REPORT OF THE
MAINE QUALITY FORUM ADVISORY COUNCIL
PURSUANT TO LD 616

December 3, 2004

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EXECUTIVE SUMMARY

Pursuant to the Legislature's mandate in LD 616, the Technology Assessment Committee of the Maine Quality Forum Advisory Council studied nurse staffing levels in Maine hospitals, the question of mandated nurse/patient staffing ratios, and the rules of the Department of Health and Human Services (DHHS) with respect to nurse staffing. We followed our previously adopted technology assessment protocol requiring analysis based on scientific validated evidence. We focused on the question of whether there was valid evidence that mandated nurse/patient ratios in specific hospital units, such as those proposed by the sponsors of LD 616, would result in improved patient safety and quality of care.

We found that each Maine hospital has its unique staffing plan. The terminology and contents of those plans differ widely. Similar units in different hospitals have widely divergent staffing plans. Despite a thorough review of nurse staffing plans and documentation from the Division of Licensing and Certification we were not able to arrive at a conclusion about the adequacy of registered nurse staffing in Maine hospitals.

We did establish that there is universal agreement that adequate nursing resources are essential to safe, quality inpatient medical care. We concluded that there is currently no reliable scientific evidence that mandated RN/patient staffing ratios are a guarantor of quality and safety of inpatient care.

We recommend the collection of 15 nurse-sensitive indicators, previously adopted by the National Quality Forum through its national voluntary consensus process, to start to assess the quality of care in Maine's inpatient hospital settings. We believe that adoption of these indicators will not only start the task of measuring the quality of inpatient care, but will also by their implementation, encourage hospitals to improve their processes of care management. We are of the opinion that hospitals and nurses should devise common format staffing plans across common sites of care. We conclude that considerable efficiencies for hospitals and the Division of Licensing and Certification could be achieved by not only standardizing staffing plan formats but also utilizing a common patient acuity tool.

We believe that Maine hospitals' demonstrated dedication to safety and quality will be enhanced by these recommendations.

Our recommendations are detailed in the Recommendations section of this report.

Forward

On February 18, 2004 the Health and Human Services Committee of the Maine State Legislature amended LD 616, *An Act to Provide Safe Staffing Levels for Patients and To Retain Registered Nurses.* The text of the original bill is included in Appendix B. The title was amended to read: *An Act To Improve the Quality of Health Care* and the text was amended to read:

> *Review and report. Resolved, that the Maine Quality [Forum] Advisory Council, established pursuant to 24-A MRSA section 6952, shall review:*
>
> *direct-care registered nurse staffing levels in general, acute and specialty care hospitals,*
>
> *the issue of minimum staffing ratios for direct-care registered nurse staffing in hospitals*
>
> *and the rules of the Department of Human Services on direct-care registered nurse staffing.*
>
> *The Maine Quality Forum Advisory Council shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters on its review under this section and any recommendations from the council by January 15, 2005.*

Process

The Maine Quality Forum Advisory Council assigned LD 616 to its Technology Assessment Committee which began its inquiry by soliciting input from stakeholders, providers, and the public to inform their work. The Committee also contracted with the Muskie School of Public Service to perform a review of the literature relating to the second charge in the amendment, the issue of minimum staffing ratios for direct-care registered nurse staff in hospitals. Two meetings were held with the Health Care Provider Group of the Maine Quality Forum for their input, and Committee representatives also met with representatives of the DHHS Division of Licensing and Certification, obtaining extensive data from the Division with respect to its practices in the regulation and review of nurse staffing plans. Numerous public committee meetings were held, including work sessions for drafting this report.

FINDINGS

I. Direct Care Nurse Staffing Levels in Maine Hospitals

A. Staffing Plans and Actual Staffing

Maine's nurse staffing regulations (Chapter X, section C) were strengthened in October 2002. In January 2003 the Department of Health and Human Services (DHHS) began including compliance with these new regulations in their regular hospital licensing reviews. From January 2003 to June 2004 DHHS conducted 41 hospital licensing reviews; 15 hospitals were cited for deficiencies in the documentation of their staffing plans. There were no staffing level deficiencies cited by DHHS. However, review of the DHHS documentation did not reveal the staffing plans or actual staffing levels in place. Therefore, we used two approaches to measure the adequacy of staffing levels in Maine hospitals: a review of hospital staffing plans and a review of the use of clinical indicators.

Hospital Staffing Plans

Our committee attempted to conduct an independent assessment of direct care registered nurse staff levels by reviewing hospital staffing plans. The Division of Licensing and Certification of the Department of Health and Human Services uses hospital staffing plans to validate staffing levels in each hospital, and because they found no deficiencies in staffing levels, we made the assumption that the staffing *plans* should be proxies for staffing *levels*.

We solicited the hospitals and received plans from 36 of the 41 hospitals in the State.[1] Though there are no established maximum or minimum nurse/patient ratios in Maine, many hospital plans reported compliance with standards and guidelines established by professional organizations.[2] Most of the plans included staffing information for all units within each hospital. Similar units in different hospitals often have widely divergent staffing plans. In our review, we found that the only unit on which there was uniform planned staffing was Obstetrics, in which every hospital reported a plan for a 1:1 ratio of RNs to patients in active labor. Some of the staffing plans were specific about the number of nursing staff to be assigned to different units, while providing for modification based on census, patient acuity, and other factors. Other plans provided little information concerning the actual number of direct care nurses to be assigned in their units, leaving that determination up to management based upon its assessment of the needs of patients.

[1] Aroostook Medical Center, Calais Regional, New England Rehabilitation, Parkview Adventist, and York hospitals did not respond to our request.

[2] Such as the Association of PeriOperative Registered Nurses (AORN), American Association of Pediatrics (AAP), American College of Obstetrics and Gynecology (ACOG), American Society of Post-Anesthesia Nurses (ASPAN), Society of Gastroenterology Nurses (SGNA), etc.

Staffing plans outline the staffing of a unit given the complexity of patient care and variables such as:

- Acuity, age, communication ability, and functional ability of patients
- Experience, education, and skill level of RNs in the specialty
- Geography of the unit and layout of the patient rooms and beds
- Volume of patients and fluctuations due to admissions, discharges, transfers
- Frequency/need of patient or family education by RNs
- Clinical staff communication, cohesion, and cooperation
- Collaborative, training or research activities that may distract from patient care
- Number and competency range of other staff (skill mix)
- Efficiency of support services (CNAs, laboratory, transfers, housekeeping)
- Technology available on the unit.

Generally, hospital plans included:

- an overall staffing plan,
- a census management plan (including variations in patient acuity),
- a unit-level staffing plan, (e.g. medical unit, surgical unit, obstetrics, etc.),
- a contingency plan for each unit,
- criteria for increasing nursing staff,
- criteria for decreasing nursing staff.

Hospital Staffing Plan Variations

The lack of standardization in nurse staffing plans that hindered our review of nursing levels includes:

a. Combining total nursing staff (RNs and LPNs), rather than differentiating direct care RN staff from LPNs in patient ratios,

b. Use of a ratio range, for example, from 1:4 to 1:8, with explanations that:

   - the unit has a wide range of average daily census of patients,
   - the staffing level is adjusted depending on patient acuity needs,
   - additional ancillary staff are engaged when higher patient ratios are required,

c. Some plans use a ratio methodology and some do not; instead plans discuss how patients on the unit are assessed for acuity level and cared for by their entire clinical staff including RN, LPN, charge nurse, unit coordinator, care planner, and CNAs,

d. Some hospitals use two 12-hour shifts while others use three 8-hour shifts per day,

e. Some hospitals use the number of beds on the unit as the patient count,

f. Other hospitals use the average daily census for the patient count. The method for the patient count is important; in the case of a 35 bed unit that uses an average daily census of 25 and has a staffing plan calling for 5 RNs, the ratio would be 1:5. However, a similar 35 bed hospital unit may also have 5 RNs, but if the plan does not report their

average daily census, and only shows a bed count; the nurse to patient ratio would be calculated at 1:7, though the census of both units may, in fact, be similar.

Several hospitals submitted *actual* staffing levels compared to *planned* levels. Other hospitals reported using a human resources indicator (see section below) that monitors the frequency with which their staffing plans are met, demonstrating that hospitals compare their plans to their actual staffing levels. Most staffing plans state that 'nursing judgment supercedes the plan.'

