to track these injuries to help identify trends and potential causes of these injuries in order to limit or prevent their occurrence.

The optimal way to prevent work-related injuries and illnesses is to track them and to use injury and illness data to identify problem areas. The more that employees know about what is going
on in the workplace, the better they can identify and report hazardous workplace conditions. In turn employees – and management - are then more likely to follow safe work practices and to report workplace hazards to get them corrected. These hazards are hazards not only for employees but also for patients and visitors as well. The failure of the hospital to document the existence of these workplace threats is part of a pattern of behavior by the Tufts administration to disregard their obligations, not only to its staff, but also to the patients under their care.

See Appendix, News release: Tufts Medical Center Signs Agreement with OSHA, Pays $5,000 Fine for Numerous Violations in Tracking Injuries to Nurses.
VI. Applicable Regulations and Nursing Specialty Organization Standards and Guidelines

Commonwealth of Massachusetts hospital licensure regulations and the Massachusetts Nurse Practice Act are of particular relevance to the unsafe patient care environment which has developed at Tufts over the last two years. They are contained in Appendix G.

In addition relevant language from CMS (Centers for Medicare and Medicaid Services) federal law concerning “Conditions of Participation” which place demands upon hospitals in order for them to remain compliant and eligible for Medicare and Medicaid reimbursement are also included with highlighting of particularly relevant language.

Commonwealth of Massachusetts hospital licensure regulations:

Massachusetts 105 CMR 130.000 Hospital Licensure

The Commonwealth of Massachusetts’ hospital licensure regulations are mandates that Tufts must meet in order to remain licensed to provide care. Some of the key regulations are listed below, with emphasis added (highlighting in bold) of sections relevant to the patient care problems and unsafe patient care environment becoming increasingly evident at Tufts.

To summarize, Massachusetts regulations call for Tufts to meet the following requirements, which Tufts is flaunting with its dangerous practices of understaffing, floating of nurses to areas where they are not necessarily familiar or expert with the patients needs, and/or mandating overtime assignments for nurses already exhausted from their attempts to care for more patients than safe, legal nursing practice guidelines dictate:

- **Evidence of Responsibility and Suitability**
  In determining whether an applicant is responsible and suitable to be granted a hospital license, the Department shall consider all relevant information including, but not limited to, the following:
  
  [...] compliance with Massachusetts state laws governing health facility operation, and 105 CMR.
  
  The applicant's financial capacity to provide hospital care in compliance with state law and 105 CMR 130.000 as evidenced by sufficiency of present resources and assessment of past history, [105 CMR 130.104]

- **Incorporation of Medicare Conditions of Participation in Hospitals**
  Each hospital shall meet all of the requirements of the Medicare Conditions of Participation for Hospitals, 42 C.F.R. 482.11 through 482.62 (hereinafter Conditions of Participation), except the requirement for institutional plan and budget specified in 42
C.F.R. 482.12(d), for utilization review specified in 42 C.F.R. 482.30, the requirement for compliance with the Life Safety Code specified in 42 C.F.R. 482.41(b), and any requirement that conflicts with the supplementary standards in 105 CMR 130.000 Subparts C and D. [105 CMR 130.200]

- **Special Requirements for Psychiatric Services**
  In addition to the requirements of 105 CMR 130.200, each psychiatric hospital subject to licensure, or psychiatric service of a hospital, shall meet the additional special staffing and medical records requirements which are considered necessary for the provision of active treatment in psychiatric hospitals as defined in 42 U.S.C. 1395x(f) and 42 C.F.R. 482.60 through 482.62 except any such requirement that conflicts with the Supplementary Standards in 105 CMR 130.000 Subparts C and D. [105 CMR 130.201]

- **Registered Nurse Coverage**
  There shall be a sufficient number of registered nurses on duty at all times to plan, supervise and evaluate nursing care, as well as to give patients the nursing care that requires the judgment and specialized skills of a registered nurse. [105 CMR 130.311]

  **Supervisory Coverage.**
  Registered nurses shall be assigned to supervise nursing care and nursing personnel according to a written staffing plan which provides for adequate coverage for all nursing units during each shift. [105 CMR 130.311]

**Unit Coverage.** At least one registered nurse shall be assigned to work in each nursing unit at all times. The only exceptions to this requirement shall be the following:

- If a registered nurse is on duty in one nursing unit of a skilled nursing unit or of a chronic disease hospital, an adjoining nursing unit (on the same floor or floor above or below, if readily accessible) may be staffed by licensed practical nurses, provided that the registered nurse on duty shall be readily available to go from one nursing unit to another when skilled nursing services are needed.
- If a registered nurse is available to provide supervision and skilled nursing services when needed, an outpatient ambulatory care unit (not an emergency service unit) in which skilled nursing care is not routinely needed, may be staffed by licensed practical nurses. [105 CMR 130.311]

**Adult Intensive Care Unit/Coronary Care Unit Coverage.** The ratio of qualified registered nurses to patients in the unit may be varied from time to time on the basis of such factors as patients' conditions and availability of other personnel. There shall be at all times, however, at least one qualified registered nurse for every four patients in the unit. [105 CMR 130.311]
• **RN, LPN, and Ancillary Staff Coverage**
  The number of registered nurses, licensed practical nurses and unlicensed nursing personnel assigned to each nursing unit shall be consistent with the types of nursing care needed by the patients and the capabilities of the staff. [105 CMR 130.312]

The following Serious Reportable Event Regulation places responsibility for patient harm upon Tufts Medical Center for its inadequate staffing and for addressing policies surrounding the lack of appropriate systems for staffing, staff coverage and other issues covered in this report.

• **Serious Reportable Events (SREs)**
  Definitions applicable to 105 CMR 130.332.

  **National Quality Forum (NQF)** means the not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting.

  **Preventable** means events that could have been avoided by proper adherence to applicable patient safety guidelines, best practices, and hospital policies and procedures.

  **Serious Reportable Event (SRE)** means an event that occurs on premises covered by a hospital's license that results in an adverse patient outcome, is clearly identifiable and measurable, has been identified to be in a class of events that are usually or reasonably preventable, and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the hospital. The Department will issue a list of SREs based on those events included on the NQF table of reportable events to which 105 CMR 130.332 applies.

  **Unambiguously the Result of a System Failure Based on the Hospital's Policies and Procedures** means events that have been determined by the hospital to result from:
  - a failure to follow the hospital's policies and procedures; or
  - inadequate or non-existent hospital policies and procedures; or
  - inadequate system design.

  **Preventability Determination.**
  ▪ A hospital shall establish policies and procedures for a documented review process to determine whether an SRE was:
    - preventable; and
    - within the hospital's control; and
unambiguously the result of a system failure. A hospital shall make a preventability determination for all SREs occurring on premises covered by its license. [105 CMR 130.332]

In addition there are numerous provisions in Massachusetts Hospital licensure regulations which all for hospitals to provide nurses who are familiar with and oriented and capable of caring for specifically the types of patients they are assigned. This legal obligation completely negates the option for Tufts to float nurses to unfamiliar patients or units at will in order to save money on the cost of nurse care.

For example:

- **Continuing Care Nursery** shall mean a nursery that is *specially equipped and staffed* to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately ill infants born at the level IB hospital or to retrotransferred stable - growing or recovery infants who do not require intensive or special care. [105 CMR 130.601]

- **Nurse Staffing.** The Maternal and Newborn service shall meet the following requirements:
  1. A registered nurse shall assess the needs, plan the care and evaluate the care delivery including the health education of each patient.
  2. A registered nurse shall observe and care for the mother, fetus and newborn during the labor, delivery and recovery periods.
  3. A registered nurse who has successfully completed a recognized program in neonatal resuscitation, such as the Neonatal Resuscitation Program (NRP), shall be present during the delivery. A second registered nurse shall be immediately available as additional support until the mother and infant are stabilized. [105 CMR 130.616(F)]

- **Cesarean/Delivery Room** shall mean a room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean births, and have capabilities of administering all forms of anesthesia, including inhalation agents. [105 CMR 130.601]

There are numerous such regulatory requirements for RN staffing that the hospital is ignoring and which Tufts nurses insist be met.
Massachusetts Nurse Practice Act:

The Commonwealth of Massachusetts Nurses Practice Act (244 CMR 9.00: STANDARDS OF CONDUCT) defines what constitutes the safe practice of nursing in the Commonwealth. The regulatory intent is to protect the public. Nurses also have a legal ownership (property) right to their license to practice nursing. This license is jeopardized should a nurse violate any provision of the Nurse Practice Act. Nurses are subject to discipline, financial costs, and loss of their license to practice, which can mean their right to earn a livelihood for themselves and their families.

The Board of Registration in Nursing is the Massachusetts state agency charged with interpretation and enforcement of the Nurse Practice Act. Their duty is to hold nurses accountable for the practice of nursing according to the Act and to standard nursing practice and ethics. Their duty is NOT to enforce hospital policy and procedure, or to necessarily even consider it when making their evaluation of whether a nurse has practiced safely. They can and do hold nurses accountable for meeting their professional obligations whether or not the nurses followed hospital procedure, policy and practice or not – unsafe hospital practice is not of concern to them and they are very clear about that. (Unsafe hospital practices are the purview of the Massachusetts Department of Public Health).

Specific key provisions of the Nurse Practice Act that apply to the unsafe patient care conditions at Tufts, and which Tufts is therefore forcing their nurses to violate, include:

- (Definition) Standards of Nursing Practice means authoritative statements that describe a level of care or performance common to the profession of nursing by which the quality of nursing practice can be judged. [244 CMR 9.00]

- (6) Compliance with Laws and Regulations Related to Nursing.

A nurse who holds a valid license shall comply with M.G.L. c. 112, §§ 74 through 81C, as well as with any other laws and regulations related to licensure and practice. Examples of such laws include, but are not limited to, the following:

- (9) Responsibility and Accountability. A nurse licensed by the Board shall be responsible and accountable for his or her nursing judgments, actions, and competency.
- (10) Acts within Scope of Practice. A nurse who holds a valid license and is engaged in the practice of nursing in Massachusetts shall only perform acts within the scope of nursing practice as defined in M.G.L. c. 112, § 80B and 244 CMR 3.00.
- (11) Performance of Techniques and Procedures. A nurse licensed by the Board shall perform nursing techniques and procedures only after appropriate education and demonstrated clinical competency. [244 CMR 9.03]
• (15) Patient Abuse, Neglect, Mistreatment, Abandonment, or Other Harm. A nurse licensed by the Board shall not abuse, neglect, mistreat, abandon, or otherwise harm a patient. [244 CMR 9.03]

• (16) Patient Confidential Information. A nurse licensed by the Board shall safeguard patient information from any person or entity, or both, not entitled to such information. A nurse licensed by the Board shall share appropriate information only as required by law or for the protection of the patient. [244 CMR 9.03]

• (17) Patient Dignity and Privacy. A nurse licensed by the Board shall safeguard a patient’s dignity and right to privacy. [244 CMR 9.03]

Note that there is a legal duty for nurses in management roles to also abide by the nurse Practice Act. These nurse managers can be found liable for failing to see that care is delivered appropriately. Although in reality nurse managers are ever or rarely disciplined, since they are viewed by the BORN as representing management, Tufts is putting their own management staff at legal risk through its understaffing and other unsafe health care practices.

(46) Responsibilities of Nurse in Management Role. A nurse licensed by the Board and employed in a nursing management role shall adhere to accepted standards of practice for that role. The responsibilities of the nurse employed in a nursing management role are to develop and implement the necessary measures to promote and manage the delivery of safe nursing care in accordance with accepted standards of nursing practice.

Finally the catchall, below. Nurses are responsible, period, for failing to practice according to the generally accepted dictates of their profession. There is no legal requirement that Tufts Medical Center provides appropriate staffing, But Tufts nurses bear the legal responsibility and burden for practicing according to the ethics and guidelines of their profession and to the accepted standards of practice taught to them in nursing school, and practiced at other academic medical centers, other hospitals and by their peers, regardless of whether they can be in two places at once, care for more patients than is humanly possible, or be made to stay at work to work longer hours than extensive scientific research has shown to be safe.

• (47) Other Prohibited Conduct. A nurse licensed by the Board shall not engage in any other conduct that fails to conform to accepted standards of nursing practice or in any behavior that is likely to have an adverse effect upon the health, safety, or welfare of the public.
CMS (Centers for Medicare & Medicaid Services) Conditions of Participation:

CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. These minimum health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs / CfCs.\textsuperscript{ix}

Conditions of Participation (CoP) and Conditions for Coverage (CfC) are the minimum health and safety standards that providers and suppliers must meet in order to be Medicare and Medicaid certified. CoPs and CfCs apply to a number of health care institutional providers, including hospitals.

These regulations are below, with emphasis added (highlighting in bold) of sections relevant to the patient care problems and unsafe patient care environment increasingly evident at Tufts.

To summarize, federal Medicare regulations call for Tufts to meet the following requirements:

- “Adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility” [42CFR482.55(b)2]
- “The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community” [42CFR482.41]
- “A hospital must protect and promote each patient’s rights” [42CFR482.13]
- “Standard: Privacy and safety. (1) The patient has the right to personal privacy” [42CFR482.13 (c)1]
- “The patient has the right to receive care in a safe setting” [42CFR482.13(c)2]
- “Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient” [42CFR482.23(b)]
- “A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available” [42CFR482.23(b)5]
In addition, Tufts is liable by Massachusetts law to abide by all federal regulations, as noted earlier. “Each hospital shall meet all of the requirements of the Medicare Conditions of Participation for Hospitals, 42 C.F.R. 482.11 through 482.62 (hereinafter Conditions of Participation)” 105 CMR 130.200

The above is just a partial listing of state and federal regulations applying to Tufts Medical Center. In addition there are numerous other requirements such as city and state fire codes, building codes, anti-discrimination and privacy laws, to name just a few categories.

**Nursing Specialty Organization Standards and Guidelines:**

In addition to the above applicable regulatory standards requiring Tufts to immediately address and remedy its dangerous staffing and patient care practices, there are also a number of guidelines, recommendations, criteria and standards of nursing practice that nurses are by law (Massachusetts Nurse Practice Act) expected to adhere to—regardless of whether it’s within their power. This is not only unsafe, but absurd.

For example, The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists supports specific Nurse/Patient ratios for perinatal care services., depending on the stage of labor, presence of complications, type of anesthesia, nature of care needed by antepartum patients and newborn. AACN (American Association of Critical care Nurses) has published criteria for 1:1 Staffing ratios. See Attachment E.
VII. Scientific Research Linking Safe RN Staffing to Patient Safety

When legislators want an answer on an issue regarding nursing or health care, they come to the nurses of the Massachusetts Nurses Association for an answer. Research clearly shows that nurses are the most trusted voice on health care issues. The MNA makes certain the bedside nurse’s voice is heard in the halls of power by helping nurses connect with elected officials on issues important to them, by linking them to legislators in their community, by supporting politicians and legislators in their community, and by helping nurses become elected to public office.

The MNA initiates and promotes sound legislation to improve health care for Massachusetts citizens and to advance the nursing profession. Furthermore, our nurses promote public policy that advances the interests of nurses and protects the patients and clients served by the nursing community. Our recommendations are based on state of the art scientific research, chiefly by nurse academicians.

According to the Agency for Health Care Research and Quality, based on extensive research by University of Pennsylvania researcher Linda Aiken, every additional patient assigned to an RN is associated with a 7 percent increase in the risk of hospital-acquired pneumonia, a 53 percent increase in respiratory failure, and a 17 percent increase in medical complications. Better RN staffing is linked to better patient outcomes, fewer deaths and shorter hospital stays.

The research is extensive. It is now beyond question that safe RN staffing levels are critically important for the survival and reduction in morbidity of hospitalized patients.

Several key studies validate the Tufts nurses’ call for safe RN to patient ratios, limitations on mandatory overtime and “flex” staffing. A sample of this body of research is described and cited in Appendix F.
VIII. Solutions

This report has laid out the situation at Tufts, the risk to patients from unsafe staffing, the regulations that apply currently. What is needed to remedy the unsafe patient care environment at Tufts is simple:

**Safe Staffing.** Contractually guaranteed RN-to-patient ratios specific to every floor and unit, adjusted for patient ratios. Nurses should have the right to stop admissions to their unit if staffing is inadequate to safely care for patients.

**Mandatory RN to Patient Ratios:** Contractual guarantees of safe RN-to-patient ratios at Tufts will improve patient care at Tufts, but not at other providers in the Commonwealth. The only way to guarantee a “floor,” or the bare minimum number of nurses to safely care for patients, is for the Commonwealth of Massachusetts to require this of hospitals as a condition of licensure.

**An End to Mandatory Overtime.** Nurses who do not feel safe to practice should be able to refuse mandatory overtime. To do otherwise is to endanger patients.

**An End to Floating.** Units must be staffed with a complement of core staff adequate to care for patients, with nurses guaranteed the right to refuse to float to a unit where they are not competent to practice. Appropriate orientation must be provided to nurses who choose the option of floating.

**Limits on “Flex” Positions.** Flex positions are contractual positions for nurses who must reduce their hours to 24, 32 or 36 hours upon request of Tufts (but who receive benefits for 40 hours per week of work). This has been used as a cost-saving measure by the hospital. It is a dangerous practice because hospitals will use their leverage to send a “Flex nurse” home and float another nurse, unfamiliar to the patients and often unfamiliar to the unit, into the Flex nurse’s slot.

Floating and Flex practices are particularly dangerous wherever they occur. At a complex, tertiary care institutions such as Tufts, it is crucial that nurses have the training, skills, orientation and understanding specific to the needs of the patients whose lives depend on their care.
### Appendix

#### A. Patients First Staffing Ratios for Tufts and Comparable Downtown Boston Teaching Hospitals

1. **Comparison of Tufts and Other Boston Teaching Hospitals on Day, Eve and Night Shifts: Units with Minimum and Maximum Patient to RN Staffing Ratios per Hospital**

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Minimum # Patients PER RN</th>
<th>Maximum # Patients PER RN</th>
<th>Minimum # Patients PER RN</th>
<th>Maximum # Patients PER RN</th>
<th>Minimum # Patients PER RN</th>
<th>Maximum # Patients PER RN</th>
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<td>4.75 : 1</td>
<td>1.43 : 1</td>
<td>4.75 : 1</td>
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<td>SICU PRATT 2</td>
<td>SICU PRATT 2</td>
<td>SICU PRATT 2</td>
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<td>BEHAVIORAL HEALTH</td>
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<td>7 : 1</td>
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<td>CVICU STONEMAN 5</td>
<td>FINARD 4 MICU-SICU</td>
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<td>SICU MP 7W MP</td>
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*Source: MHA’s Patient CareLink (“Patients First!”) Staffing Plans for Acute Care Hospitals Jan-11*
2. Comparison of Staffing at Tufts and Other Boston Teaching Hospitals* on Day, Eve and Night Shifts:

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* Boston Teaching Hospitals Staffing Mean is calculated for hospitals including Boston Medical Center, Brigham and Women’s Hospital, Beth Israel Deaconess Medical Center, Massachusetts General Hospital, New England Baptist Hospital and Tufts Medical Center
3. Comparison of Staffing at Tufts with All Other Acute Care Hospitals in the Commonwealth of Massachusetts

Tufts patient to RN staffing ratios compared to that of all other acute care hospitals in the Commonwealth.
B. Examples of Tufts Unsafe Staffing Situations filed by Tufts RNs In Recent Months

Unsafe Staffing Report #163  7 patient assignments; no sitters

Intermediate care floor is staffed with only 3 RNs. The intermediate care nurse took all 3 IC patients leaving 7 patients each for the charge nurse and other staff nurse. A confused patient on fall/flight precautions with a doctor’s order to have a 1:1 sitter was not provided with one. Because of excessive nurse patient ratios, nurses are being stretched beyond their ability to maintain safety of patients, especially those who are confused and in danger of falling out of bed because they have no supervision. Beyond the basic safety of patients, appropriate nursing care was not delivered to any patient on the floor this shift. A staff nurse offered to come in overtime and help out but this was not allowed by management. The staffing plan offered by management was for the charge nurse to sit 1:1 with the patient and alternate with the unit ancillary/tech when in-between tasks. This is not a “Staffing Plan” and is certainly a dangerous practice, placing patient safety and quality care as a non priority.

Unsafe Staffing Report #168

The PICU was scheduled with 1 regular staff nurse and 3 float nurses for 4 patients, yet a strong per-diem nurse was cancelled due to the unit’s census level. One patient required traveling, leaving only 3 nurses on the unit, with one child very acute 1:1 all day. Forty-five minutes into the shift they were forced to take an admission - an extremely sick baby with a possible brain tumor requiring intubation and cerebral angiogram. This acuity level of the infants is difficult to manage with the minimum staffing levels, but is accentuated by the lack of regular nursing staff and the high use of less experienced float nurses caring for critically ill children and babies.

Unsafe Staffing Report #212

ICU has 10 patients, 2 of whom are required to have 1:1 nursing care. One patient is post-cardiac arrest, on hypothermic protocol, the other on a pentobarbital drip and EEG for continuous seizure activity. The unit is staffed with only 5 nurses, which does not allow for these 2 critical patients to receive 1:1 nursing care per hospital policy and procedures. Instead the plan for a sixth nurse was denied. Management insisted “we have to run within the grid of staffing minimums for the floor of 5 nurses for 10 patients and triple patient assignments”. Beyond the fact that ICU patients in Boston are acutely ill and deserve to be “singled”, but doubled when able and we are requiring to triple ICU patients (non boarder patients) is the fact that there was a sixth nurse available at the time that management refused to allow her to take an assignment. She was a float ICU nurse who was part of staffing this unit for the first 4 hours of the shift. But at 11pm, the staffing grid requires a reduction of 1 nurse. Instead of allowing
her to stay part of the staff for the rest of her shift and allow the patients to remain singled as appropriate, she was forced to give up her assignment and leave the unit to run short with extremely high acuity. She was not stationed in any other unit for the rest of the shift, no other unit needed her but the CCU was not allowed to utilize her either. This is management standing on the principle of their new staffing grid and disregarding patient needs for safe and adequate care.

Many other cases of tripling in the ICUs- management states they will only triple “Boarder” patients waiting for floor beds but this is not the case. We are tripling true ICU patients. Also of note: lack of staff availability is not the case they are canceling float/ flex/ per diem staff to maintain these grid numbers of 5/10 preventing singling of any patients and enforcing tripling regardless of acuity.
(See also report # 288)

Unsafe Staffing Report #218

ICU with staffing that does not match patient care needs. The unit was staffed for 10 patients with 3 regular nurses and 4 float/agency nurses with limited CTU experience required to care for the devices in the unit (i.e.: 2 CVVH, 1 VAD, 1 IAB). An experienced night shift nurse offered to stay and help out was denied by management. The management plan was for staff to run as is, call if they needed help and change patient assignments.

Unsafe Staffing Report #219

Nurse was monitoring 6 patients in preoperative area by herself. There should be 2 nurses on in all patient care areas in case of emergency; however this area often runs with just 1 nurse. The nurse was informed she had to admit a 7th pt from and ambulance that was demented, nonverbal in wrist restraints. When she requested more staff to assist keeping this patient safe along with her other 6 patients she was told “you need to change your mind set”; no additional staff were provided.

Unsafe Staffing Report # 277

This report from the same area as above (#219) concerns the admission of a 13-year old boy with a critically elevated blood sugar. Due to short-staffing there was no nurse to assume his care. A physician had to assume responsibility for this patient without the assistance of a nurse. Management was 100% aware of this situation and still refused to provide a nurse.

Unsafe Staffing Report #278

Patient census at start of shift was 5 with 10 bed capacity. Supervisor was made aware of inadequate staffing for the morning. Despite that, she admitted patients to the unit and filled all ten beds. She said they would deal with the staffing issue in the A.M. At 5am she returned
and said there was nothing she could do about the staffing for the day shift, but in the mean
time required them to transfer out a floor patient make a bed for an acute full trauma with
unstable gunshot wound, and mandated a night shift nurse to stay and staff for day shift to
cover the admissions and high acuity.

Unsafe Staffing Report #12  9/17/09

This floor was staffed for 26 patients per the minimum staffing quotas set by the administration
with 6 nurses and 3 ancillary. However the acuity being extremely high prevented the nurses
from giving adequate care. They were required to complete 3 room changes to accommodate
ED patients that had already arrived to the floor without time given to prepare rooms. Patients
had to wait in the hallway. There were 2 encephalopathic patients requiring increased
monitoring and no sitters provided. One patient returned from the operating room in acute
distress new onset Rapid Afi with multiple cardiac alarms, requiring attention of 2 nurses to
treat with IV meds complicated by bradycardia. An additional patient in hypertensive crisis
requiring multiple meds and frequent monitoring. The secretary left at 11pm not all admit
work completed. Multiple patient complaints including call lights unanswered and bathrooms
not clean. **One patient so angry left against medical advice after midnight.**

Unsafe Staffing Report #81

Jan. 21, 2010 This floor was staffed for 16 patients per the Minimum Staffing Quotas set by
Administration with 4 nurses and 2 ancillary. They were forced to flex up to 20 patients with no
additional staff sent to absorb additional patients. Minimum staffing quotas for 20 patients
should be 4 nurses and 3 ancillary. More importantly there were no available beds for the
patients to be put into. A patient was transferred without a room available post a seizure and a
fall with head injury, actively withdrawing from alcohol. The patient had no IV access to
medicate him properly for his seizures or withdrawal. He was confused and agitated climbing
out of the stretcher. The nurses were told to “**leave him in the hallway and make due with a
bad situation**”. The nurses requested a sitter to be with the patient because he was unsafe to
leave on the stretcher in the hall but were denied. They were told “there are no sitters
available for you, just make do”. This difficult patient required 2 nurses to be managed while
still in the hallway, 2 more patients were sent up from the ED and left in the hall by a tech with
no report given and still no beds available to put them into. The other 17 patients on the floor
did not get cared for.

Unsafe Staffing Report # 111

Feb. 15, 2010 This floor was staffed for 19 patients per the minimum staffing quotas set by
administration with 4 nurses and 3 techs with average patient acuity at the time.
A pediatric patient was having a seizure the Mom pulled the call bell and no one came. The
mom then left the patient and ran to the desk to get help and there was no one there, not even
a secretary this is at 6:30 pm. All nurses where in rooms giving meds, hanging TPN, and the
techs where feeding babies. Finally **another parent ran to the other side of the unit crying for help before a nurse was found and brought to the seizing patient.** Nursing supervisor’s response was “that is why you are doing overtime to help settle patients”. Nurse forced to stay beyond her shift to help.

**Unsafe Staffing Report # 104**

Feb. 13, 2010 Night shift charge nurse was forced to give vacation time to 2 nurses scheduled for the day shift to comply with the minimum staffing guidelines in spite of high acuity. The acuity on the floor during the night shift was so high the CRN was involved for most of the night and stayed overtime into the day shift until 10am to assist the day CRN with the acuity. During the night shift one patient was intubated with no unit bed to go to. The patient remained on the floor with CRN assistance while they were forced to take an additional critically ill patient onto the floor requiring ICU care. So while 2 ICU patients being maintained on the floor in acute distress the day shift was still **knowingly forced to flex down nurses leaving an extremely unsafe environment for all patients on the floor** at the start of the shift. The night CRN stayed overtime until 10:30 because the 2nd ICU patient decompensated and required intubation as well. Now 2 intubated patients on the floor with no ICU beds. One patient extremely agitated while intubated and CRN unable to sedate adequately due to Pyxis limitations suffered a dirty needle stick from this HIV, hePC infected patient. The CRN had to be excused to obtain self care in the ED left the floor with 2 ICU patients and no ICU nurse to care for them. The floor nurses forced to accept this patient assignment had 4 other patients with these intubated patients.

**Unsafe Staffing Report #5**

September 11, 2009 This floor was staffed for 21 patients below the Minimum Staffing Quotas set by Administration with 4 nurses and only 1 ancillary instead of 2. This shift with extremely high acuity. The charge nurse was forced to take full assignment with charge role during difficult shift. Being short staffed and receiving frequent calls from supervisor regarding potential patient admissions and refusal of additional staff to assist. This charge nurse was forced to urgently discharge a patient and receive 2 admissions within 2 hours time. I transfer came STAT from PICU into a DIRTY ROOM with a tracheostomy patient. The supervisor was aware of this and stated “what am I going to do about it; you need to take this patient NOW”. This nurse was then forced to take 2 more admissions over the next 4 hours. She was unable to give good nursing care secondary to charge role, frequent supervisory calls, staffing issues and turnover of her patients while short ancillary staff to assist.

**Unsafe Staffing Report #49**

Dec. 12, 2010 This unit staffed per grid with 6 nurses. However 9 admissions in ED who do not have floor beds, 2 traumas and observation room is full. Express care area had to be opened to
place 3 patients into beds. There is no N1 nurse to care for these 9 In-Patients while caring for additional ED walk-in patients. These patients did not receive care including their daily meds or ADLs.
Tufts Medical Center Signs Agreement with OSHA, Pays $5,000 Fine for Numerous Violations in Tracking Injuries to Nurses

Agreement Responds to the Hospital’s Lack of Response to Nurse’s Concerns About Unsafe Working Conditions and the Reluctance of the Hospital to Address Workplace Safety Issues

BOSTON, April 29 /PRNewswire-USNewswire/ -- The management of Tufts Medical Center has been forced to pay a $5,000 fine, as well as to post a public notice this month for its registered nurses, detailing numerous lapses in its efforts to track injuries to nurses, including a significant number of needle stick injuries, which could have exposed nurses to life threatening pathogens, including HIV and Hepatitis C.

The settlement agreement with the Occupational Health and Safety Administration was reached this month, after OSHA issued a letter detailing a number of instances where the hospital failed to document and track injuries to staff. Under federal law all workplace injuries are required to be tracked on what are commonly known as "OSHA 300 logs." The logs are a vital tool used to monitor the type and frequency of workplace injuries, and for identifying ongoing workplace safety issues that may need to be addressed. The investigation by OSHA resulted from a complaint filed by the nurses' union, the Massachusetts Nurses Association, which discovered the lack of proper injury tracking while doing its own investigation of unreported incidents of workplace violence at the facility in 2009.

According to the OSHA investigation, Tufts Medical Center did not prepare an annual summary of work-related injuries and illnesses for 2007 or 2008, failed to track the days employees weren't able to work due to injuries (even when an employee was out for over 180 days), failed to keep the employee's name private as is mandated by law, and failed to document sharp and needle stick injuries and illnesses (this happened 67 times in 2007, 90 times in 2008 and 59 times in 2009). Needle stick injuries are a serious concern for health care workers: such injuries can expose nurses to blood borne pathogens, like HIV and Hepatitis C. It is vitally important to track these injuries to help identify trends and potential causes of these injuries.

"For a hospital, particularly a major teaching hospital, to show such a lack of concern for the health and safety of its workers is a travesty," said Barbara Tiller, RN, a clinical resource nurse at the facility and chair of the Massachusetts Nurse Association Local Bargaining Unit at the hospital. "Any health care provider knows that documenting the existence of a problem is the first and most important step in being able to address it. We see this as part of a pattern of behavior on the part of this administration to disregard their obligations, not only to its staff, but also to the patients under our care. We hope this fine
and this penalty sends a message to our administration that they need to be accountable for the conditions they create for their workforce."

The OSHA investigation over problems with worker safety is the latest in a series of ongoing issues the nurses have had with the hospital in recent years. Nurses staged a picket outside the hospital on February 11, 2010 to protest dangerous staffing conditions at the facility resulting from a change in the nurse’s staffing pattern, which the nurses claim violated the hospital's obligation to negotiate those changes as stipulated in the nurses' union contract. Since the new model of care has gone into effect, there have been hundreds of official reports filed by the nurses documenting unsafe staffing incidents. In fact, there were 132 such reports filed over a 179 day period from September 2009 through March 2010. As with the problem with the OSHA logs, the hospital has failed to address any of the nurses staffing and patient safety concerns.

The nurses continue to document their concerns and are preparing to reach out to the hospital's board of trustees as well as to local public officials for support in their efforts to improve conditions at the facility.

"If things don't change, we are afraid the next article we will read about this hospital will be about the death of a patient or a worker," said Tiller. "All we want is for our health care employer to care about the health of their staff and their patients."

Founded in 1903, the Massachusetts Nurses Association is the largest professional health care organization and the largest union of registered nurses in the Commonwealth of Massachusetts. Its 23,000 members advance the nursing profession by fostering high standards of nursing practice, promoting the economic and general welfare of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Legislature and regulatory agencies on health care issues affecting nurses and the public.

SOURCE Massachusetts Nurses Association, 2010
U.S. Department of Labor  
Occupational Safety and Health Administration  
639 Granite Street, 4th Floor  
Reprintree, Massachusetts 02184  
Phone: (617) 565-6924 Fax: (617) 565-6923

April 1, 2010

Joan Johnston, Associate Director  
Division of Health & Safety  
Massachusetts Nurses Association  
340 Turnpike Street  
Canton, MA 02021

Dear Joan Johnston:

In response to your formal complaint concerning safety and/or health hazards at:

Tufts Medical Center  
340 Turnpike Street  
Canton, MA 02021

the Occupational Safety and Health Administration conducted an inspection there. That inspection was completed on April 1, 2010.