After our initial assessment of the staffing plans, we contacted hospitals that had submitted plans, asking whether they had at any time in the previous year experienced occasions when their planned staffing levels had not been met. We got little response: one hospital advised that they might have failed to staff to their plans 5% of the time, and overstaffed another 5% of the time. Other hospitals responded that they use a number of strategies to ensure that patient safety is protected when patient census is high or staffing is low. As outlined in their contingency plans, hospitals use float staff from other units, per diem staff (temporary nurses), overtime, and/or acuity staffing (engaging non-direct care RNs, such as charge nurses). Hospitals also may close admissions to new patients or defer admissions to other units should their unit staffing fall below safe levels. We could not determine from these responses the extent or frequency of instances when unit staffing was insufficient to meet the staffing plan.

Section III below discusses the methods DHHS uses to conduct nurse staffing reviews. Auditing a sample of actual nurse staffing and comparing those findings to the staffing plans (as DHHS does) may be adequate to verify that each hospital is in compliance with its own plan. However, when we attempted to calculate meaningful nurse to patient ratios from the data provided in the plans, we found that it is currently not possible to compare staffing levels across hospital units, given the lack of standardization of hospital staffing plans. Based on these factors, we cannot report with any confidence on the actual levels of direct care registered nurse staffing in Maine hospitals.

Reports from Nurses

We asked the Maine State Nurses Association (sponsor of the original LD 616) to have nurses review the nurse staffing plans in their hospitals. Based on a small unscientific, telephonic survey there was anecdotal evidence to suggest that there was a substantial deviation from the plans in the actual staffing experienced on the floors. While these responses were not validated, they were consistent with the testimony presented before the Legislature. This committee found this of concern.

Just as concerning were reports from several nurses (including senior nurses) that they did not know the staffing plan for their unit or hospital, that they did not know where to find the plan, and that they feared retaliation if they asked management to see the plan. Such lack of familiarity with their staffing plans raises serious questions about the extent of meaningful participation by the nursing staff in the development of the plans as specified in Chapter X.C.5, which requires that direct care nursing staff be allowed input into staffing plans.

B. Clinical Indicators used for Measuring Nurse Staffing Effectiveness

As discussed in Section II B below, there is a growing body of research that examines patient conditions that are most directly associated to the number, skill level, and actions of nurses. A number of clinical indicators have been identified which appear to be "nurse-sensitive", in that the frequency of these patient conditions (i.e. bedsores, falls, medication errors, infection rates, etc.) appear to be affected by nurse staffing. Hospitals, professional, and accrediting organizations have recognized that there are multiple, complex, and shifting factors that affect nurse staffing levels and that these factors mitigate against a discrete staffing formula such as a mandated ratio. Instead, hospitals are using patient outcomes data from clinical indicators to monitor the effectiveness and adjust their nurse staffing levels appropriately.

As discussed in Section III below, current Maine regulations require hospitals to maintain 'two clinical indicators relative to staffing effectiveness and the effectiveness of nursing' (Chapter X., I.2.). Each hospital may select any two indicators - internal, 'home grown' measures or evidenced-based, nationally-accepted indicators. As part of our survey, we asked all Maine hospitals to tell us which clinical indicators they use. From the 36 responding hospitals, we learned that most hospitals collect far more than the required two indicators.

Some hospitals are tracking clinical indicators at multiple levels to identify correlations between staffing levels and patient safety issues. For example, Maine hospitals track and trend their medication errors and compare their findings to nurse overtime rates, per diem use (temporary or 'traveling' nurses), or nurse vacancy rates. Should a hospital correlate a high frequency of medication error rates with a high proportion of temporary nurses on a particular shift in a particular unit, the hospital can take corrective action such as re-training the staff in medication protocols or increasing the number of permanent nurses on that unit. One hospital tracks each of the following medication errors and correlates each error to the three staffing level indicators:

Medication Error	**Staffing Level**
Wrong dose	Target core staffing level
Wrong route	Actual staffing level
Wrong medication	Nurse vacancy rate
Wrong time	
Wrong medication note in chart	
Medication note omitted from chart	

Some clinical and human resource indicators used by Maine hospitals are required by accrediting organizations (JCAHO); others were developed and tailored to meet a specific need or interest. Some Maine hospitals report their indicator data to national databases to compare and benchmark their outcomes with those of similar hospitals.[3] Currently there is no mechanism in place in the State to collect or compare outcomes from clinical indicators used in Maine hospitals, or even to collect the type and definitions of the indicators used.

[3] Quality Indicator Project of the Maryland Hospital Association or the National Database of Nursing Quality Indicators (NDNQI).

In response to our request for information about the two legislatively-mandated nurse staffing effectiveness indicators, most hospitals submitted all nurse effectiveness indicators they use. Some use as many as twelve different indicators with multiple indicators within a particular type, such as in the medication error example above. They reported how they review and use the indicators to monitor staffing needs and that they rotate indicators they no longer find useful and develop new indicators to address emerging quality and patient safety concerns.

General and Acute Care Hospitals

The following chart shows the clinical and nurse staffing indicators currently in use in Maine's general and acute care hospitals.

Nurse Staffing Effectiveness Indicators Used in General and Acute Maine Hospitals
(32 Hospitals reporting)

Clinical Indicator	**% of Maine Hospitals**	**Nurse Staffing Indicator**	**% of Maine Hospitals**
Medication Errors	97%	Nurse Overtime	53%
Patient Falls	88%	Worked/Productive Hrs/Pt. Day	47%
Patient Feedback	66%	Nurse Turnover Rate	44%
Restraint Use	38%	Nurse Vacancy Rate	34%
Pneumonia Rate	31%	Nurse Injuries	16%
Length of Stay	31%	Nurse Satisfaction	9%
Infection Rate	25%	Variance to Staffing Plan	6%
Ulcers (bed sores)	22%	Variance to 1:1 Active Labor	6%
Pain Management	22%	RNs < 1 year Experience	3%
Family Feedback	19%	Per Diem (temporary) Use	3%
Urinary Tract Infections	16%	Clinical nurse on call/time called in	3%
Readmission Rate	9%	Limited Bed Occurrences	3%
CHF/AMI protocols	9%	Staffing Level/Acuity Levels	3%
Smoking Cessation Education	3%	Unsafe Staffing Reports	3%

The table above shows that as many as 97% of Maine hospitals collect, maintain, and use medication error rates for the purpose of monitoring nurse staffing effectiveness and as few as 3% of Maine hospitals track the frequency with which at-risk patients receive smoking cessation education prior to discharge. Please note that hospitals may provide smoking cessation education at higher rates to their at-risk patients; the indicators and the percentages above are reported only in relation to their use in monitoring nurse staffing effectiveness.

Likewise, a number of nurse staffing or human resource indicators are used separately and in concert with clinical indicators to identify areas in which nurse staffing can be buttressed. Nurse overtime is the most frequently reported human resource indicator at 53% and, at 3%, unsafe staffing reports was the least used.

Specialty Hospitals

Of the five specialty hospitals in Maine, four provide mental health services; all four responded to our inquiries regarding the use of indicators. Below are our findings relative to the use of nurse staffing effectiveness indicators used in these hospitals:

Nurse Staffing Effectiveness Indicators Used by Specialty Maine Hospitals
(4 Hospitals reporting)

Clinical Indicator	**% of Maine Hospitals**	**Nurse Staffing Indicator**	**% of Maine Hospitals**
Patient Injuries	100%	Nurse Overtime	75%
Medication Errors	75%	Nurse Injuries	75%
Restraint Use	50%	Nurse Vacancy Rate/Per Diem Use	50%
Patient Falls	50%	Number of New Staff in training	50%
Seclusion Rate	25%	Worked/Productive Hrs/Pt. Day	25%
Readmission Rate	25%	Nurse Turnover Rate	25%
Patient Feedback	25%	Nurse Feedback	25%
Infection Rate	25%		
Patient Deaths within 30 days of Discharge	25%		
Involuntary Admissions	25%		
Pharmacy Interventions	25%		

Variation of Indicators

Though Maine hospitals are using nurse staffing indicators in creative and useful ways to improve their patient safety, staffing effectiveness, and other internal functions, we were struck by the wide variation within each indicator. Such variation limits meaningful comparisons and state-wide tracking, trending, or benchmarking. For example, within the medication error category we found that hospitals use an array of definitions of medication error rates. The following is a conservative sample; many hospitals did not specify their own definition of medication error:

- Transcribing and administering medication errors
- Errors in dosage
- Wrong medication
- Wrong time for medication
- Wrong medication note in chart
- Medication note omitted from chart
- Errors with multiple medications (more than 9)
- Errors that reached the patient
- Errors that did not reach the patient
- Errors per 1,000 patient days
- Errors as a percentage of doses dispensed
- Errors per month
- Errors per 10,000 patient doses
- Medication errors only in certain units

- Medication events tracked through "event forms" (unclear how this is defined)

In addition to identifying the error rate itself, hospitals then compare the findings with nurse staffing indicators (such as nursing overtime or vacancy rates) in order to identify areas that can be improved.

Summary
Our findings show that hospitals are using clinical and human resource indicator outcomes to identify problem areas, develop remedies, improve their nurse staffing effectiveness, and ultimately, their patient care and safety. Our findings also show that there is no central data collection or reporting of indicator outcomes for the purpose of state-wide comparisons or benchmarking.

Nurse-sensitive indicator outcomes could be a valuable tool the State could use to monitor safe nurse staffing levels. Unlike current processes used to monitor nurse staffing levels, indicator outcomes take into account all variables used in providing patient care and provide an equalizer effect. That is, regardless of the level of detail in the staffing plan or the size or complexity of the unit, if the indicator shows that there is a higher rate of adverse patient outcome in a particular unit, all variables are investigated, including nurse staffing levels, until the problem is identified and corrected. However, without central collection and uniformity of the measures, each hospital can only compare its outcomes to its own experience.

Similarly, we found that hospital staffing plans lacked consistent and standardized structure for comparisons across hospitals. As a result, we are unable to reach any conclusion with regard to the assessment of direct care registered nurse staffing levels in Maine hospitals. The Recommendations section of this report identifies several ways in which the State can improve assessment and monitoring of safe staffing levels by strengthening regulations relative to direct care registered nurse staffing.

II. Evidence With Respect To Direct Care Nurse Staffing Minimum Ratios

There are no national standards that define minimum nurse staffing levels; hospitals develop their staffing plans based on a combination of factors including patient acuity, skill mix of clinical staff, patient census, etc. Hospitals and software firms have developed a variety of tools to determine patient acuity and predict the necessary nurse staffing levels.

A. Studies Concerning Nurse/Patient Ratios

We reviewed numerous studies in the medical literature which discussed the question of RN staffing and its relation to patient safety. These studies have been conducted in states other than Maine. We did not find reliable Maine-specific adverse outcome studies. Absent Maine-specific adverse outcomes data, there is no evidence that Maine's patient safety needs are different from those of the rest of the nation. These studies suggest that many potential adverse outcomes can be anticipated and avoided by nursing staff who are skilled, experienced, and who have the time to properly monitor their patients and communicate and coordinate clinical functions with other

hospital staff. Studies cited by LD 616's sponsors and our own review of the literature demonstrate the association between higher numbers of experienced nurses and improved patient outcomes.

For instance, the Aiken study found an increase in risk of patient mortality after common surgeries in hospitals with high nurse-patient ratios.[4] The study assessed differences in mortality in hospitals where average nurse workloads were 4, 6 and 8 patients, and concluded that, for each patient over 4, there was a 7% increase in mortality risk with each additional patient in the nurses' care. The difference in mortality risk rose 31% when nurses went from caring for 4 to 8 patients. The study suggests a relationship between substantive decision making roles of RNs and improved patient outcomes. Low nursing staffing ratios were found to correspond to low patient mortality rates and improved outcomes. However, the authors note, "Our results do not directly indicate how many nurses are needed to care for patients or whether there is some maximum ratio of patients per nurse above which hospitals should not venture."

Using administrative data from 799 hospitals in 11 states, Needleman reviewed more than six million medical and surgical discharges to study the link between nurse hours and patient outcomes.[5] This study found that a lower number of adverse outcomes and shorter lengths of stay were associated with a higher proportion of RN hours. There was no association between staffing levels by licensed practical nurses or nurses aids and adverse events.

A 1995 study conducted by Lucien Leape found that 86% of medication errors made by physicians, pharmacists, and others were intercepted by nurses before they reached the patient.[6]

However, other than in ICUs, where the Institute of Medicine (IOM) proposes a ratio of 1:2, none of the studies suggest or conclude that a specific ratio, at the unit level, is necessary to optimize patient outcomes. The problem with all of these studies is that, while it appears clear that lower RN/patient ratios are associated with better patient safety, there is insufficient evidence to demonstrate the specific minimum RN staffing ratios necessary to optimize patient safety in the various types of hospital units.

One reason for the insufficiency of evidence is that many studies were conducted by aggregating data from either the entire hospital or a combination of units (medical/surgery, ICU, recovery). Aggregating data in this way limits the ability to determine minimum staffing ratios in each type of hospital unit, as had been proposed by the sponsors of the original LD 616. Where data were collected only with respect to a specific hospital unit, specifically in ICUs, there has been sufficient evidence for the IOM to propose a ratio of 1:2. Thus, one basic reason for our inability to recommend specific ratios, as originally envisaged in LD 616 before amendment, is that most studies to date have not conducted unit-specific examination of the data. Studies comparing outcomes in specific hospital units with different RN staffing ratios have not been reported. Appendix B is a more detailed discussion of the literature on the issue of nurse staffing ratios.

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[4] Aiken, L., et. al., Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction, *Journal of the American Medical Association.* October 2002 288(16):1987-93.

[5] Needleman, J., et. al. Nurse-Staffing Levels and the Quality of Care in Hospitals, *New England Journal of Medicine.* May 2002, 346(22):1715-22.

[6] Leape, L. et al., Systems Analysis of Adverse Drug Events. *Journal of the American Medical Association.* 1995. 274(1):35-43.

B. Nurse-Sensitive Performance Indicators

There is a growing body of research that examines patient conditions that are most directly associated to the number, skill level, and actions of nurses. These conditions range from those affecting mortality such as failure to rescue (the death of a patient with a preventable, life-threatening complication) to hospital-acquired infections and increased length of hospital stay. Please refer to the *What are Current Standards?* section of Appendix B for a discussion of the conditions linked to sensitivity to nurse capacity.

In recent years a number of organizations have taken the initiative to identify specific nurse-sensitive indicators - conditions, particularly influenced by nurses, that take into account the experience, skill level, skill mix, as well as the numbers of nurses – to gauge patient safety. These include initiatives by the American Nurses Association (ANA), Joint Commission of Accreditation of Healthcare Organizations (JCAHO), the National Quality Forum, and the Institute of Medicine.

In addition, several states have established programs to study or increase patient safety in relation to nurse staffing. During the past five years bills requiring minimum nurse-patient ratios have been proposed in 23 states. California passed legislation requiring minimum staffing ratios in 1999, but remains the only state to do so.

These initiatives and programs are described in Appendix B, a summary of literature on the issue of nurse staffing ratios.

C. Provider Group Input

We asked the Health Care Provider Group of the Maine Quality Forum, established in accordance with 24-A MRSA Section 6952(7), for input on the issue of RN/patient ratios. Appendix C contains the membership list of this group. In the course of two meetings, that group provided valuable input and specific recommendations concerning adoption of quality performance indicators discussed in detail in the Recommendations section below.

The Provider Group felt that the legislature's request for information on RN staffing ratios is an important question, but that the issue of nurse staffing is extremely complex and is impacted by many factors including the acuity of the patient, the team composition of the nurses, the nurse/physician relationship, the role of supervisory nurses, the level of specialization of the hospital, and the type of hospital unit.

The Provider Group did not find clear research on the impact of requiring specific RN staffing ratios on the complex system interactions that result in good patient care, and so for that reason did not recommend specific RN staffing ratios. Rather, recognizing that the central issue is ensuring quality nursing care that results in excellent patient outcomes, the Provider Group recommended adoption of the measurements established by the CMS/NQF National Voluntary Consensus Standards for Nursing-Sensitive Care. The Provider Group advised that all Maine hospitals use all of the measurements recommended, so that hospitals will be able to learn both from their own measurements over time and by comparing themselves with other hospitals.

The Provider Group further recommended the establishment of a transparent system of overall quality measurement for health care facilities, so that the question of nursing levels can be determined by specific and ongoing monitoring and study of the current situation in Maine.

The Technology Assessment Committee unanimously agreed to adopt the Provider Group's recommendations, and to incorporate them into this report.