The results of our investigation of your complaint items are as follows:

1. Regarding the allegation that OSHA 300 injury and illness logs for 2008 and 2009 are incomplete and do not contain the location of the injury, description of the injury, job title or injured employee, year of the log, and facility name:

   OSHA requested and obtained OSHA 300 Logs from 2006 – 2009. OSHA found several deficiencies in the OSHA 300 Logs such as the where the injury occurred, description of the injury, job title of injured employee, and number of days away or restriction were not entered. See Citation 1 Items 2a, 2b, 3, 5a, and 5b.

2. Regarding the allegation that privacy cases (such as needlesticks) on the OSHA 300 injury and illness logs for 2008 and 2009 were not listed as privacy cases and contained employees’ names:

   OSHA requested and obtained OSHA 300 Logs from 2006 – 2009. On the OSHA 300 Logs for 2007, 2008, and 2009, for privacy concern cases, employees’ names were listed on the logs. See Citation 1 Items 7a, 7b, and 7c.
Attached for your information is a copy of the OSHA 2, Citation and Notification of Penalty, which was sent to the employer on April 1, 2010 and should have been posted at the workplace for at least three days after receipt.

If you do not agree with our inspection results, you may contact me for a clarification of the matter. You also have the right to an informal review by the OSHA Regional Administrator who may be contacted at the following location:

Marthe B. Kent, Regional Administrator
Occupational Safety and Health Administration
U.S. Department of Labor
JFK Federal Building, Room E340
Boston, MA 02203
(617) 565-9860

This review may be obtained by submitting a written statement of your position to the Regional Administrator. The Regional Administrator will provide the employer with a copy of such statement by certified mail. Your identity will be withheld unless you explicitly request that it be revealed. Section 11(c) of the OSH Act provides protection for employees against discrimination because of their involvement in protected safety and health related activity. If your client is being treated differently or action is being taken against your client because of your safety or health activity, your client may file a complaint with OSHA. Your client should file this complaint as soon as possible, since OSHA normally can accept only those complaints filed within 30 days of the alleged discriminatory action.

Thank you for your concern for a safe and healthful workplace.

Sincerely,

Brenda Gontob
Assistant Area Director

Enclosure
D. Nursing Specialty Organization Standards and Guidelines

Criteria for 24-Hour 1:1 Nursing Care

Stability Level I

• Patients with unstable cardiac rhythms that cause hemodynamic compromise and necessitate frequent assessments, pharmacological interventions, and/or mechanical termination of the rhythm and patients who require external cardiac pacing and/or placement of a transvenous pacemaker
• Patients who experience hypertensive or hypotensive crisis and require rapid stabilization of blood pressure
• Patients with symptomatic cardiac tamponade who require immediate intervention on the unit including drainage and stabilization
• Patients who experience inadequate myocardial perfusion who exhibit ongoing symptoms of chest discomfort resulting in decreased cardiac output and severe hemodynamic instability
• Patients who develop symptomatic bleeding and require immediate intervention
• Patients who experience cardiac arrest and remain severely compromised requiring ventilatory and pharmacological support with continuous adjustments
• Patients who exhibit symptoms of extreme dyspnea, acute anxiety, orthopnea, and diffuse pulmonary congestion who are highly complex and vulnerable in the acute phase of their illness
• Patients who require insertion of an intracranial pressure monitoring device (ventricular drain or camino) and demand continuous intracranial pressure monitoring with frequent assessment and interventions
• Patients with an acute change in neurological status who require continuous nursing assessment and interventions
• Nonventilated patients exhibiting life-threatening airway compromise who require frequent treatments and continuous observation
• Patients in metabolic crisis with multisystem compromise who require continuous monitoring, assessment, and interventions
• Patients who must leave the critical care area for a procedure or test and require continuous nursing assessment and monitoring for the duration of the test

Highly Complex Level I

• Patients assigned to a research protocol who require initiation into the study that necessitates documentation every 15 minutes or more often
• Patients who require a diagnostic or therapeutic intervention in conjunction with conscious sedation and recovery
• Patients who are potential organ donors who require immediate, extensive preparation and/or management
• Patients who are severely compromised and require continuous arteriovenous hemofiltration
• Patients who require pressure control ventilation in the acute stage of acute respiratory distress or ventilated patients in the critical stage of acute lung injury with high-PEEP and high oxygen requirements

**Vulnerability Level 1**
• Patients whose families require frequent interventions including complex teaching and help resolving ethical concerns; for example, families who require counseling because they are considering terminating life support measures and/or donating organs for transplantation
• Patients exhibiting emotional trauma who require intensive care, collaboration, and coordination with other support services, including but not limited to victims of sexual assault

**Resiliency Level 1**
• Patients in the acute phase of their illness who exhibit signs of confusion, sensory overload, or psychosis and require continuous assessment and immediate pharmacological interventions
• Patients who require continuous intravenous sedation and/or neuromuscular blockade for control of anxiety in the acute phase of their illness and those who exhibit withdrawal symptoms as they are weaned from long-term sedation.

See: [http://www.aacn.org/wd/certifications/content/synpract8.pcms?pid=1&menu=practice](http://www.aacn.org/wd/certifications/content/synpract8.pcms?pid=1&menu=practice)
Progressive Care Fact Sheet

Background
In the early 1970s, advertisements were placed in *Heart and Lung* by major medical center recruiters for both critical care and progressive care nurses. Initially, progressive care units were used to house post myocardial infarction patients who needed cardiac monitoring but who did not require intensive care and observation. As the health care environment began to change, the acuity of patients admitted to the hospital steadily increased and with it the demand for critical care beds also increased. With an increased demand for and decreased availability of critical care beds, patients were often transferred from critical care units while still requiring an increased level of nursing care and vigilance. Patients who were admitted to critical care units five years ago are now routinely admitted to progressive care.

Progressive care is the term the American Association of Critical-Care Nurses (AACN) uses to collectively describe areas that are also referred to as Intermediate Care Units, Direct Observation Units, Step-down Units, Telemetry Units, or Transitional Care Units as well as to define a specific level of patient care. AACN recognizes the need to define and identify the special needs of progressive care nurses. In 2001, a task force and advisory panel were created to define the progressive care environment and patient populations served, as well as the core competencies and basic knowledge and skill requirements of progressive care nurses.

Definition
The American Association of Critical-Care Nurses recognizes progressive care as part of the continuum of critical care. AACN's vision is dedicated to creating a healthcare system driven by the needs of patients and families where critical care nurses make their optimal contribution. The AACN Synergy Model for Patient Care is the conceptual framework that actualizes the vision. It defines nursing practice based on the needs of the patient and the characteristics of the nurse to attain optimal patient outcomes.

Progressive care defines the care that is delivered to patients whose needs fall along the less acute end of that continuum. Progressive care patients are moderately stable with less complexity, require moderate resources and require intermittent nursing vigilance or are stable with a high potential for becoming unstable and require increased intensity of care and vigilance. Characteristics of progressive care patients include: a decreased risk of a life-threatening event, a decreased need for invasive monitoring, increased stability, and an increased ability to participate in their care.

Progressive Care Patient Location
Using AACN’s Synergy Model will assist in defining the progressive care patient. The Synergy Model identifies patients based on the characteristics and needs that they present and not on the location of the bed they occupy. As in critical care, the geographic domain of progressive care is expanding. Care provided to progressive care patients is not limited by geography but is based on the needs and required interventions of the patient. While specific progressive care units can be identified, patients requiring progressive care nursing can be located throughout the hospital.
Progressive care can be very specialized, with care focused on a specific system such as cardiac, or more generalized, as in the care of patients with multi-system problems.

Educational Requirements

Progressive care nursing has expanded beyond the basic cardiac telemetry that marked its beginning and now encompasses many of the same technologies and therapies that were once limited to critical care units. To meet the changing needs of the patient, nurses caring for progressive care patients must demonstrate competencies that are influenced by ever changing technology. Progressive care nurses must demonstrate the following core competencies:

- Dysrhythmia monitoring techniques
- Basic & advanced life support
- Basic dysrhythmia interpretation and treatment
- Drug dosage calculation, continuous medication infusion administration, and patient monitoring for medication effects (i.e., non-titrated vasoactive agents, platelet inhibitors, anti-arrhythmic agents, and insulin)
- Patient monitoring using standardized procedures for pre, intra, and post procedures (i.e.; cardioversion, TEE, cardiac catheterization with PCI, bronchoscopy, EGD, PEG placement, chest tube insertion)
- Hemodynamic monitoring including equipment setup and troubleshooting, monitoring and recognition of signs and symptoms of patient instability
- Recognition of the signs and symptoms of cardiopulmonary emergencies and initiation of standardized interventions to stabilize the patient awaiting transfer to critical care
- Interpretation of ABGs and communication of findings
- Recognition of indications for and management of patients requiring non-invasive O2 delivery systems including oral airways, bipap, and nasal CPAP
- Assessment of the ventilated patient to assure delivery of the prescribed treatment and patient response
- Assessment and understanding of long term mechanical ventilation and weaning
- Recognition of the indications for and complications of enteral and parental nutrition
- Assessment, monitoring and management of patients requiring renal therapeutic interventions; For example hemodialysis, peritoneal dialysis, stents, continuous bladder irrigation, and urostomies
- Recognition of and evaluation of the family’s need for enhanced involvement in care to facilitate the transition from hospital to home

According to the Synergy Model, stability, complexity, vulnerability, resiliency, predictability, resource availability, participation in care and participation in decision making are the patient characteristics that describe patient function. The nurse characteristics that typically represent comprehensive nursing practice include clinical judgment, advocacy, caring practices, collaboration, systems thinking, response to diversity, clinical inquiry and learning facilitator. The framework therefore takes into account the
unpredictability of the progressive care patient, and based on the patient and family's needs the competencies of the progressive care nurse.

Reference List


Burke, W., Eckland, M. "Keep Pace with Step-down Care" Nursing Management: 33(2): 26-29, 2002


E. Scientific Research Linking Safe RN Staffing to Patient Safety

Implications of the California Nurse Staffing Mandate for Other States
Linda H. Aiken, Ph.D., et al., Health Services Research, August 2010

- The researchers surveyed 22,336 RNs in California and two comparable states, Pennsylvania and New Jersey, with striking results, including: if they matched California ratios in medical and surgical units, New Jersey hospitals would have 13.9 percent fewer patient deaths and Pennsylvania 10.6 percent fewer deaths. “Because all hospitalized patients are likely to benefit from improved nurse staffing, not just general surgery patients, the potential number of lives that could be saved by improving nurse staffing in hospitals nationally is likely to be many thousands a year,” according to Linda Aiken, the study’s lead author. California RNs report having significantly more time to spend with patients, and their hospitals are far more likely to have enough RNs on staff to provide quality patient care. Fewer California RNs say their workload caused them to miss changes in patient conditions than New Jersey or Pennsylvania RNs. In California, where hospitals have better compliance with the staffing limits, RNs cite fewer complaints from patients and families and the nurses have more confidence that patients can manage their own care after discharge. California RNs are substantially more likely to stay in their jobs because of the staffing limits, and less likely to report burnout than nurses in New Jersey or Pennsylvania. Two years after implementation of the California staffing law—which mandates minimum staffing levels by hospital unit—“nurse workloads in California were significantly lower” than Pennsylvania and New Jersey. “Most California nurses, bedside nurses as well as managers, believe the ratio legislation achieved its goals of reducing nurse workloads, improving recruitment and retention of nurses, and having a favorable impact on quality of care,” the authors write.

The Impact of Medical Errors on 90-Day Costs and Outcomes: An Examination of Surgical Patients
William E. Encinosa and Fred J. Hellinger, Health Services Research, July 2008

- A new study published in the journal Health Services Research found that the large difference in calculations for medical error expenses might mean that interventions to increase patient safety -- like adding more nursing staff -- could be more cost-effective than previously reported. The study found that insurers paid an additional $28,218 (52 percent more) and an additional $19,480 (48 percent more) for surgery patients who experienced acute respiratory failure or post-operative infections, respectively, compared with patients who did not experience either error. Preventing these and other preventable medical errors would reduce loss of life and could reduce healthcare costs by as much as 30 percent, the researchers said. "Many hospitals are struggling to survive
financially," study co-author William Encinosa, senior economist at the Agency for Healthcare Research and Quality, said in a statement. "The point of our paper is that the cost savings from reducing medical errors are much larger than previously thought." Pointing to previous research that looked at the business case for improving RN staffing ratios, the researchers concluded: "It is quite possible that the post-discharge costs savings achieved by reducing adverse events might just be enough for the hospital to break-even on the investment in nursing."

**Overcrowding and Understaffing in Modern Health-care Systems: Key Determinants in Meticillin-resistant Staphylococcus Aureus Transmission**

*Archie Clements, et al, Lancet Infectious Disease, July 2008*

- A new study published in the July issue of the journal Lancet Infectious Disease finds that understaffing of nurses is a key factor in the spread of meticillin-resistant Staphylococcus aureus (MRSA), the most dangerous type of hospital acquired infection. “Overcrowding and understaffing have had a negative effect on patient safety and quality of care, evidenced by the flourishing of health-care-acquired MRSA infections in many countries, despite efforts to control and prevent these infections from occurring. There is an urgent need for a requirement for developing resource allocation strategies that minimize MRSA transmission without compromising the quality and level of patient care,” the researchers concluded. The authors note that common attempts to prevent or contain MRSA and other types of infections such as requirements for regular and repeated hand washing by nurses are compromised when nursing staff are overburdened with too many patients. They also note that hospitals now involve nurses in a “vicious cycle” where a call for nurses to increase their infection control procedures “are seldom accompanied by increases in staffing levels and thus represent an additional work burden on nursing staff” that leads to a greater spread of infections.

**Nurse Satisfaction and the Implementation of Minimum Nurse Staffing Regulations**

*Joanne Spetz, Ph.D, Policy, Politics & Nursing Practice, April 3, 2008*

- A statewide survey of nurses in California found that nurses perceived a significant improvement in their working conditions and were more satisfied with their jobs in the two years following implementation of the landmark California staffing law in 2004. According to the researchers, “Nurse satisfaction with many aspects of work increased significantly between 2004 and 2006. The largest changes in satisfaction, in percentage terms, were with adequacy of staff (a 12.95 % increase), providing patient education (+7.3%), clerical support (6.9%) and satisfaction with the job overall (5.9%).” The authors concluded: “A large body of research links job satisfaction, heavy workload, job stress, effective management and career development opportunities with turnover rates...It is possible that the improvements in RN satisfaction documented here will facilitate higher quality of care. High nurse turnover has a negative effect on the quality of care delivered to patients. If minimum staffing regulations improve nurse satisfaction, reduce job stress,
and relieve workload, nurse turnover may indeed decline, further improving the quality of hospital care.”

**Survival From In-Hospital Cardiac Arrest During Nights and Weekends**
*Mary Ann Peberdy, MD, et al., JAMA, February 20, 2008*

- A national study on the rate of death from cardiac arrest in hospitals found that the risk of death from cardiac arrest in the hospital is nearly 20 percent higher on the night shift. The authors highlight understaffing during the night shift as a potential explanation for the death rate. “Most hospitals decrease their inpatient unit nurse-patient ratios at night… Lower nurse-patient ratios have been associated with an increased risk of shock and cardiac arrest,” the authors stated.

**Nurse Staffing and Patient, Nurse and Financial Outcomes**
*Lynn Unruh, PhD, RN, AJN, January 2008*

- This report provides a comprehensive literature review of more than 21 studies published since 2002 that, according to the author, “underscore the importance of hospitals acknowledging the effect nurse staffing has on patient safety, staff satisfaction, and institutions’ financial performance.” According to the report, “the evidence clearly shows that adequate staffing and balanced workloads are central to achieving good patient, nurse, and financial outcomes. Efforts to improve care, recruit and retain nurses, and enhance financial performance must address nurse staffing and workload. Indeed, nurses’ workloads should be a prime consideration. If a proposed change would improve care and also reduce excessive (or maintain acceptable) workloads, it should be implemented. If not, it shouldn’t be.”