D. Summary Of The Status Of The Issue Of Ratios

There is little doubt that RN staffing levels have an important impact on patient safety, as well as on nurse job satisfaction and "burn-out". However, other than in the ICU, no study demonstrates that a specific ratio, at the unit level, is necessary to assure appropriate patient outcomes.

III. The Rules of the Department of Health and Human Services on Direct-Care Registerd Nurse Staffing

The Regulations

The complete text of Department of Health and Human Services (DHHS) regulations governing hospital nurse staffing is included in Appendix B. We extracted the following regulations that are salient to our review:

> *X.C.Staffing: There must be a system in place to determine staffing requirements, which reflects the needs of the patients. The system must meet, at a minimum, the following: The staffing plan must be based on the following:*
>
> *a. Number of patients on the unit;*
> *b. Unit core staffing;*
> *c. Unit core staff-mix;*
> *d. Care needs of the patients including, but not limited, to acuity.*
>
> *X.I. Quality Management: Nursing Services, with input from direct care nursing staff, must have a quality improvement/quality assurance plan in place to continually monitor and evaluate the nursing care provided. The plan must identify issues and potential issues, propose and implement recommendations for improvements and reevaluate to determine if further improvement is possible/needed.*
>
> *The Nursing Services Quality Improvement/Quality Assurance Plan must include at least two (2) clinical screening indicators relative to staffing effectiveness, and the effectiveness of nursing. The data collected and analyzed from the selected clinical screening indicators is used to identify potential staffing effectiveness issues. Evidence of action must be taken, as appropriate, in response to analyzed data.*

To assess the adequacy of current regulations and to conduct a review of nurse staffing levels, we reviewed documents from the 41 licensing reviews the DHHS conducted from January 2003 to June 2004. This time period was selected because the Maine legislature enacted modifications

to nurse staffing regulations in October 2002; the new regulations were included in regular licensing reviews effective January 2003.

Responsibilities of the Division of Licensing and Certification
The Division of Licensing and Certification of the Department of Health and Human Services is responsible for ensuring compliance with Maine regulations governing nurse staffing. In accordance with federal requirements, the Division conducts licensing reviews of Maine hospitals that are accredited by JCAHO every three years. Non-JCAHO accredited hospitals are surveyed annually according to State requirements. State and federal licensing reviews and complaint investigations conducted by the Division result in a *Statement of Deficiencies and Plan of Correction* document, the only official product of a licensing review.

Methods for Review of Staffing Levels by the Division of Licensing and Certification
To determine whether a staffing deficiency exists, the Division reviewers identify a sample of seven random dates in the past year. They then compare the numbers of RNs, LPNs, and CNAs who worked each shift, on specific hospital units, on the seven random dates, to each hospital's mandated staffing plan. Staffing and patient data are verified and documented to determine whether there is a staffing deficiency. Licensing reviewers use two nursing staff survey tools – one for federal licensing reviews and another they developed to capture nurse staffing data required for State licensing reviews.

According to the Division, if there is one occurrence of the actual staffing level not meeting the hospital unit's staffing plan, the hospital is cited for a deficiency. However, it is important to note that there is no standard for staffing plans and each hospital's actual staffing levels are compared only to each hospital's plan.

The Division's responsibility is to evaluate each hospital to determine whether any deficiencies in complying with the regulations exist and to ensure corrective action is taken when such deficiencies have been identified. Only deficiencies are reported on the official product of a licensing review, the Statement of Deficiencies report. The following documents, used to verify compliance during a licensing review, are not available subsequent to the review:

- Working documents, staffing tools, reviewers notes that may contain nurse staffing level information,
- Hospital staffing plans that are collected during the licensing review and used to verify staffing levels,
- Clinical indicator documentation, including names, definitions or outcomes data,
- Quality Improvement Plans,
- Other documents/data collected from hospitals during the review.

Regulations governing nurse staffing do not specify methods or protocols for conducting the review, selection of materials for review, retention of review data subsequent to the review or disclosure of data for external review.

Nurse Staffing Reviews
The Division cited no deficiencies for staffing levels for any hospital during our reporting period; consequently, the work products from these licensing reviews contained no staffing level information. We requested more detail, including work documents and tools used during the licensing reviews. Division staff shared with us their internal nursing survey tools from the 22 state licensing reviews that were conducted during the study period. Work documents and staffing tools used in Federal licensing reviews are protected and, therefore, were not available for our review.

The Division allows great latitude in the way the reviewers conduct nursing staff audits and each reviewer is allowed flexibility in the methods, tools, and level of documentation. Specifically, for state licensing surveys, reviewers may use a federal or state staffing tool or use their own notes entirely and not use any staffing tool. They may use a combination of a survey tool and separate notes or annotate the nursing plans. Their role is to identify whether a staffing deficiency exists; if it does, detail is provided on the Statement of Deficiencies report. The nursing survey tools have not previously been used for external review purposes.

In conducting our nursing staff level review for this report, our committee attempted to use data from these nurse staffing tools. We found various types of inconsistencies on these tools that prohibited us from using them for our nurse staffing review. Some of the inconsistencies include:

- Missing or incomplete patient census data, prohibiting calculation of a nurse/patient ratio
- Missing dates
- Missing unit names
- Incomplete core staffing data
- Incomplete data for all shifts
- RN to patient ratios that were higher than the staffing plan allowed, but were not cited as staffing level deficiencies.

Representatives from the Division explained that the reviewers take notes during their reviews and that the notes are not always filed with the staffing tools. They suggested that explanations of inconsistencies may have been recorded in these notes.

Clinical Indicator Documentation
Current Maine regulations require hospitals to maintain 'two clinical indicators relative to staffing effectiveness and the effectiveness of nursing;' the results of the indicators are reported annually to each hospital's board. During regular licensing certifications, the Division reviews evidence that two indicators are used; however, the type of indicator, definitions of the indicators or results of indicator data collection [*i.e*. frequency of falls or medication errors] are not recorded or evaluated during the audit.

Summary
The process for conducting the staffing audit for State licensing – choosing a random sample of seven dates during the previous 12 months often including holidays – should yield ample data on which to review staffing levels. However, without a consistent methodology, a standard protocol

for conducting the review, and a means of retaining all relevant data, the findings were not useful to our external review process. We were frustrated that the source of data could not be used either for our nurse staffing level review or to confirm findings from the Division's reviews.

CONCLUSIONS

Mandated nurse-patient ratio legislation was proposed with the goal of improving the safety of patients in Maine hospitals. There is ample evidence, at a national level, that improvements in hospital patient safety must be made. Absent Maine-specific adverse outcomes data, there is no evidence that Maine's patient safety needs are different from those of the nation's. Nurse staffing levels are of great concern to nurses themselves and to the hospitals in which they work, as well as to patients and the public at large.

Legislative imposition of specific nurse staffing ratios in specific hospital units would not be justified at this time. There is no evidence that staffing by ratios, alone or in combination with other mandates, will guarantee the quality or safety of inpatient care. There is reliable evidence that demonstrates that an appropriate level of nursing care is essential to safe quality care. There is further evidence, that in certain circumstances, the cost of increasing nursing hours is offset by the savings resulting from avoided complications of care.

We also note that patient safety is dependent on several factors including technology, staff mix, experience and proficiency of clinical staff, availability of support staff, and other factors, such that it is not possible to state at this juncture that, when such studies have been done, there will be a minimum RN/patient ratio which can be established for all hospital units. We do not anticipate that mandated RN/patient staffing ratios in isolation will be a useful tool to ensure safe quality care. There is presently in Maine no standardized information collection on staffing levels, or on quality performance indicators from which informed judgments may be made concerning the factors which affect patient safety.

The Division of Licensing and Certification does not collect information on a standardized basis concerning actual staffing levels, or on the practical use of quality performance indicators. The information which it does collect is not available outside of the agency for analysis, comparison or use in developing patient safety information. Due to inconsistencies in the Division's sampling procedures we were unable to utilize the information collected by the Division with respect to nurse staffing to evaluate quality and safety of care. The present use of often non-validated and non-standard indicators makes collection of the indicators by the Division futile. There is a need to standardize data collection from Maine's hospitals, to allow the MQF, the Legislature, the Division of Licensing and Certification, and the public to assess an institution's use of nursing resources and the resulting safety and quality of care. We believe, and there is some evidence to demonstrate, that public information describing commitment to adequate staffing will help ensure that adequate resources will be employed to serve the interests of safety and quality.

RECOMMENDATIONS

We are unable to recommend legislative imposition of nurse staffing ratios at this time, based on above factors. Rather, we recommend strengthening the focus on patient safety outcomes and other nurse-sensitive indicator data.