**The Impact of Nurse Staffing on Hospital Costs and Patient Length of Stay: A Systematic Review**
*Petsunee Thungjaroenkul, RN, MS, Nursing Economics, Vol. 25, 2007*

- This study provides a comprehensive review of the research on the impact of RN staffing ratios on hospital costs and patient length of stay (LOS). It identified 17 studies published between 1990 and 2006 and concluded: "the evidence reflected that significant reductions in cost and LOS may be possible with higher ratios of nursing personnel in hospital settings. Sufficient numbers of RNs may prevent patient adverse events that cause patients to stay longer than necessary. Patient costs were also reduced with greater RN staffing as RNs have higher knowledge and skill levels to provide more effective nursing care as well as reduce patient resource consumption. Hospital administrators are encouraged to use higher ratios of RNs to non-licensed personnel to achieve their objectives of quality patient outcomes and cost containment."
Newly Licensed RNs' Characteristics, Work Attitudes, and Intentions to Work
Christine T. Kovner, PhD, RN, et al, AJN, September, 2007

- A national study on the work experience and attitudes of newly licensed nurses in America found that the majority of new grads had been given full patient assignments immediately following their orientation, with poor supervision and management, while more than 45 percent reported having recently been given more than 6 patients to care for at one time - a patient load that the researchers said placed their patients at an increased risk of injury or death. More than 55 percent reported that they had to work too fast; 33 percent reported having little time to get things done and nearly a third of new grads reported they had too many patients to get their job done well, Not surprisingly, as a result of these conditions, more than 37% of the new nurses say they plan to leave their current job in the next two years, and more than 41% say they, if free to do so, would take another job immediately. The authors conclude: "The proportion of newly licensed RNs who expressed negative attitudes on individual survey items raises the concern that employers will not be able to retain them in the acute care settings where they start out."

Staffing Level: a Determinant of Late-Onset Ventilator-Associated Pneumonia
Stephanie Hugonnet, et al, Critical Care, July 19, 2007

- Understaffing of registered nurses in hospital intensive care units increases the risk of serious infections for patients; specifically pneumonia, a preventable and potential deadly complication that can add thousands of dollars to the cost of care for hospital patients. This type of pneumonia is a leading cause of as many as 2,000 patient deaths in Mass. hospitals, costing as much as $400 million annually.

Nurse Working Conditions and Patient Safety Outcomes
Patricia W. Stone, Ph.D., et al., Medical Care, 45(6): 571-578, June. 2007

- A review of outcomes data for more than 15,000 patients in 51 U.S. hospital ICUs showed that those with higher nurse staffing levels had a lower incidence of infections, such as central line associated bloodstream infections (CLSBIs), a common cause of mortality in intensive care settings. The study found that patients cared for in hospitals with higher staffing levels were 68 percent less likely to acquire an infection. Other measures such as ventilator-associated pneumonia and skin ulcers were also reduced in units with high staffing levels. Patients were also less likely to die within 30 days in these higher-staffed units. Increasing RN staffing could reduce costs and improve patient care by reducing unnecessary deaths and reducing days in the hospital.
**Hospital Workload and Adverse Events**
*Joel S. Weisman, Ph.D., et al, Medical Care, 45(5): 448-454, May. 2007*

- A study conducted by researchers at Brigham & Women's Hospital and Massachusetts General Hospital found that overcrowded and understaffed hospitals that are pushing too hard to streamline and cut costs are putting their patients at risk for medication errors, nerve injuries, infections and other preventable mistakes. A 10% increase in the number of patients assigned to a nurse leads to a 28% increase in adverse events such as infections, medication errors, and other injuries.

**Nurse Staffing and Quality of Patient Care**

- A comprehensive analysis of all the scientific evidence linking RN staffing to patient care outcomes found consistent evidence that an increase in RN-to-patient ratios was associated with a reduction in hospital-related mortality, failure to rescue, and other nurse sensitive outcomes, as well as reduced length of stay. Every additional patient assigned to an RN is associated with a 7% increase in the risk of hospital-acquired pneumonia, a 53% increase in respiratory failure, and a 17% increase in medical complications.

**Quality of Care for the Treatment of Acute Medical Conditions in U.S. Hospitals**
*Bruce E. Landon, MD, MBA., et al, Archives of Internal Medicine, 166: 2511-2517, Dec 11/25. 2006*

- A national study of the quality of care for patients hospitalized for heart attacks, congestive heart failure and pneumonia found that patients are more likely to receive high quality care in hospitals with higher registered nurse staffing ratios.

**Impact of Hospital Nursing Care on 30-day Mortality for Acute Medical Patients**

- A study of 46,000 patients in 76 hospitals found the adequacy of nursing staffing and proportion of registered nurses is inversely related to the death rate of acute medical patients within 30 days of hospital admission. The study's authors recommend that "if hospitals have goals of minimizing unnecessary patient death for their acute medical patient population, they should maximize the proportion of Registered Nurses in providing direct care."
**HeathGrades Quality Study: Third Annual Patient Safety in American Hospital Study**
*HealthGrades, Inc: April 2006*

- 80,000 Medicare patients each year died between 2002 - 2004 in our nation's hospitals from preventable medical errors, with 63% of those deaths attributable to failure to rescue by a registered nurse or physician. Mass. Ranked 22nd in patient safety, with no improvement since the previous year’s study.

**Nurse Staffing in Hospitals: Is There a Business Case For Quality?**
*Jack Needleman, Ph.D., Peter Buerhaus, Ph.D., R.N., et al., Health Affairs, 25(1): 204-211, Jan.-Feb. 2006*

- Increasing the proportion of RNs without increasing total nursing hours per day could reduce costs and improve patient care by reducing unnecessary deaths and reducing days in the hospital.

**Longitudinal Analysis of Nurse Staffing and Patient Outcomes - More About Failure to Rescue**
*Jean Seago, Ph.D., et al., JONA, 36(1): 13-21, Jan. 2006*

- Increasing RN staffing increased patient satisfaction with pain management and physical care; while "having more non-RN" care "is related to decreased ability to rescue patients from medication errors."

**Correlation Between Annual Volume of Cystectomy, Professional Staffing, and Outcomes - A Statewide, Population-Based Study**
*Linda Elting, Ph.D., et al., Cancer, 104(5): 975-984, Sept. 2005*

- Patients undergoing common types of cancer surgery are safer in hospitals with higher RN-to-patient ratios. High RN-to-patient ratios were found to reduce the mortality rate by greater than 50% & smaller community hospitals that implement high RN ratios can provide a level of safety and quality of care for cancer patients on a par with much larger urban medical centers that specialize in performing similar types of surgery.

**Improving Nurse-to-Patient Staffing Ratios as a Cost-Effective Safety Intervention**
*Michael Rothberg, et. al, Medical Care, 43(8): 785-791, Aug. 2005*

- Improving RN-to-patient ratios could save thousands of lives each year and is more cost effective than clot-busting medications for heart attacks and strokes, and cancer screenings.
**Hospital Speedups and the Fiction of the Nursing Shortage**

- "There is no shortage of nurses in the United States. The number of licensed registered nurses in the country who are choosing not to work in the hospital industry due to stagnant wages and deteriorating working conditions is larger than the entire size of the imagined 'shortage.' Thus, there is no shortage of qualified personnel there is simply a shortage of nurses willing to work under the current conditions created by hospital managers."

**Nurses' Working Conditions: Implications for Infectious Disease**
Patricia W. Stone, et al., Emerging Infectious Disease, 10(11): 1984-1989, Nov. 2004

- Improving nurse staffing and working conditions "are likely to improve the quality of health care by decreasing incidence of many infectious diseases, and assisting in retaining qualified nurses."

**The Working Hours of Hospital Staff Nurses and Patient Safety**

- Nurses working mandatory overtime are three times more likely to make a medical error. "Overtime, especially that associated with 12-hour shifts, should be eliminated."

**Association Between Evening Admissions and Higher Mortality Rates in the Pediatric Intensive Care Unit**
Yeseli Arias, M.D., et. al, Pediatrics, 113(6): e530-e534, June 2004

- Children admitted to pediatric intensive care units at night are more likely to die in the first 48 hours of care; authors point to fatigue and lighter nurse staffing levels as contributing factors.

**Consumer Perspectives: The Effect of Current Nurse Staffing Levels on Patient Care**
National Consumers League Report, May 2004

- National survey of recent patients in hospitals found that 45% believed their safety was compromised by understaffing of nurses; 12% believe their safety was extremely compromised. 78% of respondents support safe staffing legislation.
Nurse Staffing Levels and Quality of Care in Hospitals
Mark W. Stanton, M.A., AHRQ Research in Action, 14; March 2004

- Poor hospital registered nurse staffing is associated with higher rates of urinary tract infections, post-operative infections, pneumonia, pressure ulcers and increased lengths of stay, while better nurse staffing is linked to improved patient outcomes.

Nurse Burnout and Patient Satisfaction
Doris C. Vahey, Ph.D., et al., Medical Care, 42(2): II-57-II-66, Feb. 2004

- Improvements in nurse staffing in hospitals "simultaneously reduces nurses' high burnout and risk of turnover and increases patients' satisfaction with their care."

Is More Better? The Relationship Between Nurse Staffing and the Quality of Nursing Care in Hospitals
Julie Sochalski, Medical Care, 42(2): II-67-II-73, Feb 2004

- Survey of 8,000 RNs in Pennsylvania hospitals found workload and understaffing contributed to medical errors and patient falls and to a number of important nursing tasks left undone at the end of every shift.

Nurse Staffing and Mortality for Medicare Patients with Acute Myocardial Infarction
Sharina D. Peterson, Ph.D., et al., Medical Care, 42(1): 4-12, Jan. 2004

- "Medicare patients with AMI (heart attack) who were treated in higher RN staffing environments had a significant in-hospital mortality advantage." Conversely, patients are more likely to die in hospitals with high LPN staffing environments. "The mortality difference we observed are related to differences in hospital staffing patterns and may derive from substitution of personnel with less training or experience."

The Shocking Cost of Turnover in Health Care

- The cost for advertising, training and loss in productivity associated with recruiting new nurses to a facility is $37,000 per nurse at minimum and can add as much as 5% to a hospital's annual budget. Improving nurses' staffing conditions is a primary strategy for hospitals that can generate significant cost savings.
Keeping Patients Safe: Transforming the Work Environment of Nurses (Executive Summary)
Institute of Medicine, National Academy of Sciences, Nov. 2003

- Following up on the 1999 report on patient safety, To Err is Human, the Institute for Medicine calls for improved nurse-to-patient ratios, limits on mandatory overtime, and nurse involvement on every level to protect patients.

Licensed Nurse Staffing and Adverse Events in Hospitals
Lynn Unruh, Ph.D., Medical Care, 41(1): 142-152, 2003

- Hospitals with better licensed nurse staffing had a significantly lower incidence of adverse patient events, including bed sores, patient falls and pneumonia.

Nurse Staffing, Quality, and Hospital Financial Performance

- Increased staffing of registered nurses does not significantly decrease a hospital's profit margin, even though it boosts the hospital's operating costs.

The Effects of Nurse Staffing on Adverse Events, Morbidity, Mortality, and Medical Costs

- Increasing nurse staffing by just one hour per patient day resulted in a 10% reduction in the incidence of hospital-acquired pneumonia. The cost of treating hospital acquired pneumonia is $28,000 per patient.

Patient-to-Nurse Staffing Ratios: Perspectives from Hospital Nurses
Peter D. Hart Research Corp., A Research Study for AFT Health Care, April 2003

- Three in five nurses say they are responsible for too many patients and the problem is harming care. 82% of nurses support legislation setting limits on nurses' patient assignments.

Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction
Linda Aiken Ph.D., R.N., Journal of the American Medical Association, October 22, 2002

- For each additional patient over four assigned to an RN, the risk of death increases by 7% for all patients. Patients in hospitals with a 1:8 nurse-to-patient ratio have a 31% greater risk of dying than patients in hospitals with 1:4 nurse-to-patient ratios. Legislation to regulate RN-to-patient ratios is a credible means of protecting patients and to ending the nursing shortage.
Strengthening Hospital Nursing

• "The implications of doing nothing to improve nurse staffing levels in many low-staffed hospitals are that a large number of patients will suffer avoidable adverse outcomes and hospitals and patients will continue to incur higher costs than are necessary."

Nurse Staffing and Healthcare-associated Infections

• "There is compelling evidence of a relationship between nurse staffing and adverse patient outcomes," including serious bloodstream infections in hospital patients.

Nurse-Staffing Levels and Quality of Care in Hospitals

• A higher proportion of RNs in the staff mix and a greater number of nursing hours per day are associated with better patient outcomes.

Health Policy Report - Nursing in the Crossfire

• Provides a review of the research underlying the current crisis in nursing with recommendations for policy, including legislation to regulate RN ratios and to recruit nurses into the profession.

Health Care at the Crossroads: Strategies for Addressing the Evolving Nursing Crisis
Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 2002

• JCAHO found that low staffing levels were a contributing factor in 24% of patient safety errors resulting in injuries or death since 1996. Recommends transforming the nursing workplace and giving hospitals an incentive to invest in high quality nursing care.

Intensive Care Unit Nurse Staffing and the Risk of Complications After Abdominal Aortic Surgery

• Patients treated in hospitals with fewer ICU nurses were more likely to have medical complications, respiratory failure or need a breathing tube inserted. The study also found the ICUs with fewer RNs incurred a 14% increase in costs.
Nurses' Reports on Hospital Care in Five Countries

- Study finds widespread job dissatisfaction among hospital nurses in the US due to understaffing and poor working conditions. Half of US nurses report the quality of care at their hospital has deteriorated in the last year; one in five nurses overall and one in three nurses under 30 plan on leaving bedside nursing.

The Nursing Crisis in Massachusetts
Report of the Legislative Special Commission on Nursing and Nursing Practice, May 2001

- "It is the unanimous consensus of licensed nurses, health care personnel and administrators that the shortage of nursing care in the Commonwealth is endangering the quality of care that our nurses can provide to the patient." The Commission's top two recommendations to solve the crisis include legislation to ban mandatory overtime and to set RN-to-patient ratios.

ICU Nurse-to-Patient Ratio is Associated with Complications and Resource Use After Esophagectomy
Peter J. Pronovost, M.D., Ph.D., et al., Intensive Care Medicine, 26: 1857-1862, 2000

- A nurse caring for more than two ICU patients at night increases the risk of several post-operative pulmonary and infectious complications and was associated with increased resource use. The study advocates a ratio of one RN to no more than two patients.

Organization and Outcomes of Inpatient AIDS Care

- Higher nurse-to-patient ratios are strongly associated with a lower mortality for patients with AIDS in hospitals.

Nurse Staffing and Patient Outcomes

- Inpatient units with a higher proportion of RN care had fewer adverse patient outcomes, including fewer medication errors, bedsores and patient complaints. Conversely, when more care was delivered by non-RN team members, rates of bedsores, complaints and patient deaths increased.
Hospitals cut nurse staffing levels in the 90s by 7.3% nationally, while all other categories of hospital personnel increased, including a 46% increase in non-nurse administrative personnel and 50% increase in other direct care staff. Massachusetts cut its RN staffing by 27%, highest in the nation.
F. Applicable Regulations: Commonwealth of Massachusetts hospital licensure, Massachusetts Nurse Practice Act and CMS (Center for Medicare and Medicaid Services) Conditions of Participation

Massachusetts 105 CMR 130.000 Hospital Licensure

130.104: Evidence of Responsibility and Suitability

(A) In determining whether an applicant is responsible and suitable to be granted a hospital license, the Department shall consider all relevant information including, but not limited to, the following:

1. The applicant's history of prior compliance with Massachusetts state laws governing health facility operation, and 105 CMR. Assessment of this factor shall include the ability and willingness of the applicant to take corrective action when notified by the Department of regulatory violations; and
2. The applicant's financial capacity to provide hospital care in compliance with state law and 105 CMR 130.000 as evidenced by sufficiency of present resources and assessment of past history, including financial involvement with health care facilities that have filed petitions for bankruptcy; and
3. The history of criminal conduct of the applicant, and of the chief executive officer and chief financial officer of the applicant, as evidenced by criminal proceedings against those individuals or against health care facilities in which those individuals either owned shares of stock or served as corporate officers, and which resulted in convictions, or guilty pleas, or pleas of nolo contendere, or admissions of sufficient facts; and
4. The applicant's history of statutory and regulatory compliance for health care facilities in other jurisdictions, including proceedings in which the applicant was involved which proposed or led to a limitation upon or a suspension, revocation, or refusal to grant or renew a health care facility license or certification for Medicaid or Medicare to the applicant.

(B) The Commissioner or his/her designee will consider the evidence produced and make licensure recommendations accordingly.

130.130: Grounds for Refusal to Renew and Revocation of a License

The Department may refuse to renew, or revoke a license, either wholly or with respect to a specific service or specific services, or a part or parts thereof, for cause. Cause shall include but shall not be limited to the following:

(A) Lack of legal capacity to provide the service(s) to be covered by a license, as determined pursuant to 105 CMR 130.103; or

(B) Lack of responsibility and suitability to operate a hospital, as determined pursuant to 105 CMR 130.104; or

(C) Failure to submit the required license fee; or
(D) Violation of any state statute pertaining to hospital licensure; or

(E) Violation of any applicable provision of 105 CMR 130.000; or

(F) Lack of financial capacity to provide hospital care; or

(G) Willful misrepresentation of information or data submitted to the Department or any other agency of the Commonwealth.