A. Regulations currently require hospitals to use data from two clinical indicators to evaluate nurse-staffing effectiveness, and mandate no particular indicators. In accordance with the recommendations of the Provider Group, we recommend that all Maine hospitals be required to collect and report data on the following 15 indicators from the CMS/NQF national voluntary consensus standards for nursing-sensitive care:

1. Failure To Rescue- all units
2. Pressure Ulcer Prevalence- all units except pediatrics
3. Falls- all units except pediatrics
4. Falls With Injury- all units except pediatrics
5. Restraint Prevalence- all units of the Quality Indicator Definitions
6. Urinary Catheter Associated urinary tract infections (UTIs) for the ICU
7 Central Line Catheter Infection for ICU and High Risk Nursery Patients
8. Ventilator Associated Pneumonia for ICU and High Risk Nursery patients
9. Smoking Cessation Counseling (AMI patients) – all units
10 Smoking Cessation Counseling (heart failure patients) – all units
11. Smoking Cessation Counseling (pneumonia patients) – all units
12. Skill mix (RN, LPN, UAP and contract) – all units
13. Nursing Care Hours Per Patient Day- all units
14. Practice environment scale- useful for larger hospitals, not smaller ones
15. Voluntary Staff Turnover- all units.

Data must be collected in accordance with the definitions contained in the CMS/NQF National Voluntary Consensus Standards for Nursing-Sensitive Care. Appendix D contains further descriptive information on these indicators.

The purpose of such reporting is to develop data which will permit hospital administrators, regulators, and the public to have access to meaningful information concerning both processes and outcomes in Maine's hospitals. This will allow them to make "apples to apples" comparisons among hospitals, and longitudinally over time within each hospital, of staffing level data and nursing-sensitive indicators.

Data should be collected within NQF specifications and reported quarterly to the Maine Health Data Organization under MQF/MHDO rules. Without such data, improving Maine's quality of care and patient safety will be far more difficult and uncertain. Unless a standard set of accepted quality indicators is utilized, hospitals miss an opportunity to examine outcomes relative to their peers and to target improvements in identified areas; the State misses an opportunity to review the effects of current policy and to understand the extent to which problems exist, relative to these indicators.

We recognize that the 'failure to rescue indicator' is not presently practical in Maine. We urge the MHDO to rapidly adopt the 'Present on Admission' functionality to facilitate this and other indicators. We further recommend that, unlike the other indicators, indicators 6, 7, & 8 should be reported de-identified within hospital peer groups until such time that the stability and statistical validity of these indicators have been established for Maine hospitals.

B. Direct care nurses and nursing management should be responsible for establishing nursing plans for their nursing units. The originators should use a common format where possible across the State for units providing similar services. The plans should be created using substantial, meaningful, and ongoing involvement of direct care nurses and other front line personnel. The plans must be transparent to another nursing observer. The plans shall be based on accepted principles of nursing care.

C. Nurse staffing plans must at all times be readily available to the personnel responsible for delivering patient care.

Information that some nurses did not have access to their nurse staffing plans, or were fearful of seeking them out, was concerning. Direct care nurses should be encouraged to participate in the daily implementation of the unit's nursing plan. The Division of Licensure and Certification should seek out evidence of ongoing input in daily staffing decisions by a collaborative effort between direct care givers and management.

We also feel that nurse staffing plans should be made available on hospital web pages or other publicly available hospital media.

D. Under present regulations, patient acuity must be a factor in each hospital's nurse staffing plan. Hospitals appear to use acuity systems of uneven quality.

While we feel that a standardized patient acuity system may be a critical component of RN staffing decisions, and that such a system should be adopted for use throughout the State, we have not explored acuity systems currently in use or available, or which should be adopted. We suggest that Maine hospitals of similar service profile should consider adopting the same acuity tools.

E. We recommend that the MHDO enforce compliance with nurse-sensitive clinical indicator data submissions as it does with other data submissions. We suggest that the Division of Licensing be provided with the resources to validate data submissions of nurse-sensitive clinical indicators. Data submissions should be validated by an appropriate level of sampling during routine licensing and complaint reviews.

Public access to non-confidential information should be maximized and the Division of Licensing and Certification should also consider release of de-identified confidential data [such as sentinel events reported pursuant to 22 MRSA 8751] in order to allow other hospitals, the Legislature, and the public to have a better understanding of patient safety issues in the State of Maine.

Appendix A:

Technology Assessment Committee

Jonathan S.R. Beal, Chair	Attorney
Laureen Biczak, D.O.	Department of Health and Human Services
Rebecca K. Colwell, R.N., M.B.A.	HealthReach HomeCare & Hospice
Lisa Miller, M.P.H.	The Bingham Program
Dennis Shubert, M.D., Ph.D.	Maine Quality Forum
David White	MDI Imported Car Service, Inc.

Maine Quality Forum Advisory Council

Jonathan S. R. Beal	Attorney
Laureen Biczak, DO	Department of Health and Human Services
Richard M. Bruns, DO	Bruns Chiropractic Clinic
Rebecca K Colwell, RN, MBA	HealthReach HomeCare & Hospice
Jeffrey Holmstrom	Aetna, Inc.
Frank Johnson	State of Maine Office of Employee Health & Benefits
Nancy Kelleher	Sweetser
Becky Martins	National Patient Safety Foundation, Patient and Family Advisory Council
Robert E. McArtor, MD, MPH, Chair	MaineHealth
Jim McGregor	Maine Merchants Association
Lisa Miller, MPH	The Bingham Program
Charles A. Morrison	Androscoggin County Chamber of Commerce
Daniel I. Roet	Bath Iron Works Co.
Clifford J. Rosen, MD	St. Joseph's Hospital
Stephen C. Shannon, DO, MPH	University of New England
David White	MDI Imported Car Service, Inc.
Janice M. Wnek, MD	Midcoast Pediatrics of Brunswick

Appendix B:

Discussion Paper

A Review of Minimum Staffing Ratios for Direct-Care Registered Nurses in Hospitals

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Institute for Health Policy
Muskie School of Pubic Service
University of Southern Maine

July 21, 2004

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Appendices

1 Forward

On February 18, 2004 the Health and Human Services Committee of the Maine State Legislature amended LD 616, *An Act to Provide Safe Staffing Levels for Patients and To Retain Registered Nurses.* The text of the original bill is included in Appendix A. The title was amended to read: *To Improve the Quality of Health Care* and the text was amended to read:

> *Review and report. Resolved, that the Maine Quality Advisory Council, established pursuant to 24-A MRSA section 6952, shall review:*
>
> - *direct-care registered nurse staffing levels in general, acute and specialty care hospitals,*
> - *the issue of minimum staffing ratios for direct-care registered nurse staffing in hospitals*
> - *and the rules of the Department of Human Services on direct-care registered nurse staffing.*
>
> *The Maine Quality Forum Advisory Council shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters on its review under this section and any recommendations from the council by January 15, 2005.*

Process
The Maine Quality Forum assigned LD 616 to its Technology Assessment Committee which began its inquiry by soliciting input from stakeholders, providers, and the public to inform their work. The Committee also contracted with the Muskie School of Public Service to prepare this paper to inform their review of the second charge in the amendment, *the issue of minimum staffing ratios for direct-care registered nurse staff in hospitals*. The Committee is separately collecting data to complete the first and third charges of the amendment.

Methods
The Technology Assessment Committee adopted the COSI protocol as a standard method for studying topics under consideration by the committee and instructed the Muskie School to use the protocol to conduct this review. The COSI protocol (COre, Standard, Ideal) was developed by New Zealand Health Technology Assessment.[7] It is a method for gathering information and organizing it using a series of questions framed in terms of the population or patient group, the intervention, the comparison and the outcome; these questions appear in the section headings of this paper beginning with section 3, "Why is this proposal (mandated nurse staffing ratios) being made?".

The views and opinions expressed in this report are the author's and should not be attributed to collaborating organizations, funders, or the University of Southern Maine.

[7] New Zealand Health Technology Assessment: The Clearing House for Health Outcomes and Technology Assessment. http://nzhta.chmeds.ac.nz/nzhtainfo/protocol htm and http://www nlm nih.gov/nichsr/ehta/chapter3 html.

2 Limitations and Scope of Review

The purpose of this paper is to provide the Technology Assessment Committee with a broad review of the current literature pertaining to the application of minimum nurse staffing ratios to inform their deliberations. This review is one of several parallel processes the Committee is using to gather information relative to its legislative charge. It does not attempt to encompass a review of current staffing levels or to research the efficacy of nurse staffing-related rules of the Department of Human Services. The Committee will separately review those topics in addition to information, materials, and ideas gathered from stakeholders and the public.

As instructed by the Committee, this review uses COSI protocol questions as a framework. In the following sections of this paper, we attempt to respond to the COSI questions with evidenced-based research when available and with informed hypotheses when evidence is not available in the published literature. While we are fortunate to be able to take advantage of the recent release of substantive national studies on this topic, this is not an exhaustive study and there are several limitations that are of note to the reader:

- Due to time constraints, this study relies on secondary research only.
- There is a lack of nurse-sensitive adverse outcome data in Maine.
- The study primarily examines national trends to better understand potential implications in Maine.

3 Why is this proposal (mandated nurse staffing ratios) being made? What are the underlying reasons for it?

Stimulated by the findings of the Institute of Medicine's report *To Err Is Human* that between 44,000 and 98,000 patient deaths occur annually due to medical errors in hospitals, many states, health care organizations, and professional associations are struggling to identify ways to address this mounting concern.[8] The extent of Maine's patient safety problem is not clear due to the current unavailability of relevant data. We know that Maine hospitals have been ranked third highest in the country for certain quality indicators for Medicare patients.[9] We also know that approximately 11,500 discharges from Maine hospitals in 2001 reported at least one diagnosis for complications of surgical and medical care, accidental poisoning, or other complications that may or may not have been attributable to medical care or medical misadventure. This number increased from slightly over 11,300 in 1999.[10] Maine-specific data from the AHRQ Patient Safety Indicator project are expected to become available soon.[11] Sentinel event data resulting from Maine's new mandatory reporting requirement will be available from the Department of Health and Human Services early in 2005.[12] Data from these sources will assist policymakers

[8] To Err is Human, Building a Safer Health System, Institute of Medicine, National Academy Press, 1999.
[9] Jencks, S., et al., *Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2002*, JAMA 2003. Vol. 289, No3.
[10] Reported in *The Case for Quality Reform*, Dirigo Health Action Team Report. 2004. Data source: Maine Health Data Organization.
[11] Agency for Healthcare Research and Quality Patient Safety Indicators. May 2004. http://www.qualityindicators.ahrq.gov/data/hcup/psi.htm.
[12] Maine Title 22, Subtitle 6, Chapter 1684, Section 7852, Sentinel Event Definitions.

with understanding the extent of Maine's patient safety problem and framing an appropriate response.

The Maine State Nurses Association proposed LD 616 to improve patient safety by recommending that nurse to patient ratios be mandated in all acute, general, and specialty hospitals in Maine. The recommended ratios are specific to 24 types of hospital units. For example, the proposal calls for one registered nurse for one patient in triage units and one registered nurse for every four patients in medical and surgical units. The bill also includes other provisions that are beyond the scope of this review. Please refer to Appendix A for the complete text of the proposed legislation.

Proponents of the bill believe that application of the ratios will reduce medical errors and improve patient safety and the overall quality of care. The bill would increase the skill level of nursing staff by specifying that only registered nurses (RNs), as opposed to licensed practical nurses (LPNs) or other clinical support staff, may satisfy the staffing requirement. For some hospital units this requirement may increase the number of registered nurses in each specified unit for each shift.

Many potentially adverse outcomes can be anticipated and avoided by nursing staff who are skilled, experienced, and who have the time to properly monitor their patients and communicate and coordinate clinical functions with other hospital staff. Studies cited by the bill's sponsors and our own review of the literature highlight the association between higher numbers of experienced nurses and improved patient outcomes; however, none of the studies suggest or conclude that a specific ratio, at the unit level or hospital level, will improve patient outcomes.

The bill's sponsors cite the following studies in support of minimum ratio legislation:

- The Aiken study found a 31% increase in risk of patient mortality after common surgeries in hospitals with high nurse-patient ratios.[13] Funded by the National Institute for Nursing Research, the study reports a 7% increase in mortality risk with each additional patient in the nurses' care. The study linked registered nurse staffing data to more than 200,000 general, orthopedic and vascular surgery discharges from 168 Pennsylvania hospitals and suggests a relationship between substantive decision making roles of RNs and improved patient outcomes. Low nursing staffing ratios were found to correspond to low patient mortality rates and improved outcomes. However, the author notes, "Our results do not directly indicate how many nurses are needed to care for patients or whether there is some maximum ratio of patients per nurse …"

- Using administrative data from 799 hospitals in 11 states, Needleman reviewed more than six million medical and surgical discharges to study the link between nurse hours and patient outcomes.[14] This seminal study found that a lower number of adverse outcomes and shorter lengths of stay were associated with a higher proportion of RN

[13] Aiken, L., et. al., Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction, *Journal of the American Medical Association.* October 2002 288(16):1987-93.

[14] Needleman, J., et. al. Nurse-Staffing Levels and the Quality of Care in Hospitals, *New England Journal of Medicine.* May 2002, 346(22):1715-22.

hours. There was no association between staffing levels by licensed practical nurses or nurses aids and adverse events. Adverse outcomes were identified as failure to rescue, increased infections, gastrointestinal bleeding, pneumonia, shock, and cardiac arrest, measures that are considered to be sensitive to nursing care. The author notes that the levels of nurse staffing, while a major factor influencing patient outcomes, is often mitigated by other environmental factors such as communication between clinical staff communication and a positive work environment.

- A 1995 study conducted by Lucien Leape found that 86% of medication errors made by physicians, pharmacists, and others were intercepted by nurses before they reached the patient. This study reviewed records of two hospitals over a six month period.[15]

- A longitudinal study of 422 hospitals by McCue studied the relationship of increased numbers of RNs on hospital profitability.[16] This Agency for Health Research and Quality (AHRQ) funded study found that higher RN staffing levels resulted in increased operating costs, but not on hospital profit margins. The author concluded that hospitals with fewer RNs had increased costs associated with high turnover rates (overtime, recruitment costs, temporary nurses, etc) that affected their profitability. This study is often cited to conclude that a higher density of RN staff is cost effective.

It is important to note the unit of analysis of these studies; many were conducted by aggregating data from either the entire hospital or a combination of units (medical/surgery, ICU, recovery). Aggregating data in this way limits the usefulness of any findings due to the diverse nature of each hospital unit.

[15] Leape, L. et al., Systems Analysis of Adverse Drug Events. *Journal of the American Medical Association.* 1995. 274(1):35-43.

[16] McCue, M., et. al., Nurse Staffing, Quality and Financial Performance. *Journal of Health Care Finance.* 2003, Vol. 29(4) , 54-76.

4 What are the policy issues?

Three policies are directly related to the proposed bill: state licensure requirements that dictate nurse staffing composition, Maine's mandatory reporting system of serious adverse events, and quality management activities of hospitals.

Current Nursing Regulations

In October 2002, the following staffing requirements were incorporated into licensing regulations governing nursing services provided in Maine Hospitals:

> *There must be a system in place to determine staffing requirements, which reflects the needs of the patients. The system must meet at a minimum, the following: individual staffing plans must be developed for each patient care unit and the staffing plan must be based on the following:*
>
> *a) number of patients on the unit;*
> *b) unit core staffing;*
> *c) unit core staff-mix;*
> *d) care needs of the patients including, but not limited to, acuity. Some examples of care needs of patients may be geography of the unit and impact of the technology.*

The regulations call for direct care nursing staff to provide input into both the nursing quality management plan and into staffing plans. It further requires the Nursing Services Quality Improvement/Quality Assurance Plan to have at a minimum, two clinical indicators 'relative to staffing effectiveness, and the effectiveness of nursing' that would be used to identify staffing concerns. Hospitals may use any two clinical indicators relative to staffing effectiveness. Hospital-specific findings with respect to performance against these indicators are not publicly disclosed. Data related to the effectiveness of staffing are reported at least annually to the hospital's governing board. Please refer to Appendix B for the complete policy.

Maine Department of Human Services' Division of Licensing and Certification reviews compliance with these policies during each hospital's normal licensing review. Reviews are conducted annually or, for hospitals that are accredited by JCAHO, every three years. The Division of Licensing began including the new criteria in their normal reviews in January 2003. In addition to the normal review cycle, the Division investigates hospitals pursuant to complaints by patients, family members or hospital staff.