(H) Failure to participate in risk management programs as required under M.G.L. c. 111, § 203(d) and related regulations of the Board of Registration in Medicine at 243 CMR 3.00 et seq.

130.200: Incorporation of Medicare Conditions of Participation in Hospitals

Each hospital shall meet all of the requirements of the Medicare Conditions of Participation for Hospitals, 42 C.F.R. 482.11 through 482.62 (hereinafter Conditions of Participation), except the requirement for institutional plan and budget specified in 42 C.F.R. 482.12(d), for utilization review specified in 42 C.F.R. 482.30, the requirement for compliance with the Life Safety Code specified in 42 C.F.R. 482.41(b), and any requirement that conflicts with the supplementary standards in 105 CMR 130.000 Subparts C and D.

130.201: Special Requirements for Psychiatric Services

In addition to the requirements of 105 CMR 130.200, each psychiatric hospital subject to licensure, or psychiatric service of a hospital, shall meet the additional special staffing and medical records requirements which are considered necessary for the provision of active treatment in psychiatric hospitals as defined in 42 U.S.C. 1395x(f) and 42 C.F.R. 482.60 through 482.62 except any such requirement that conflicts with the Supplementary Standards in 105 CMR 130.000 Subparts C and D.

130.311: Registered Nurse Coverage

There shall be a sufficient number of registered nurses on duty at all times to plan, supervise and evaluate nursing care, as well as to give patients the nursing care that requires the judgment and specialized skills of a registered nurse.

(A) Supervisory Coverage. Registered nurses shall be assigned to supervise nursing care and nursing personnel according to a written staffing plan which provides for adequate coverage for all nursing units during each shift.

(B) Unit Coverage. At least one registered nurse shall be assigned to work in each nursing unit at all times. The only exceptions to this requirement shall be the following:

(1) If a registered nurse is on duty in one nursing unit of a skilled nursing unit or of a chronic disease hospital, an adjoining nursing unit (on the same floor or floor above or
below, if readily accessible) may be staffed by licensed practical nurses, provided that the registered nurse on duty shall be readily available to go from one nursing unit to another when skilled nursing services are needed.

(2) If a registered nurse is available to provide supervision and skilled nursing services when needed, an outpatient ambulatory care unit (not an emergency service unit) in which skilled nursing care is not routinely needed, may be staffed by licensed practical nurses.

(C) Adult Intensive Care Unit/Coronary Care Unit Coverage. The ratio of qualified registered nurses to patients in the unit may be varied from time to time on the basis of such factors as patients' conditions and availability of other personnel. There shall be at all times, however, at least one qualified registered nurse for every four patients in the unit.

130.312: RN, LPN, and Ancillary Staff Coverage

The number of registered nurses, licensed practical nurses and unlicensed nursing personnel assigned to each nursing unit shall be consistent with the types of nursing care needed by the patients and the capabilities of the staff.

130.332: Serious Reportable Events (SREs)

(A) Definitions applicable to 105 CMR 130.332.

Ambulatory Surgery Center (ASC) means an entity subject to licensure or licensed under M.G.L. c. 111, § 51 and 105 CMR 140.000 to provide surgical services.

National Quality Forum (NQF) means the not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting.

Preventable means events that could have been avoided by proper adherence to applicable patient safety guidelines, best practices, and hospital policies and procedures.

Serious Reportable Event (SRE) means an event that occurs on premises covered by a hospital's license that results in an adverse patient outcome, is clearly identifiable and measurable, has been identified to be in a class of events that are usually or reasonably preventable, and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the hospital. The Department will issue a list of SREs based on those events included on the NQF table of reportable events to which 105 CMR 130.332 applies.

Unambiguously the Result of a System Failure Based on the Hospital's Policies and Procedures means events that have been determined by the hospital to result from:

(a) a failure to follow the hospital's policies and procedures; or
(b) inadequate or non-existent hospital policies and procedures; or
(c) inadequate system design.

(B) Reporting of SREs.

(1) Within seven days of the date of discovery of an SRE, a hospital shall:
(a) file a written report with the Department of an SRE (SRE report);
(b) provide a copy of the SRE report to any responsible third-party payer;
(c) inform the patient or the patient's representative verbally and in writing about:
   1. the occurrence of the SRE including unanticipated outcomes of care, treatment and services provided as the result of an SRE;
   2. the hospital's policies and procedures and documented review process for making a preventability determination as required by 105 CMR 130.332(C); and
   3. the option to receive a copy of the SRE report filed with the Department; and
(d) affirm on the SRE report that the hospital has complied with the patient notification requirements of 105 CMR 130.332(B)(1)(c).

(2) A hospital that provides services resulting from an SRE that did not occur on its premises shall file a written report with the Department within seven days of the date of discovery of the SRE. The reporting hospital shall comply with the requirements of 105 CMR 130.332(B)(1), but need not make a preventability determination for the SRE.

(C) Preventability Determination.

(1) A hospital shall establish policies and procedures for a documented review process to determine whether an SRE was:
   (a) preventable; and
   (b) within the hospital's control; and
   (c) unambiguously the result of a system failure. A hospital shall make a preventability determination for all SREs occurring on premises covered by its license.

(2) No later than 30 days after the date of reporting of the SRE to the Department the hospital shall:
   (a) make the preventability determination required by 105 CMR 130.332(C)(1);
   (b) file an updated SRE report with the Department describing the hospital's preventability determination including, at a minimum, the following:
      1. narrative description of the SRE;
      2. analysis and identification of the root cause of the SRE;
      3. analysis of the preventability criteria required by 105 CMR 130.332(C)(1);
      4. description of any corrective measures taken by the hospital following discovery of the SRE; and
      5. whether the hospital intends to charge or seek reimbursement for services provided by the hospital as a result of the SRE; and
   (c) provide a copy of the updated SRE report to the Department, the patient and any responsible third-party payer.

(D) Reimbursement for SREs.

(1) A hospital may not charge or seek reimbursement from a patient or responsible third-party payer for services provided as a result of an SRE occurring on premises covered by the hospital's license if the hospital determines that the SRE was:
   (a) preventable; and
   (b) within the hospital's control; and
(c) unambiguously the result of a system failure, as required by 105 CMR 130.332(B) and (C).

(2) A hospital shall immediately suspend or rescind any claims to any patient or responsible third-party payer pending the preventability determination and notification requirements of 105 CMR 130.332(C).

(3) A hospital may charge or seek reimbursement for services it provides that result from an SRE that did not occur on its premises; however a hospital that provides services resulting from an SRE (treating facility) occurring on premises of a separately licensed hospital or an ambulatory surgery center licensed pursuant to 105 CMR 140.000 (responsible facility), may not charge or seek reimbursement for those services, if the treating facility and the responsible facility have common ownership or a common corporate parent.

(4) Any dispute(s) arising between the hospital and any responsible third-party payer resulting from a charge or claim for reimbursement for services provided by the hospital as a result of an SRE shall be addressed through the third-party payer's provider claims appeals process.

(5) The provisions of 105 CMR 130.332(D) shall not be construed to prohibit a Medicare provider from submitting a claim for reimbursement to the Medicare program.

130.601: Definitions

The following definitions apply in 105 CMR 130.000 when used with regard to maternal and newborn services:

Antepartum Patient shall mean any pregnant woman who is characterized as having a high-risk obstetric complication or a pregnant patient with a medical or surgical condition.

Birthing Room shall mean a room designed to provide family-centered care in a "homelike" environment for low-risk mothers throughout the labor, delivery and immediate recovery periods.

Certified Nurse Midwife shall mean an individual authorized by the Board of Registration in Nursing under M.G.L. c. 112, § 80C and authorized to practice as a nurse-midwife pursuant to 244 CMR 4.00 et seq.

Cesarean/Delivery Room shall mean a room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean births, and have capabilities of administering all forms of anesthesia, including inhalation agents.

Clinical Nurse Specialist shall mean a registered nurse with a current license from the Massachusetts Board of Registration in Nursing. For the purpose of 105 CMR 130.601 through 130.650, the clinical nurse specialist must be master's prepared with clinical expertise in advance nursing practice in the specialty area of maternal or neonatal health.

Critical Care Obstetrics Team shall mean a team including representatives from the following available 24 hours a day, seven days a week: Maternal-fetal medicine consultant; in-house obstetrician; in-house nursing staff with demonstrated competency in critical care; in-house anesthesia; in-house neonatologist and other medical specialties available, as needed, including at a minimum infectious disease, pulmonary, surgery, and cardiology.
**Continuing Care Nursery** shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately ill infants born at the level IB hospital or to retrotransferred stable - growing or recovery infants who do not require intensive or special care.

**Designated Service Levels** shall mean levels of care based on services provided by the hospital as approved by the Department of Public Health.

**Family-centered Care** shall mean a method of providing services that fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the father, mother and child and/or include other identified support persons (biologically or nonbiologically related) for the mother and infant.

**Family Practitioner** shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who has completed a residency in family medicine, which includes training in internal medicine, pediatrics and obstetrics and is certified or an active candidate for certification by the American Board of Family Practice.

**Freestanding Pediatric Hospital with Neonatal Subspecialty Services** shall mean a service that has the capabilities to provide care to moderately to severely ill neonates who require neonatal intensive care services and to newborns with actual medical problems.

**Gynecology Patient** shall mean any woman with or suspected of having a health problem related to her reproductive organs.

**Labor Room** shall mean an area in which the mother experiences the first stage of labor.

**Labor-delivery Suite** shall mean that part of a maternal and newborn service used to care for patients during labor, delivery and recovery. It shall include physically contiguous labor room(s), cesarean/delivery room(s) and ancillary facilities.

**Labor-delivery-recovery Room (LDR)** shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery and recovery periods.

**Labor-delivery-recovery-postpartum Room (LDRP or Single-Room Maternity Care)** shall mean a room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery, recovery and postpartum periods.

**Lactation Consultant** shall mean an individual certified as an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience.

**Level I - Community-based Maternal and Newborn Service** shall mean a community-based maternal and newborn service including Level IA and Level IB services that meets the requirements in 105 CMR 130.630.

**Level I A service** shall mean a community-based maternal and newborn service with a well newborn nursery that provides for the care and management of maternal conditions consistent with American
College of Obstetricians and Gynecologists (ACOG) guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.

**Level IB** Service shall mean a Level I community-based maternal and newborn service with a continuing care nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.

**Level II Service** shall mean a community-based maternal and newborn service with a Special Care Nursery including Level IIA and Level IIB services that meets the requirements in 105 CMR 130.640.

**Level IIA Service** shall mean a community-based maternal and newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 34 weeks gestation.

**Level IIB Service** shall mean a community-based maternal and newborn service with a Special Care Nursery that provides for the care and management of pregnancies judged unlikely to deliver before 32 weeks gestation and that meets the requirements in 105 CMR 130.640.

**Level III Maternal and Newborn Service** shall mean a maternal and newborn service that provides for the care and management of maternal conditions consistent with ACOG guidelines, including pregnancies at all gestational ages and that meets the requirements in 105 CMR 130.650.

**Maternal-fetal Medicine Specialist** shall mean an obstetrician/gynecologist who is licensed by the Massachusetts Board of Registration in Medicine and is certified or is an active candidate for certification in the subspecialty of maternal-fetal medicine by the American Board of Obstetrics and Gynecology.

**Maternal and Newborn Service** shall mean that part of the hospital in which care is routinely delivered to mothers and newborns.

**Neonatal Fellow** shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is completing a fellowship in neonatology.

**Neonatal Intensive Care Unit** shall mean a unit located either in a hospital with a Level III maternal and newborn service or a freestanding pediatric hospital with neonatology specialty services that provides a comprehensive range of specialty and subspecialty services to severely ill infants.

**Neonatal Nurse Practitioner** shall mean an individual authorized by the Massachusetts Board of Registration in Nursing under M.G.L. c. 112, § 80B and authorized to practice as a nurse practitioner pursuant to 244 CMR 4.00 et. seq. who holds certification as a neonatal nurse practitioner from a nationally recognized accrediting body acceptable to the Board.

**Neonatal Resuscitation Program (NRP)** shall mean the American Academy of Pediatrics’ course designed to teach resuscitation of the newborn.
Neonatologist shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics.

Obstetrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine and who is either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology.

Pediatrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in pediatrics by the American Board of Pediatrics.

Postpartum Unit shall mean that part of a maternal and newborn service that is used exclusively for postpartum care. Postpartum beds include beds located in labor-delivery-recovery postpartum rooms.

Recovery Area shall mean a specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.

Recovery Infant shall mean an infant who required acute care services for diagnosis and treatment, whose acute phase of illness has passed, and who now needs limited therapeutic intervention prior to discharge.

Retrotransferred Infant shall mean an infant who required transfer to a more acute level facility for diagnosis or treatment not available in the birth hospital, who no longer requires these services, and is transferred back to the birth hospital or to another hospital with the level of service meeting his/her needs.

Risk Assessment of the Infant shall mean the process of evaluating the newborn to determine whether he/she has special risks or combination of risks for adjustment to extrauterine life, health or survival in order to determine the need for specialized services, which includes a review of social, economic, genetic, and medical history findings prior to delivery or within the newborn period.

Risk Assessment of the Maternal Patient shall mean the process of medically evaluating the mother to determine whether she has special risks or combination of risks to her own health and well-being or to that of the fetus in order to determine the need for specialized services and which includes a review of social, economic, genetic and/or medical conditions during the antepartal, intrapartal and/or postpartal periods.

Special Care Nursery shall mean a nursery that is specially equipped and staffed to offer a variety of specialized services to moderately ill infants who do not require intensive care.

Stable-growing Infant shall mean the medically stable infant with a low birth weight who requires only a weight increase to be ready for discharge.

Transfer Infant shall mean any infant who is transferred from the birth hospital because he/she requires acute services for diagnosis and treatment not available at the birth hospital.

Well Newborn Nursery shall mean a room housing newborns who do not need continuing care, special care of intensive care newborn services.
130.605: Department Designation of Level of Maternal and Newborn Care in a Hospital

(A) The Department shall designate the level of maternal and newborn care of each hospital subject to Department licensure that provides maternal and/or newborn services as defined in 105 CMR 130.020.

(B) As directed by the Department, each hospital with maternal and/or newborn services shall file an application with the Department identifying the level of maternal and/or newborn services for which the hospital requests designation.

(C) The Department shall base such designation upon documentation submitted by each hospital regarding its maternal and/or newborn services and/or on-site evaluations by Department staff to determine compliance with the requirements of that level. The designation process is not intended to supersede the Department’s authority to determine what constitutes a major service or a substantial change in service for determination of need purposes.

(D) After the initial designation, the hospital shall re-apply for designation of its maternal and/or newborn services each time that it applies for renewal of its hospital license.

130.616: Administration and Staffing

(F) Nurse Staffing. The Maternal and Newborn service shall meet the following requirements:

(1) A registered nurse shall assess the needs, plan the care and evaluate the care delivery including the health education of each patient.

(2) A registered nurse shall observe and care for the mother, fetus and newborn during the labor, delivery and recovery periods.

(3) A registered nurse who has successfully completed a recognized program in neonatal resuscitation, such as the Neonatal Resuscitation Program (NRP), shall be present during the delivery. A second registered nurse shall be immediately available as additional support until the mother and infant are stabilized.

(4) A registered nurse shall complete an initial newborn nursing assessment and shall be responsible for notifying the physician of any abnormalities or problems.

(5) A registered nurse shall be on duty in each patient care unit on every shift.

(6) The hospital shall ensure that all licensed nursing staff caring for maternal and newborn patients have demonstrated current competency in providing care in the specialty area. All licensed nursing staff shall receive orientation and periodic in-service education related to the current best practices for maternal and newborn care including training or documented skill in at least the following areas:

(a) Evaluation of the condition of the mother, fetus and newborn.

(b) Assessment of risk during the labor, delivery, recovery and postpartum periods.

(c) Fetal assessment modalities including use of electronic fetal monitor, auscultation tools, interpretation of fetal heart-rate patterns and initiation of appropriate nursing interventions for non-reassuring patterns (for nurses caring for pregnant women).

(d) Nursing management of emergency situations that specifies communication and decision-making responsibilities and chain of command.

(e) Adult and newborn resuscitation.

(f) Immediate care and assessment of the newborn.
(g) Family-centered care that is culturally and linguistically appropriate.
(h) Support of the normal processes of labor and birth.
(i) Mother and infant security.
(j) Initiation and support of lactation.

(7) The licensed nursing staff shall receive documented retraining in adult and neonatal cardio-pulmonary resuscitation every two years and mock code drills every year. Each maternal and newborn service shall provide licensed nursing staff with continuing education in specialty areas of the service.