Current Patient Safety-Related Policy

Proponents of nurse-patient ratios believe that the bill will improve the safety of all patients and reduce adverse outcomes. The Maine Legislature has recently mandated that hospitals report certain sentinel event adverse outcomes to the Division of Licensing and Certification.[17] Data from individual hospital reports are not publicly disclosed; however, cumulated sentinel event

[17] Maine Title 22, Subtitle 6, Chapter 1684, Section 7852, Sentinel Event Definitions.

data, some of which may be nursing-related, will be available in February 2005. Sentinel events are defined as:

- an unanticipated death,
- a major permanent loss of function that is not present when the patient is admitted to the health care facility,
- surgery on the wrong patient or wrong body part,
- hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities,
- suicide of a patient in a health care facility where the patient receives inpatient care,
- infant abduction or discharge to the wrong family, or
- rape of a patient.

Quality Management Regulations

Current regulations governing hospital quality assurance/quality improvement activities call for each hospital to have a plan for ongoing process of identification, measurement, and improvement of services that 'impact, in any manner, upon the diagnosis, care, treatment, or safety of patients.'[18] Included in the areas for QA/QI activities are infection control, blood utilization, and sub-optimal outcomes, indicators considered to be nurse-sensitive. Hospitals are required to submit their plans or revisions to their plans to the Division of Licensing and Certification.

Policy Questions

Given Maine's current nurse staffing regulations, the essential policy question for this review is:

- Is there evidence to suggest that nurse staffing ratios have validity and should they be incorporated into state licensure requirements to improve patient safety?

Other policy questions the Committee may explore in its review for LD 616 are:

- Are current nurse staffing regulatory controls effective or should they be improved?

- Is there evidence of poor patient safety outcomes, related to nurse staffing levels in Maine, that should be addressed by state government?

5 How many patients may be affected by mandated nurse-patient ratios?

Virtually all patients would be affected by implementing minimum nurse staffing requirements in all units of all hospitals. In 2003, there were 165,000 discharges, representing approximately 129,000 people who were served by Maine hospitals.

[18] Chapter 112: Regulations for the Licensure of General and Specialty Hospitals in the State of Maine, Sub-Chapter 21, Quality Management Process.

6 What is the clinical significance of the conditions that nurse-patient ratios are intended to address?

There is a growing body of research that examines patient conditions that are most directly associated to the number, skill level, and actions of nurses. These conditions range from those affecting mortality such as failure to rescue (the death of a patient with a preventable, life-threatening complication) to hospital-acquired infections and increased length of hospital stay. Please refer to the *What are Current Standards?* section of this paper for a discussion of the conditions linked to evidence showing sensitivity to nurse capacity.

7 What is the efficacy of this intervention (mandated nurse-patient ratios)?

A fundamental challenge to instituting minimum staffing ratios in hospitals is the diverse and dynamic nature of both the patient population and the context in which care is provided. Unlike nursing facilities that have relatively homogenous care and skill level requirements and a comparatively stable population, each hospital unit has different levels of patient acuity, nursing needs, and fluctuating numbers of patients in each unit.

A number of important studies have concluded that there is a positive correlation between high nurse staffing levels and improved patient outcomes.[19] These studies conclude that a greater number and more experienced nursing staff result in better patient outcomes, but they do not provide evidence that a particular RN ratio or staff mix ratio to patients will provide higher quality care or a lower number of adverse events. Indeed, the recent IOM report on patient safety and nursing recommends, among its comprehensive set of recommendations, that future research should be supported to determine safe staffing levels within different types of nursing units (Appendix C).

In addition to the numbers of RNs on the unit, other factors influence patient outcomes:

- Education and experience of nurses have been linked to patient outcomes in a number of studies. Clarke and Aiken describe two case studies that illustrate the effect of experienced nurses on patient outcomes. Both cases involve rescue of patients after common surgeries.[20] The first case involves a higher acuity level patient whose post-surgery condition became compromised. An experienced nurse was able to anticipate the extent of the risk, prepare for the possible need for rescue, and the patient survived. The second case was a patient attended on a floor with a high proportion of nurses with fewer than three years of experience. Their collective inability to recognize symptoms of shock, together with repeated reporting of elevated vital signs as normal, resulted in a failure to rescue for this patient.

[19] Ibid and Aiken LH, et al. Organization and outcomes of inpatient AIDS care. *Medical Care.* 1999; 37(8):760-72. Aiken LH, Clarke SP, Cheung RB, et al. Education levels of hospital nurses and patient mortality. *JAMA.* 2003; 290(12):1-8.

[20] Clarke, S., Aiken, L., Failure to Rescue, *American Journal of Nursing.* January 2003 Vol. 103, No. 1, p42-47.

- The presence of time-saving technology systems and devices is cited as affecting the amount of time nursing and other staff spend on routine or administrative duties that take away from direct patient care. For example, electronic medical records (EMR) systems that summarize daily events and orders can reduce nurse staff time needed to write up notes at the end of shifts. Fail-safe drug dispensing devices and access to critical information and patient data through hand-held computers can reduce demands placed on nurses while improving patient safety.

- The complex skill mix of clinical and support staff relating to each patient is an important factor in patient outcomes. The language in the proposed ratios calls for 'direct care RNs;' however, non-direct care RNs, though not at the bedside, also provide essential services such as care coordinators and discharge planners.

- The numbers and efficiency of support staff, including CNAs, transport staff, and other auxiliary staff, are not accounted for in the proposed ratios, though the capacity and competency of these staff can allow RNs to spend more quality time with patients. In a survey of nurses in Pennsylvania hospitals, 43% of the RNs reported that they routinely delivered and retrieved food trays and 35% reported conducting housekeeping duties.[21] The same study population reported lacking time for patient education and discharge coordination.

A variety of factors influence staffing needs in hospital units; the following should also be considered in any staffing scheme:

- Acuity, age, communication, and functional ability of patients
- Experience, education, and skill level of RNs in the specialty
- Geography of the unit and layout of the patient rooms and beds
- Volume of patients and fluctuations due to admissions, discharges, transfers
- Frequency/need of patient or family education
- Staff communication, cohesion, and cooperation
- Collaborative, training or research activities that may distract from patient care
- Number and competency range of other staff (skill mix)
- Efficiency of support services (laboratory, transfers, housekeeping)
- Quality improvement activities
- Standard technology (beepers)
- Higher level technology including hand-held computers and EMR systems

These influencing factors may vary greatly between small rural hospitals and larger urban hospitals, an important aspect to consider when reviewing the impact of the proposed bill on hospital units in Maine.

8 Will significant infrastructure be required for nursing ratios to be implemented effectively? What competencies and training programs will need to be introduced?

[21] Aiken, L., et.al. Nurses' reports on hospital care in five countries. *Health Affairs* 20(3):43-53.

Infrastructure changes including increase to the workforce supply, hospital monitoring systems, and state compliance review, would be required if minimum RN staffing ratios were implemented.

Workforce Supply

Mandating RN minimum staffing levels would likely require attracting new applicants to the RN workforce or encouraging those who had left the profession to re-enter, though the extent to which these activities would be needed is unknown. Hospitals may also react to the proposed requirement by reassigning RNs serving in administrative capacities to direct patient care. Proponents of nursing ratio legislation in California cited an increase to the nurse supply as a secondary reason for the initiative.[22] Requiring more RNs in hospitals would increase demand, thereby increasing salary rates, improve working conditions and result in increased admissions to nursing schools and the return to the workforce for those who had left the field.

Prior to this minimum nurse staffing proposal, the Maine legislature's concern about Maine's workforce supply in 2001 led to the commission of the report *Maine's Health Care Skilled Worker Shortage: A Call to Action* submitted to the Governor's office.[23] The report includes several recommendations designed to expand and improve the health care workforce and maintain supply and demand data. The report resulted in the establishment of the Health Care Workforce Leadership Council charged with producing a final report to the Health and Human Services Committee of the legislature by November 3, 2004. The council's work was not funded and, therefore, the scope of their work is limited. However, their report is expected to recommend the development of a coherent state-wide system to predict supply and demand of all health care workers in Maine including registered nurses.

The College of Nursing and Health Professions at the University of Southern Maine collects and analyzes nursing work force data; their 2003 report is expected at the end of this year.[24] The Maine Hospital Association also addressed the workforce shortage issue in Maine in a special report dated September 2001.[25] The report outlines the Association's education, recruitment, health careers promotion, and outreach initiatives it hopes will increase the workforce supply.