(8) The hospital shall plan, develop and budget its nurse staffing pattern for the maternal and newborn service using data from a patient classification system acceptable to the Department. If a classification system is not used, the hospital shall apply nationally recognized staffing standards acceptable to the Department to the facility's case-mix and volume.

(G) Lactation Care and Services.

(1) Each hospital shall deliver culturally and linguistically appropriate lactation care and services by staff members with knowledge and experience in lactation management. At a minimum, each hospital shall provide every mother and infant requiring advanced lactation support with ongoing consultation during the hospital stay from an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience.

(2) Each maternal and newborn service shall develop written, evidence-based breastfeeding policies and procedures and include these in staff education and competency reviews.

(3) An educational program of lactation support for maternal and newborn staff shall be offered by qualified staff and shall address the following areas:

(a) The nutritional and physiological aspects of human lactation.
(b) Positioning of mother and infant to promote effective sucking, milk release and production.
(c) Practices to avoid, recognize and treat common breastfeeding complications.
(d) Nutritional needs of the mother during lactation and monitoring the nutritional needs of the infant.
(e) Safe techniques for milk expression and storage of milk.
(f) Information about community support services available to the family after discharge.
(g) Cultural values related to breastfeeding

130.630: Level I - Community-based Maternal and Newborn Service

The Level I capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IB, IIA, IIB or Level III services. Provides for the care and management of well newborns, stable infants born at >= 35 weeks gestation, including stable retro-transferred infants not needing Level IB, IIA, IIB or III services.

The Level I Service shall meet all of the General Requirements for Maternal and Newborn Services contained in 105 CMR 130.601 through 130.628 and, in addition, the following:
(A) **Collaboration/Transfer Agreements.** The Level I service shall establish formal written collaboration/transfer agreements with at least one Level III hospital within geographic proximity and other hospitals to which the service regularly refers patients.

(B) **Administration and Staffing.**

1. An obstetrician either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology shall be designated as medical director of the maternal service. The medical director or his/her designee shall be available on-call 24 hours a day.

2. A pediatrician either certified or an active candidate for certification by the American Board of Pediatrics and experienced in the care of newborns shall be designated as medical director of the newborn service. The medical director or his/her designee shall be available on-call 24 hours a day.

3. The medical directors of the maternal service and the newborn service shall collaborate in the overall medical management of the maternal and newborn service.

4. An obstetrician either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available on-call 24 hours a day.

5. A pediatrician either certified or an active candidate for certification by the American Board of Pediatrics with newborn privileges or board certified or an active candidate for certification by the American Board of Family Practice with newborn privileges shall be available on-call 24 hours a day.

6. A registered nurse designated by the hospital shall be accountable for the 24 hour nursing management of the Level I service. At a minimum, this nurse shall be baccalaureate prepared (master's preferred) and have at least two years experience in the care of stable newborns.

7. A registered nurse educator, prepared at the baccalaureate level, shall have dedicated responsibility for coordinating and providing educational and training activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service.

8. Anesthesiologists shall be available in-house or on-call such that emergency cesarean deliveries can be started within 30 minutes of the recognition of the need for the procedure.

(E) **Level IB Service Designation.** The services capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IIA, IIB or Level III services. Provides for the care and management of well newborns, stable infants born at >= 35 weeks gestation, including stable retro-transferred infants not needing Level IIA, IIB or III services. A Level I service may be designated as a Level IB service with a continuing care nursery service if the requirements of 105 CMR 130.630(E)(1) through (4) are met 24 hours a day, seven days a week:

1. **Administration and Staffing.**
   - A physician certified by the American Board of Pediatrics with experience in the care of special care newborns shall be designated as the medical director of the Level IB Continuing Care Nursery Service. The medical director or his/her designee shall be available on-call 24 hours a day.
   - A physician who is either certified or an active candidate for certification by the American Board of Pediatrics with Continuing Care Nursery privileges shall be available on-call 24 hours a day.

2. **Nursing.**
   - The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Continuing Care Nursery service. At a minimum, such nurse shall be baccalaureate prepared (master's preferred) and have additional education in
the specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

(ii) The hospital shall provide a baccalaureate prepared nurse educator with dedicated responsibility for coordinating and providing education activities to enhance staff knowledge or relevant procedures and technological advances for staff of the maternal and newborn service.

(d) A respiratory therapist with pediatric experience trained in neonatal transition and disease pathology (e.g. NRP) shall be present in-house to provide consultation on oxygen therapy and equipment maintenance.

(e) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.

(D) Maternal Service.

1. Collaboration/Transfer Agreements. Each Level IIA or IIB service shall establish formal written collaboration/transfer agreements with at least one hospital with a Level III maternal service.

2. Administration and Staffing.

(a) A physician certified by the American Board of Obstetrics and Gynecology shall be designated medical director of the maternal service. This physician shall collaborate with the pediatrician responsible for newborn patients in the medical management of the entire maternal and newborn service.

(b) A physician certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available on-call 24 hours a day.

(c) Nursing.

1. The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the maternal service. At a minimum, such nurse shall be prepared at the baccalaureate level and have additional education in the specialty area. She or he shall also have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

(E) Special Care Nursery.

1. Collaboration/Transfer Agreements. Each hospital providing a Level II maternal and newborn service shall establish formal written collaboration/transfer agreements with at least one Level III service.

2. Administration and Staffing.

(a) A physician certified by the American Board of Pediatrics who has qualified to appear for the neonatology board shall be designated the medical director of the Special Care Nursery. A pediatrician meeting the requirements of 105 CMR 130.640(E)(2)(b) shall be designated to act in the absence of the director.

(b) A neonatologist who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics shall be available on-call 24 hours a day.

(c) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Special Care Nursery service. At a minimum, such nurse shall be baccalaureate-prepared and have additional education in the neonatology specialty area. She or he shall have at least two years experience in the specialty area and meet the qualifications for the management position as defined by hospital policy.

3. Special On-site Staffing Requirements. Each hospital providing special care nursery services shall provide on-site coverage 24 hours a day by either a neonatologist or a pediatrician who meets the requirements of 105 CMR 130.640(E)(3)(a) or neonatal nurse practitioner who meets
the requirements of 105 CMR 130.640(E)(3)(b), who shall be immediately available to the special care nursery and the delivery room.

(a) Pediatricians. A pediatrician qualified to provide on-site coverage in the special care nursery shall be either a pediatric resident who, at a minimum, has completed the first year of postgraduate residency training with at least two months neonatal intensive care unit rotations or a pediatrician who is certified or an active candidate for certification by the American Board of Pediatrics. Pediatricians shall meet the hospital's requirements for special care nursery privileges. Pediatric residents shall meet criteria for special care nursery coverage established by the Director of the special care nursery. At a minimum, criteria for privileges and coverage shall include the specific clinical skills to provide emergency newborn resuscitation in the delivery room and essential special care nursery skills such as intubation, emergency pneumothorax management, umbilical artery catheterization, and drawing arterial blood gases. Before assignment to provide on-site coverage, pediatricians and residents shall successfully complete the American Heart Association/American Academy of Pediatrics neonatal resuscitation course (or an equivalent).

(b) Neonatal Nurse Practitioner.

(i) A neonatal nurse practitioner qualified to provide on-site coverage in the special care nursery shall

a. preferably have a master's degree but at a minimum have a baccalaureate degree;
b. be certified as a neonatal nurse practitioner by a nationally recognized organization; and
c. be authorized to practice as an advanced practice registered nurse by the Massachusetts Board of Registration in Nursing.

(ii) Before assignment to provide on-site coverage, each neonatal nurse practitioner shall successfully complete the American Heart Association/ American Academy of Pediatrics neonatal resuscitation course (or an equivalent).

(iii) There shall be a planned schedule for the practitioner to rotate regularly to the Level III service with which the Level II service has a collaboration agreement. Rotation to the Level III service shall occur with such frequency as to assure that the neonatal nurse practitioner has the opportunity to maintain skills in the emergency procedures outlined in 105 CMR 130.640(E)(3)(a). At a minimum, the rotation shall occur annually. The practitioner shall be periodically evaluated by both the Level II and Level III services.

(iv) Neonatal nurse practitioners shall be credentialed through the hospital's nursing department and medical staff and function under approved written guidelines for practice. Neonatal nurse practitioners shall also meet the criteria for delivery room and special care nursery coverage established by the director of the special care nursery. Criteria shall include the skills necessary to provide emergency care to newborns as outlined in 105 CMR 130.640(E)(3)(a).

(v) The nurse practitioner providing Level II coverage shall have at least one year's recent experience functioning as a neonatal nurse practitioner on a service that provides high risk obstetrical and neonatal intensive care unit services.

(vi) Neonatal nurse practitioners shall be part of a team providing patient care and not retained only to provide off hour or holiday coverage at the level II service. The schedule for coverage of the delivery room and special care nursery shall reflect that pediatricians and neonatal nurse practitioners who are members of the team share responsibility for covering all shifts and collaborate in the ongoing care of infants and their families and in professional education activities.
(vii) There shall be written policies and procedures outlining the specific criteria for summoning pediatrician or neonatologist back-up coverage for consultation and for on-site assistance in the delivery room and special care nursery.

(6) Other Policies and Procedures. The Special Care Nursery shall have written policies and procedures for the following:
(a) Nursing orientation and ongoing education including theory and skills required to function in the Special Care Nursery.
(b) If therapeutic formulas are made on-site, policies governing preparation and sealing containers to prevent tampering.
(c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

130.650: Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services

(A) Level III Service. The Level III maternal and newborn service has the capabilities to provide care for stable to severely ill neonates: well newborns, premature infants, and infants who require neonatal intensive care services. The service provides newborn care to patients with routine medical needs, as well as to those with actual medical problems. The maternal service has the capabilities to manage complex maternal conditions with the expertise of a Critical Care Obstetrics Team.

(B) A service shall be eligible for designation as a Level III service with a neonatal intensive care nursery if one of the following conditions is met:
(1) the service has a minimum of 2,000 births per year in any one of the past three years; or
(2) the service has satisfactorily demonstrated to the Department that a minimum volume of 2,000 births per year will be reached in the next three years; or
(3) the service has satisfactorily demonstrated that the percent of low birth weight infants (< 2,500 grams) delivered is no less than 10% of the annual births.

(C) The Level III service shall meet the requirements contained in 105 CMR 130.601 through 130.628 and, in addition, the requirements set forth in 105 CMR 130.650(D) and (E).

(D) Maternal Service.

(1) Administration and Staffing.
(a) A physician certified by the American Board of Obstetrics and Gynecology with a subspecialty (special competency) in maternal-fetal medicine shall be designated medical director of the maternal service. This obstetrician shall collaborate with the neonatologist responsible for the neonatal intensive care unit in the medical management of the maternal and newborn service.
(b) A physician certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available in-house 24 hours a day.
(c) An obstetrician in training who has completed the second year of post-graduate residency shall be immediately available to the unit, in-house, 24 hours a day.
(d) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour a day nursing management of the Level III Maternal Service. At a minimum, such nurse shall be master's-prepared and have additional education in the maternal specialty area. She or he shall also have at least five years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.
(e) Qualified registered nurses shall be on duty to care for maternal patients 24 hours a day. The team of nurses shall demonstrate competencies in critical care and be Advanced Cardiac Life Support certified.

(f) A full time master's prepared nurse, preferably a clinical nurse specialist with clinical experience in neonatology or perinatology or a neonatal nurse practitioner, shall be available with dedicated responsibility for coordinating the in-service education for maternal and newborn staff.

(g) A master's-prepared licensed social worker with experience in assessment of perinatal patients (mother/infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patients' needs.

(h) A dietician registered by the American Dietetics Association with expertise in both normal and high risk maternal and newborn nutritional needs and with access to neonatal nutritional resources shall be available seven days a week.

(E) Neonatal Intensive Care Unit.

(1) Administration and Staffing.

(a) A board-certified neonatologist shall be designated the medical director of the Neonatal Intensive Care Unit. The medical director or his/her designee shall be available on-call 24 hours a day.

(b) A board certified neonatologist or an active candidate for certification in neonatology by the American Board of Pediatrics shall be available in-house 24 hours a day.

(c) A pediatrician-in-training who has completed the second year of post-graduate residency shall be present in-house and immediately available to the unit, 24 hours a day.

(d) A nurse designated by the hospital shall be responsible for the 24 hours a day nursing management of the neonatal intensive care service. At a minimum, this nurse shall be masters-prepared and have experience and advanced education in caring for sick newborns. She or he shall have at least five years of clinical experience, two of which are in the specialty area, and, in addition, meet the qualifications for the position as defined by hospital policy.

(e) Qualified registered nurses shall be on duty to care for neonates 24 hours a day. The team of nurses shall demonstrate competencies in critical care and be Neonatal Resuscitation Program (NRP) certified.

(f) A freestanding pediatric hospital with a neonatology subspecialty shall meet the requirements for a nurse educator stipulated in 105 CMR 130.650(D)(1)(f).

(g) A masters-prepared licensed social worker with experience in assessment of perinatal patients (mother/infant dyad), education, discharge planning, community follow-up programs, referrals and home care arrangements shall be available as needed to meet patient needs.

(h) A dietician registered by the American Dietetics Association who has expertise in both normal and high risk maternal and newborn nutritional needs and with access to neonatal nutritional resources shall be available seven days a week.

(i) A respiratory therapist trained in the neonatology specialty area shall be available to the unit 24 hours a day.

(j) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written policy.

(k) A lactation consultant shall be available seven days a week. Lactation consultants shall have training and experience in providing care and services to infants with special needs and their families.
(2) Services. The Neonatal Intensive Care Unit shall be located within either a hospital with Level III Maternal and Newborn Service or a Freestanding Pediatric Hospital with Neonatal Subspecialty Services.

The Level III Neonatal Intensive Care Unit shall provide the following:
(a) Access to emergency transport team for transferring sick newborns from the birth hospital to the neonatal intensive care unit.
(b) Ventilatory assistance and/or complex respiratory management including high-frequency ventilation.
(c) Capability of continuous intravenous administration of vasopressor agents.
(d) Insertion and maintenance of all types of venous and arterial lines.
(e) Nitric oxide therapy.
(f) Phototherapy.
(g) Exchange transfusions.
(h) Continuous cardio-respiratory monitoring including oxygen saturation monitoring.
(i) Complex nutritional and metabolic management including total parenteral nutrition.
(j) Full range of emergency pediatric radiology and subspecialty services available 24 hours a day.
(k) Full range of laboratory services including microchemistry and full service blood bank available 24 hours a day.
(l) Access to emergency surgical interventions in the neonate (or written agreements with other institutions providing subspecialty surgical procedures) available 24 hours a day.
(m) Post-surgical care.
(n) Access to pediatric subspecialty consultation and services including surgery, neurology, cardiology, gastroenterology, infectious disease, hematology and genetics available 24 hours a day.
(o) Where indicated, a developmental plan including, but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents. (Attention shall also be given to elimination of negative or extraneous environmental stimuli and to pain management and monitoring.)
(p) Availability of developmental consultation, including occupational and physical therapies.
(q) Continuous involvement of parents in infant's care and opportunity for mothers to room-in for pre-discharge education in caring for the infant.
(r) Crisis-oriented support and ongoing psychosocial services including social work service and the availability of psychiatric consultation for the parents. (Provision for parent support group is recommended.)
(s) Ongoing written discharge planning.
(t) Transport capabilities to return patients to a hospital with a Level I or II service.
(u) Ethics committee for review of complex patient care issues with focus on parental involvement in decision making.
(v) Professional education program.
(w) Availability of educational offerings to collaborating community hospitals.
(x) Parent education appropriate to meet the needs of the infant and family.
(y) Breastfeeding support.

(3) Policies and Procedures. The neonatal intensive care unit shall have written policies and procedures for the following:
(a) Nursing orientation and ongoing education in theory and skills required to function in the NICU.
(b) Admission, transfer and discharge of patients.
(c) Emergency transport of infants from collaborating hospitals. These policies shall require the presence of a physician or neonatology specialty-trained nurse on the transport team and access to telephone consultation with a neonatologist.

(d) Research on infants.

(e) Membership and functioning of the ethics committee.

(f) If therapeutic formulas are made on-site, policies for preparation and sealing of containers to prevent tampering.

(g) Newborn pain management.

(h) Other policies and procedures as determined by the hospital perinatal committee or the multidisciplinary neonatal intensive care committee.

130.700: Definitions

Terms used in 105 CMR 130.700 shall be interpreted as set forth in 105 CMR 130.700.

General Pediatric Service (Level II), a service which provides care for pediatric patients with uncomplicated and complicated medical and surgical problems who do not require the specialized pediatric intensive care and/or comprehensive specialized services found on a tertiary pediatric service (Level III). A Level II service must have a pediatric unit with suitable personnel and access to subspecialty consultation, supportive laboratory facilities, and ancillary services necessary to provide for the level of care offered.

130.700 continued

(R) Only Level III pediatric services may have pediatric intensive care units. Ordinarily, patients under 15 years of age requiring intensive care shall be admitted to pediatric intensive care units in hospitals with Level III pediatric services. When this is inadvisable, such a patient may be admitted to an adult intensive care unit (ICU) if the ICU meets the following criteria for the duration of the pediatric patient's stay:

1. A physician who is capable of pediatric resuscitation is available in-hospital 24 hours a day.
2. There is a consultation with a board qualified or certified pediatrician for every pediatric patient under 15 admitted to the ICU.
3. A registered nurse with clinical pediatric experience is available to the ICU for nursing consultation and/or care whenever a pediatric patient requires it.
4. Emergency pediatric drug dosages are available in the ICU.
5. Pediatric-sized emergency resuscitation equipment is available in the ICU.
6. Emergency laboratory services utilizing microtechniques shall be available in-hospital 24 hours a day.
7. A radiology technician shall be available in-hospital 24 hours a day.

130.720: Requirements for all Pediatric Services (Levels I-III)

Pediatric services (Levels I-III) shall comply with the following requirements:

(A) Hospitals providing inpatient care to children under 15 years of age must admit these patients to a level I pediatric area as described in 105 CMR 130.730(C) or a level II pediatric unit or sub-unit, or a level III pediatric unit, with the exception of those patients who require specialized care which cannot be provided in such a pediatric area, unit or sub-unit, such as obstetrics or other care designated by the Department. Pediatric patients 15 years of age and
over may, at the option of the admitting physician, be cared for on a service other than the pediatric service.

(B) (1) Any patient 21 years of age or older may be admitted to a pediatric service when in the opinion of the Chiefs of Pediatrics, and the Director of Nursing or their designees, he has a condition most appropriately treated on a pediatric service.

(2) When a temporary medical emergency fills the medical/surgical service, and the admission to a pediatric unit a sub-unit of certain medical/surgical patients 21 years of age or older poses no danger to pediatric patients, such a medical/surgical patient may be admitted to a pediatric unit or sub-unit with the approval of the Chief of Pediatrics and the Director of Nursing or their designees, provided:

(a) No such patient occupies a bed in the same room as a pediatric patient, and
(b) The hospital keeps a log of each such admission, which is available for the Department's inspection.

(C) Every pediatric service shall establish an advisory multidisciplinary Pediatric Committee, chaired by the Chief of Pediatrics, to advise it on issues related to the service.

(D) Each pediatric service shall have written policies and procedures for patients requiring transfer and/or consultation.

(E) The hospital shall establish a policy identifying which patients must have a consultation by a pediatrician.

(F) Each pediatric service shall develop a policy for the management of infectious disease and isolation.

(G) At least one pediatric patient room shall be available for isolation use.

(H) Each pediatric service shall have written protocols for the management of pediatric patients with known or suspected psychiatric, child abuse or neglect problems.

(I) The pediatric service shall have a policy regarding parental involvement which allows for constant parental support of and contact with the pediatric patient throughout hospitalization. However, parental access to specialized areas like operating rooms may be denied.

(J) The clinical laboratory services available for pediatric patients shall be defined by the Director of Laboratory Services in consultation with the Chief of Pediatrics, the chiefs of other services caring for pediatric patients, and hospital administration.

(K) The diagnostic radiological procedures available for pediatric patients shall be defined by the Chief of Radiology in consultation with the Chief of Pediatrics, the chiefs of other services caring for pediatric patients, and hospital administration.

(L) Equipment sized appropriately for pediatric patients must be available in all areas and services providing care to pediatric patients.

(M) All pediatric service equipment, including beds, cribs, wheelchairs, and toys, shall meet the minimum safety standards established by the hospital’s Pediatric Committee.

(N) Provision shall be made for the safe storage of drugs, external solutions, and other potentially toxic substances kept on pediatric services.

(O) Laundry chutes on pediatric services must be locked.

(P) All personnel providing direct care to pediatric patients shall participate in a pediatric orientation program which meets the needs of the hospital and its patients.

(Q) Each pediatric service shall have pediatric emergency resuscitation equipment and medication readily available. A visible sign or chart listing pediatric doses for emergency drugs shall accompany such equipment.

(R) Only Level III pediatric services may have pediatric intensive care units. Ordinarily, patients under 15 years of age requiring intensive care shall be admitted to pediatric intensive care units in hospitals with Level III pediatric services. When this is inadvisable, such a patient may be
admitted to an adult intensive care unit (ICU) if the ICU meets the following criteria for the duration of the pediatric patient’s stay:
(1) A physician who is capable of pediatric resuscitation is available in-hospital 24 hours a day.
(2) There is a consultation with a board qualified or certified pediatrician for every pediatric patient under 15 admitted to the ICU.
(3) A registered nurse with clinical pediatric experience is available to the ICU for nursing consultation and/or care whenever a pediatric patient requires it.
(4) Emergency pediatric drug dosages are available in the ICU.
(5) Pediatric-sized emergency resuscitation equipment is available in the ICU.
(6) Emergency laboratory services utilizing microtechniques shall be available in-hospital 24 hours a day.
(7) A radiology technician shall be available in-hospital 24 hours a day.
(8) Every pediatric service shall make available informational material on chronic and other related conditions to families of pediatric patients with such conditions, and services to such families.
(T) Every pediatric service admitting a newborn infant, as defined under 105 CMR 130.629, from either another hospital, birth center, or home, shall verify that the newborn hearing screening has been conducted by the hospital or birth center from which the newborn infant has been transferred or where the newborn infant was born and, in the event it has not been conducted, shall ensure that the screening is performed prior to discharge of the newborn infant, in a manner consistent with standards established by the Department under 105 CMR 130.629.

130.730: Requirements for Uncomplicated Pediatric Services (Level I)

Uncomplicated pediatric services (Level I) must meet the following requirements in addition to those listed in 105 CMR 130.720:
(A) A physician with pediatric experience shall be designated as the Chief of Pediatrics. The Chief of Pediatrics or the Chief’s designee shall be on call at all times for the care of pediatric patients.
(B) There must be a registered nurse with clinical pediatric experience on duty 24 hours a day for the direct supervision of pediatric nursing care.
(C) There must be specific beds within an adult care unit designated for pediatric patients. These beds and other equipment must be adaptable for pediatric patients under 15 years of age. The area must be equipped with bathroom facilities for the exclusive use of pediatric patients.
(D) Social services for pediatric patients shall be available in-hospital or through consultant arrangements and their existence must be made known to the families of pediatric patients.
(E) At a minimum, consultant arrangements shall be made for the provision of physical and occupational therapy for pediatric patients.

130.740: Requirements for General Pediatric Services (Level II)

General pediatric services (Level II) must meet the following requirements in addition to those listed in 105 CMR 130.720:
(A) The hospital must have either:
   (1) a discrete unit designated for pediatric patients, or
   (2) a discrete sub-unit within an adult care unit containing beds permanently designated as pediatric beds, provided this sub-unit meets the following requirements:
(a) Such pediatric beds are located in a specific room, or contiguous specific rooms, and such beds and other support equipment are appropriate for pediatric patients under 15 years of age.

(b) The nursing station or sub-station serving pediatric patients is adjacent to the room(s) containing beds designated for pediatric patients. Observation of these rooms is possible from the nursing station or sub-station.

(c) The pediatric service has written policies specifying the ages and types of diagnoses of patients who may be admitted to the sub-unit for elective and emergency purposes, and the types of procedures that may be performed on them. The hospital has written policies specifying the types of diagnoses that adult patients may not have to be admitted to the adult care unit in which pediatric sub-unit is located. These policies are approved by the Department, with the advice of the Pediatric Advisory Committee, as assuring an adequate standard of care for pediatric patients admitted to the sub-unit.

(d) The pediatric sub-unit is situated in such a way that the flow of adult patients through it is discouraged.

(B) The hospital must have a designated Chief of Pediatrics who is a board qualified or certified pediatrician. The Chief of Pediatrics or one or more physicians designated by the Chief shall be on call at all times for the care of pediatric patients.

(C) There must be a physician trained in pediatric resuscitation available in-hospital 24 hours a day.

(D) Any pediatric residents and interns assigned to a Level II service shall be supervised by a staff pediatrician.

(E) The head nurse or equivalent who has 24-hour responsibility for the direction and supervision of patient care on the general pediatric service shall be a registered nurse, preferably with a B.S. in nursing, and shall have had documented pediatric nursing experience within the past five years.

(F) At least one registered nurse with pediatric nursing experience shall be assigned to work in each pediatric unit or sub-unit at all times. Nursing personnel regularly assigned to the pediatric unit or sub-unit shall have this as their primary patient care responsibility.

(G) Social services for pediatric patients must be available in-hospital or through consultant arrangements, and their existence must be made known to the families of pediatric patients.

(H) Physical and occupational therapy services shall be available in-hospital or through consultant arrangements.

(I) The Chief of Pediatrics and the Laboratory Director shall determine what laboratory tests, including those utilizing microtechniques, the hospital must have the capacity to perform for pediatric patients. A technician to perform such tests shall be available on a 24-hour basis, in-hospital or on call within 15 minutes.

(J) A radiology technician shall be available on a 24-hour basis, in-hospital or on call within 15 minutes.

(K) When necessary, a registered dietitian shall be available to Level II service staff and the families of pediatric patients for consultation concerning pediatric nutrition.

(L) The hospital shall provide documentation of training and experience in pediatric anesthesiology of anesthesiologists providing care to pediatric patients.

(M) Pharmacy services including 24-hour availability of medications and intravenous solutions must be available in-hospital. Pharmacy consultations must be available on call 24 hours a day.

(N) The pediatric service must have a protocol for a recreational and educational program sufficient to meet the needs of its patients.
(O) The service must have an area (areas) which is (are) used primarily for recreation or play, and which is (are) equipped with items appropriate for the pediatric patients of the age using the area(s).

130.750: Requirements for Tertiary Pediatric Services (Level III)

Tertiary pediatric services (Level III) must meet the requirements listed in 105 CMR 130.720 and 130.740. In addition, Level III services must meet the following requirements (in case of conflict between these requirements and those listed in 105 CMR 130.740, Level III services must meet the requirements listed in 105 CMR 130.750):

(A) There must be a designated Chief of Pediatrics and an alternate or alternates designated by the Chief who will assume the responsibilities of the Chief in the Chief's absence. Each must be a board qualified or certified pediatrician.

(B) A board qualified or certified pediatrician or pediatric resident with a minimum of two years' residency training must be in the hospital 24 hours a day.

(C) The pediatric service must have a supervisory level nursing coordinator, who has at least a B.S. in nursing and pediatric experience, and preferably an M.S. in pediatric nursing.

(D) At least one social worker with an M.S.W. and experience working with pediatric patients and their families must be assigned to the pediatric service.

(E) Occupational therapy services must be available in-hospital and given or supervised by an occupational therapist with documented experience as a pediatric occupational therapist.

(F) Physical therapy services must be available in-hospital and given or supervised by a physical therapist with documented experience as a pediatric physical therapist.

(G) There must be a board qualified or certified radiologist or a radiology resident in-hospital at all times.

(H) At least one radiologist and one radiology technician in the hospital must have training and experience in pediatric radiology and radiologic technology respectively beyond that required for board certification in radiology and certification in radiologic technology.

(I) There must be a pediatric patient recreation program run by at least one trained activity therapist, whose education and experience is in one or more of the following fields: child development, early childhood education, or early childhood counseling.

(J) Each Level III service must have a pediatric intensive care unit (PICU), discrete from the adult ICU, which is designed and staffed to provide for critically ill or potentially critically ill pediatric patients who need highly specialized intervention and advanced life-support technology. The PICU shall meet the following requirements:

(1) The PICU shall be directed by a board-certified pediatrician, or a pediatric anesthesiologist board-certified in anesthesiology, who has documented special training and experience in the care and management of critically-ill pediatric patients.

(2) The PICU Director shall be assisted by at least one Associate Director who is a board-certified pediatrician or anesthesiologist with special training and experience in the care and management of critically ill pediatric patients.

(3) A physician who is responsible for the PICU patients shall be in-hospital 24 hours a day.

(4) A person capable of intubating and resuscitating pediatric patients shall be available within or immediately adjacent to the PICU 24 hours a day.

(5) Consultant board-certified physicians with training and experience in the following: pediatric surgery, cardio-thoracic surgery, neurosurgery, and neurology shall be available to the PICU 24 hours a day. Consultants from other subspecialties shall be available as necessary.
(6) The registered nurse in charge of the nursing staff in the PICU shall have at least two years of pediatric nursing experience and documented education in the care and management of critically ill pediatric patients.
(7) Registered nurses in the PICU shall have had documented experience in either clinical pediatric nursing or adult medical/surgical nursing and shall have received specialized orientation in the care and management of critically-ill pediatric patients prior to assuming PICU staff nurse positions.
(8) The registered nurse/patient ratio in the PICU shall be between 1:1 and 1:2, depending upon the number of nursing care hours required by each patient.
(9) Support personnel necessary to operate, maintain, regulate, or repair monitoring and ventilatory equipment shall be available to the PICU 24 hours a day.

130.1411: Continuing Health Professional Education

The hospital shall provide hospital-based staff education that addresses the needs of physicians, nurses, allied health professionals, and Emergency Medical Services (EMS) personnel. The program shall include ongoing formal training of ED and EMS system personnel in acute stroke prevention, diagnosis and treatment.
Massachusetts Nurse Practice Act

244 CMR 9.00: STANDARDS OF CONDUCT

9.01: Purpose
9.02: Definitions
9.03: Standards of Conduct for Nurses
9.04: Standards of Conduct for Advanced Practice Nurses (APNs)

9.01: Purpose

244 CMR 9.00 defines the standards of conduct for all nurses licensed by the Board of Registration in Nursing.

9.02: Definitions

Abandon means to intentionally terminate any nurse/patient relationship without reasonable notice to the patient or appropriate other person(s), or both, so that arrangements can be made for necessary continuation of care.

Abuse means any impermissible or unjustifiable contact or communication with a patient which in any way harms or intimidates, or is likely to harm or intimidate, a patient. Abuse may be verbal or non-verbal, and may cause physical, sexual, mental, or emotional harm.

Address of Record means the address of a nurse licensed by the Board as provided by the nurse and maintained by the Board on its license database.

Advanced Practice Nurse (APN) means a Registered Nurse to whom the Board has granted written authorization, under authority of M.G.L. c. 112, § 80B, to engage in advanced practice nursing as defined in 244 CMR 4.00.

Advanced Practice Nursing means professional nursing activity engaged in by a Registered Nurse in accordance with 244 CMR 4.00.

APN Authorization means the written authorization granted by the Board to a Registered Nurse in accordance with 244 CMR 4.00 to engage in advanced practice nursing.

Agreement means a legally binding document reflecting the agreement, including specified terms and conditions, entered into by a nurse licensed by the Board and the Board in resolution of any complaint against such nurse.

Authorized Prescriber means a person who holds current and valid controlled substances registrations issued by the United States Drug Enforcement Administration and the Division of Food and Drugs of the Massachusetts Department of Public Health.

Board means the Massachusetts Board of Registration in Nursing.
CMR means the Code of Massachusetts Regulations published by the Regulations Division of the Massachusetts Office of the Secretary of State.

**Competency** means the application of knowledge and the use of affective, cognitive, and psychomotor skills required for the role of a nurse licensed by the Board and for the delivery of safe nursing care in accordance with accepted standards of practice.

Complaint means a communication to, or other information obtained by, the Board alleging that a nurse licensed by the Board has engaged in conduct related to the practice of nursing that violates any laws or regulations, or both, related to such practice.

Controlled Substance means a drug, substance, or immediate precursor in any schedule or class referred to in M.G.L. c. 94C. Any drug or medication requiring a prescription in Massachusetts is a controlled substance.

Drug means a substance recognized as a drug in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, and all revisions and supplements thereto.

Impaired means the inability to practice nursing with reasonable judgment, skill, and safety by reason of alcohol or drug abuse, use of other substances, a physical or mental illness or condition, or by any combination of the foregoing.

Licensed Practical Nurse (LPN) means a nurse who meets the criteria for licensure under M.G.L. c. 112, § 74A and 244 CMR 8.00, and who holds a valid license to engage in the practice of nursing as a Licensed Practical Nurse.

M.G.L. means Massachusetts General Laws.

Mistreatment means the improper use of any drug, physical or chemical restraint or confinement, or any combination thereof.

Neglect means the unjustified failure to provide treatment or services, or both, necessary to maintain the health or safety, or both, of a patient.

Nurse Licensed by the Board means a nurse to whom the Board has at any time issued a Registered Nurse or Licensed Practical Nurse license, or both, whether or not such license is expired, surrendered, suspended, or revoked.

Practice of Nursing means the practice of nursing as defined in M.G.L. c. 112, § 80B and 244 CMR 3.00. The practice of nursing includes, but is not limited to, the provision of a nursing service by a nurse physically located outside Massachusetts to a person physically located within Massachusetts using telecommunications technology, seeking or accepting any paid or voluntary position as a Registered Nurse or Licensed Practical Nurse or any paid or voluntary position requiring that the applicant hold a valid license to practice nursing.

Prescription Drug means any and all drugs determined to be prescription drugs under M.G.L. c. 94C.
Prescriptive Practice means the written and oral issuance of any prescription and medication order for prescription and non-prescription drugs.

Professional Boundaries mean the limits of the professional relationship that allow for a safe and therapeutic interface between the professional and the patient.
Registered Nurse (RN) means a nurse who meets the criteria for licensure under M.G.L. c. 112, § 74 and 244 CMR 8.00, and who holds a valid license to engage in the practice of nursing in Massachusetts as a Registered Nurse.

Standards of Nursing Practice means authoritative statements that describe a level of care or performance common to the profession of nursing by which the quality of nursing practice can be judged.

Substance Abuse means a dysfunctional pattern of human response characterized by excessive, inappropriate, or unhealthy use of chemical substances including alcohol or drugs, or both.

Telecommunications Technology means those modalities used in the practice of nursing over distance, whether intrastate or interstate. Such modalities include, but are not limited to: telephones, facsimile, cellular phones, video phones, computers, e-mail, voice mail, CD-ROM, electronic bulletin boards, audio tapes, audio-visual tapes, teleconferencing, video conferencing, on-line services, World Wide Web, Internet, interactive television, real-time camera, and still-imaging.

Unlicensed Practice of Nursing means engaging, or attempting to engage, in the practice of nursing in Massachusetts without holding a valid license. Unlicensed practice of nursing also means using any title or other designation indicating licensure as a Registered Nurse or Licensed Practical Nurse, or authorization to engage in advanced practice nursing, without the requisite valid license or APN authorization.

Valid License means a license to practice nursing in Massachusetts properly issued to a nurse by the Board on the basis of truthful information related to the qualifications for licensure as a Registered Nurse or Licensed Practical Nurse, and which license is not expired, surrendered, suspended, or revoked.

9.03: Standards of Conduct for Nurses

Each nurse licensed by the Board and engaged in the practice of nursing shall have knowledge and understanding of the Standards of Conduct for Nurses set forth in 244 CMR 9.00, all state laws and Board regulations governing the practice of nursing, and all other state and federal laws and regulations related to such practice.
The Board may take disciplinary action against the license of any nurse licensed by the Board or against any APN authorization, or both, or against the nurse’s right to renew such license, upon the nurse’s failure to comply with the Standards of Conduct for Nurses or with any other laws and regulations related to the practice of nursing.

(1) Practice Under Valid License. Except as provided by M.G.L. c. 112, §§ 80, 80A, and 81, a nurse shall only engage in the practice of nursing in Massachusetts with a valid license.
(2) Practice as Advanced Practice Nurse (APN). A Registered Nurse may only engage in advanced practice nursing in Massachusetts after receiving written authorization from the Board in accordance with 244 CMR 4.00.

(3) Practice Following Loss of License. A nurse licensed by the Board shall not engage in the practice of nursing in Massachusetts, or in any way represent himself or herself as a Registered Nurse or Licensed Practical Nurse, after the effective date of:
(a) license expiration;
(b) license surrender under the terms and conditions of a written agreement entered into with the Board;
(c) a license suspension order or license revocation order contained in a final decision and order issued by the Board;
(d) a summary suspension order issued by the Board in accordance with 244 CMR 7.05.
The practice of nursing in Massachusetts after the occurrence of any of the events set forth in 244 CMR 9.03(3)(a) through (d) shall constitute the unlicensed practice of nursing.

(4) Practice of Nursing in Another Jurisdiction Using Telecommunications Technology. A nurse licensed by the Board who, while physically located within Massachusetts, provides a nursing service using telecommunications technology to a person physically located outside Massachusetts, shall also be governed by the licensure and practice laws and regulations of the state or jurisdiction in which the recipient of such a service is located.

(5) Adherence to Standards of Nursing Practice. A nurse licensed by the Board shall engage in the practice of nursing in accordance with accepted standards of practice.

(6) Compliance with Laws and Regulations Related to Nursing.
(a) A nurse who holds a valid license shall comply with M.G.L. c. 112, §§ 74 through 81C, as well as with any other laws and regulations related to licensure and practice. Examples of such laws include, but are not limited to, the following:
1. M.G.L. c. 19A, § 15 (obligation to report elder abuse);
2. M.G.L. c. 19C, § 10 (obligation to report abuse of disabled person);
3. M.G.L. c. 38, § 3 (report of death to medical examiner);
4. M.G.L. c. 46, § 9 (death pronouncement);
5. M.G.L. c. 62C, § 47A(d) (obligation to pay state taxes);
6. M.G.L. c. 71, § 55A (obligation to sick school child);
7. M.G.L. c. 71, § 55B (obligation to file report certifying freedom from tuberculosis in communicable form);
8. M.G.L. 94C (Controlled Substances Act - requirements for possessing, dispensing, administering, and prescribing controlled substances);
9. M.G.L. c. 111, § 70E (Patients’ or Residents’ Rights);
10. M.G.L. c. 111, § 70F (HTLV-III Tests);
11. M.G.L. c. 111, § 72G (obligation to report abuse of patient or resident);
12. M.G.L. c. 111, § 110 (obligation to report infant with swollen, red, or inflamed eye(s) or with unnatural discharge within two weeks after birth);
13. M.G.L. c. 111, § 110B (obligation to report examination or treatment of child with Reyes syndrome);
14. M.G.L. c. 111, § 191 (obligation to report lead poisoning);
15. M.G.L. c. 112, § 12CC (obligation to provide patient records);
16. M.G.L. c. 112, § 61 (obligation to pay student loans);
17. M.G.L. c. 119, § 51A (obligation to report child abuse);
18. M.G.L. c. 119A, § 16 (obligation to pay child support);
19. M.G.L. c. 123, § 12 (requirements for commitment of mentally ill person);
20. M.G.L. c. 123, § 21 (requirements for use of restraint and seclusion of mentally ill person); and

(b) A nurse licensed by the Board who no longer holds a valid license shall comply with 244 CMR 9.03(6)(a)5., 16., and 18., as well as with the good moral character requirement contained in M.G.L. c. 112, § 74 (RNs) and § 74A (LPNs).

(7) Aiding Unlawful Activity. A nurse licensed by the Board shall not aid any person in performing any act prohibited by law or regulation.

(8) Identification Badge. A nurse who holds a valid license and who examines, observes, or treats a patient in any practice setting shall wear an identification badge which visibly discloses at a minimum his or her first name, licensure status and, if applicable, advanced practice authorization.

(9) Responsibility and Accountability. A nurse licensed by the Board shall be responsible and accountable for his or her nursing judgments, actions, and competency.

(10) Acts within Scope of Practice. A nurse who holds a valid license and is engaged in the practice of nursing in Massachusetts shall only perform acts within the scope of nursing practice as defined in M.G.L. c. 112, § 80B and 244 CMR 3.00.

(11) Performance of Techniques and Procedures. A nurse licensed by the Board shall perform nursing techniques and procedures only after appropriate education and demonstrated clinical competency.

(12) Competency. A nurse who holds a valid license shall only assume those duties and responsibilities within his or her scope of practice and for which he or she has acquired and maintained necessary knowledge, skills, and abilities.

(13) Discrimination. A nurse licensed by the Board shall not withhold or deny nursing care based on age, ancestry, marital status, sex, sexual orientation, race, color, religious creed, national origin, diagnosis, or mental or physical disability.

(14) Asepsis and Infection Control. A nurse licensed by the Board shall adhere to standard precautions and to principles of asepsis and infection control, and shall not place a patient, himself or herself, or others at risk for the transmission of infectious diseases.

(15) Patient Abuse, Neglect, Mistreatment, Abandonment, or Other Harm. A nurse licensed by the Board shall not abuse, neglect, mistreat, abandon, or otherwise harm a patient.

(16) Patient Confidential Information. A nurse licensed by the Board shall safeguard patient information from any person or entity, or both, not entitled to such information. A nurse licensed by the Board shall share appropriate information only as required by law or for the protection of the patient.

(17) Patient Dignity and Privacy. A nurse licensed by the Board shall safeguard a patient’s dignity and right to privacy.

(18) Participation in Research. A nurse licensed by the Board who enrolls subjects in a research study or conducts such a study, or both, shall verify that a board, committee, or other group designated by an institution to ensure the protection of human subjects has approved the study in accordance with accepted standards for the protection of human subjects.

(19) Exercise of Undue Influence. A nurse licensed by the Board shall not exercise undue influence on a patient, including the promotion or sale of services, goods, appliances or drugs, in such a manner as to exploit the patient for financial gain of the nurse or a third party.

(20) Borrowing from Patients. A nurse licensed by the Board shall not borrow money, materials, or other property from any patient.

(21) Undue Benefit or Gain. A nurse licensed by the Board shall care for, and refer, a patient without undue benefit or gain to the nurse or a third party.
(22) Advertising. A nurse licensed by the Board shall not engage in false, deceptive, or misleading advertising related to the practice of nursing.

(23) Sexual Contact. A nurse licensed by the Board shall not have sexual contact with any patient with whom he or she has a nurse/patient relationship or with any former patient who may be vulnerable by virtue of emotional status, age, illness, or cognitive ability.

(24) Professional Boundaries. A nurse licensed by the Board shall establish and observe professional boundaries with respect to any patient with whom he or she has a nurse/patient relationship. A licensed nurse shall continue to observe professional boundaries with his or her former patients who may be vulnerable by virtue of emotional status, age, illness, or cognitive ability.

(25) Relationship Affecting Professional Judgment. A nurse licensed by the Board shall not initiate or maintain a nurse/patient relationship that is likely to adversely affect the nurse’s professional judgment.

(26) Duty to Report to the Board. A nurse who holds a valid license and who directly observes another nurse engaged in any of the following shall report that nurse to the Board in accordance with Board guidelines:
(a) abuse of a patient;
(b) practice of nursing while impaired by substance abuse;
(c) diversion of controlled substances.

(27) Change of Personal Data. A nurse who holds a valid license shall inform the Board in writing within 30 days of any change of his or her name, address of record, or Social Security number.

(28) Action Against Certificate. A nurse who holds a valid license and who holds a certificate issued by a certifying body related to the practice of nursing shall report to the Board in writing within 30 days any action against, or surrender of, his or her certificate issued by such certifying body.

(29) Examinations. In connection with any examination related to the practice of nursing, an applicant to the Board for licensure or a nurse licensed by the Board shall not:
(a) impersonate or act as proxy for an applicant for nurse licensure, APN authorization, or certification;
(b) disclose the contents of any examination, or solicit, accept, or compile information regarding the contents of any such examination before, during, or after its administration, or in any other way compromise or attempt to compromise the integrity of any such examination; or
(c) in any other way cheat on any examination.

(30) Practice Under a False or Different Name. A nurse who holds a valid license shall engage in the practice of nursing only under the name in which such license has been issued.

(31) Falsification of Information. A nurse licensed by the Board shall not knowingly falsify, or attempt to falsify, any documentation or information related to any aspect of licensure as a nurse, the practice of nursing, and the delivery of nursing services.

(32) Fraudulent Practices. A nurse licensed by the Board shall not engage in any fraudulent practice including, but not limited to, billing for services not rendered or submitting false claims for reimbursement.

(33) Impersonation. A nurse licensed by the Board shall not impersonate another nurse or other health care provider, or knowingly allow or enable another person to impersonate him or her.

(34) Misrepresentation of Credentials. A nurse licensed by the Board shall not misrepresent his or her credentials related to the practice of nursing including, but not limited to, those indicating education, type of nurse licensure, APN authorization, or certification related to the practice of nursing.

(35) Security of Controlled Substances. A nurse licensed by the Board and engaged in the practice of nursing shall maintain the security of controlled substances that are under his or her responsibility and control.

(36) Practice While Impaired. A nurse licensed by the Board shall not practice nursing while impaired.

(37) Unlawful Acquisition and Possession of Controlled Substances. A nurse licensed by the Board shall not unlawfully obtain or possess controlled substances.
(38) Administration of Drugs. A nurse licensed by the Board shall not administer any prescription drug or non-prescription drug to any person in the course of nursing practice except as directed by an authorized prescriber. 244 CMR 9.03(38) shall not apply where a Registered Nurse authorized by the Board to practice as a nurse anesthetist administers anesthesia or peri-operative medications, or both, under guidelines required by 244 CMR 4.25(4).

(39) Documentation of Controlled Substances. A nurse licensed by the Board shall document the handling, administration, and destruction of controlled substances in accordance with all federal and state laws and regulations and in a manner consistent with accepted standards of nursing practice.

(40) Circumvention of Law. A nurse licensed by the Board shall not receive from, or offer, give, or promise anything of value or benefit to, any official to circumvent any federal and state laws and regulations related to the practice of nursing.

(41) Compliance with Board Order. A nurse licensed by the Board shall comply with any order for disciplinary action issued by the Board against his or her license to engage in the practice of nursing or right to renew such license except as otherwise may be determined by the appropriate court in the course of an appeal of a Board final decision and order.

(42) Compliance with Agreements. A nurse licensed by the Board shall comply with all provisions contained in any agreement he or she has entered into with the Board.

(43) Violence. A nurse licensed by the Board shall not endanger the safety of the public, patients, or coworkers by making actual or implied threats of violence, or carrying out an act of violence.

(44) Documentation. A nurse licensed by the Board shall make complete, accurate, and legible entries in all records required by federal and state laws and regulations and accepted standards of nursing practice. On all documentation requiring a nurse’s signature, the nurse shall sign his or her name as it appears on his or her license.

(45) Alteration or Destruction of Records. A nurse licensed by the Board shall not inappropriately destroy or alter any record related to the practice of nursing.

(46) Responsibilities of Nurse in Management Role. A nurse licensed by the Board and employed in a nursing management role shall adhere to accepted standards of practice for that role. The responsibilities of the nurse employed in a nursing management role are to develop and implement the necessary measures to promote and manage the delivery of safe nursing care in accordance with accepted standards of nursing practice.

(47) Other Prohibited Conduct. A nurse licensed by the Board shall not engage in any other conduct that fails to conform to accepted standards of nursing practice or in any behavior that is likely to have an adverse effect upon the health, safety, or welfare of the public.

REGULATORY AUTHORITY
244 CMR 9.00: M.G.L. c. 13, § 14; c. 112, §§ 61, 74, 74A, 79, 80, 80A, 80B and 80F.
Federal Medicare Regulations Applicable to Patient Care Problems at Tufts

Title 42--Public Health

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS

Sec. 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.
(b) The hospital must be--
   (1) Licensed; or
   (2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.
(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws...

http://edocket.access.gpo.gov/cfr_2004/octqtr/42cfr482.11.htm
Sec. 482.55  Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) Standard: Organization and direction. If emergency services are provided at the hospital--

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) Standard: Personnel. (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

http://edocket.access.gpo.gov/cfr_2004/octqtr/42cfr482.55.htm
The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) Standard: Life safety from fire. (1) Except as otherwise provided in this section--


(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may Waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) Standard: Facilities. The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by
the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas. [51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004]

http://edocket.access.gpo.gov/cfr_2004/octqtr/42cfr482.41.htm
(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with Sec. 489.100 of this part (Definition), Sec. 489.102 of this part (Requirements for providers), and Sec. 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) Standard: Privacy and safety.
   (1) The patient has the right to personal privacy.
   (2) The patient has the right to receive care in a safe setting.
   (3) The patient has the right to be free from all forms of abuse or harassment.

(d) Standard: Confidentiality of patient records. (1) The patient has the right to the confidentiality of his or her clinical records.
   (2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) Standard: Restraint for acute medical and surgical care. (1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.
   (2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.
   (3) The use of a restraint must be--
      (i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;
      (ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must--
         (A) Never be written as a standing or on an as needed basis (that is, PRN); and
         (B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;
      (iii) In accordance with a written modification to the patient's plan of care;
      (iv) Implemented in the least restrictive manner possible;
In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

(f) Standard: Seclusion and restraint for behavior management. (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term `restraint' includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be--

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is--

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.
(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

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TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 482_CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart C_Basic Hospital Functions

Sec. 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

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(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff
personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under Sec. 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under Sec. 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under Sec. 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. When telephone or oral orders must be used, they must be--

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.
(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.


http://edocket.access.gpo.gov/cfr_2004/octqtr/42cfr482.23.htm