Nationally, the shortage of nurses has been documented since the early 1990s. Low job satisfaction, high stress levels, coupled with low salary rates are cited as contributing factors to attrition from the profession and lack of appeal to new graduates coming into the workforce. Recent surveys show that 85% of licensed nurses in Maine are employed in nursing – a higher proportion than the national rate of 82%.[26] A 2001 report by the General Accounting Office shows that Maine has the sixth highest per capita RN rate in the country with 1,025 employed RNs per 100,000 of the population.[27] The report also notes a 3% decrease of working RNs in

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[22] Coffman, J. Minimum Nurse-To-Patient Ratios in Acute Care Hospitals in California, *Health Aff*airs. 2002. 21(5):53-64.

[23] Report of the Committee to Address the Health Care Skilled Worker Shortage. October 2001. www mcts net/NewFiles/healthcare html

[24] USM College of Nursing and Health Professions website: http://www.usm maine.edu/conhp/

[25] Maine Hospital Association. Maine's Workforce, Examining the Implications of a Growing Labor Shortage on Access to Hospital Care. 2001. Accessed June 2004. http://www.themha.org/pubs/Maine_s%20Healthcare%20Workforce.pdf

[26] Kirschling, Jane, Maine's Nursing Workforce: 2001-2002 Sample, College of Nursing and Health Professions, University of Southern Maine. March 2003.

[27] U. S. General Accounting Office, Report to the Chairman, Nursing Workforce, Emerging Nurse Shortages Due to Multiple Factors. 2001. GAO-01-944.

Maine between 1996 and 2000 and predicts a national shortage due to aging of the workforce and increased demand.

A workforce survey of health care providers, conducted by the Health Resources and Services Administration (HRSA), predicts that the national RN shortage will expand from 30 states in 2000 to 44 states in 2020. The prediction model allows for educational and workforce patterns, and the anticipated impact of demographic forces, most especially, the aging baby boomer population. Maine's shortage rate parallels the national rate in the table below.

Table 1: HRSA Projected Supply, Demand and Shortages of Registered Nurses in Maine and in the US[28]

Year	Maine Supply of RNs	Maine Demand for RNs	Maine Shortage Rate	US Shortage Rate
2000	10,936	12,383	-12%	-6%
2005	12,002	13,169	-9%	-7%
2010	12,440	14,204	-12%	-12%
2015	12,114	15,486	-22%	-20%
2020	11,719	16,930	-30.8%	-28.8%

Health care organizations have typically addressed nursing shortages with short term salary increases, sign-on bonuses or by recruiting and re-training foreign nurses; such measures have resulted in few long-term effects. To address the anticipated future need, the federal government passed the Nurse Reinvestment Act in 2002 which provides funds for recruitment and retention activities including student loans and scholarships, social marketing to encourage applicants to the nursing profession, career ladder programs, and best practice grants for nursing administration.[29] In 2003 Maine nursing programs received $128,500 from this fund. The federal allocation for 2004 is $142M.

Internal Hospital Monitoring and Tracking Systems

In addition to increasing the supply of RNs to meet the requirement, other infrastructural adjustments, such as comprehensive monitoring systems, would need to be developed to ensure compliance at the unit level for each shift's minimum staffing requirements. Each hospital's system would need to be sensitive to RNs leaving each unit for any reason (lunch, transfers, meetings) whether planned or unplanned and fluctuations in patient admissions and discharges.

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[28] U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Bureau of Health Professions, National Center For Health Workforce Analysis, July 2002. http://bhpr.hrsa.gov/healthworkforce/reports/rnproject/default htm

[29] U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Bureau of Health Professions, http://bhpr.hrsa.gov/nursing/reinvesttext.htm

Each unit would need a plan for how they will limit admissions should their RN-patient ratios dip below the legislated level.

State Compliance and Review

The State of Maine would need to develop infrastructure to monitor compliance with the legislation and impose sanctions, if required. Given the breadth of the ratio requirements (different ratio staffing requirements in 24 types of hospital units), this could be a substantial effort.

9 Are there any essential timing considerations?

The California experience is the only nurse-patient ratio model to date. (Please refer to the *Staffing and Patient Safety Initiatives in Other States* section of this paper for more information about that legislation). California passed a comprehensive nurse-patient ratio law in 1999 and required a phased-in implementation plan beginning in 2003 with complete implementation required by 2008. The phase-in period allows hospitals to assess their needs relative to the required unit level ratios, and subsequently to recruit, hire, and train nursing staff.

Implementing nurse-patient ratios in Maine would require an initial assessment of current needs by hospital type and the development of a reasonable time schedule for all hospitals to be in compliance. Smaller rural hospitals, that may have more challenges recruiting RNs in a more competitive market, would likely need special timing consideration.

10 What are the capital, set up, and recurring costs? How will they be met? What are the opportunity costs? Are any cost savings envisioned?

California's nurse-patient ratio initiative is expected to yield research findings including cost-benefit analyses beginning in 2008. A cost analysis of the proposed unit-level, nurse-patient ratios in Maine is beyond the scope of this review, however, we can speculate that anticipated cost-related factors might include:

Costs to Hospitals

- Initial costs to hospitals might be incurred by a number of administrative activities including analyses of current staffing, possible re-organization of current nursing and administrative nursing staff, and identification of hiring needs to meet the new requirements.
- Recruitment of medical, surgical or specialty nurses nationally is estimated to be between $42,000 and $64,000 per nurse.[30] In California, Kaiser Permanente met the ratio requirement for its medical and surgical units by investing approximately $200 million to recruit and hire 1,300 new nurses.[31]

[30] McCue, M., et al., Nurse Staffing, Quality, and Financial Performance. *Journal of Health Care Finance*, 2003, 29(4) p. 54-76.

[31] http://www.nurseweek.com/news/features/04-02/ratios.asp

- Ongoing salary benefit and training costs associated with each hire would likely rise from current rates due to increased demand. In addition to increased costs of new hires, current salaries of RNs would likely be adjusted to ensure equity.
- To be in compliance at all times, including during planned or unplanned absences for sick or vacation time, hospitals may hire nurse replacements from temporary agencies at a higher cost.
- A monitoring system would be needed to ensure that each unit is in compliance and sensitive to fluctuations in patient admissions and discharges, changes in shifts, nurses on break, calling in sick or planned sick or vacation leaves, in-hospital transfers, etc.

Costs to the State of Maine

- A system to track, verify compliance, and impose sanctions at the hospital unit level of all hospitals would need to be developed and maintained by the State. This would require additional staff in the Division of Licensing and Certification of the Department of Health and Human Services, computer systems support, and possible contract auditors.
- When the California nurse-patient ratio legislation was enacted, the governor of that state authorized $60M of state funds to assist hospitals with hiring the anticipated 5,000 nurses needed. It is not clear how this amount was derived or negotiated.

Costs to Payers

- Costs associated with increased staffing levels may be passed on to payers, thus increasing the cost of health insurance rates in Maine.

Opportunity Costs

- In a time of limited resources and high patient safety concerns, policymakers should weigh the value and potential outcomes of any high intensity initiative. Selecting one method may limit the possibility of directing resources to another initiative that may produce more effective or actionable results. Hospital or state-level resources intended to improve patient safety may be spent monitoring the levels of staff per hospital unit and divert resources for other patient safety improvement activities.

Cost Savings

- Nursing turnover often results in both hiring more expensive temporary nurses and also higher spending on recruitment of each new nurse permanent replacement. Proponents of mandatory nurse-patient legislation suggest that increasing the numbers of nurses will improve nurse job satisfaction, reduce job burnout and turnover, thus reducing hospital costs.[32]

- Proponents of nurse-patient ratio legislation suggest that higher quality service that would result from more direct care RNs would likely lead to reductions in malpractice suits and possibly lower associated insurance costs.

[32] Ibid.

11 Are there any areas for discussion with or between health care professionals?

Virtually every report on the issue of nurse staffing and patient outcomes references the need for all employees in health care organizations to work together to develop a culture of safety in which adverse events can be reduced.[33] Intrinsic in developing a culture of safety in hospitals is good communication and trust among all staff. The literature recommends developing collaborative relationships among all clinical staff. Though in the interest of time, heavy workloads are often managed by hierarchical decision making, evidence is showing that collaborative interactions can be time-saving in the long run.

The IOM's *Keeping Patients Safe* report discusses the value of interdisciplinary practices in which physicians, nurses, pharmacists, and managers work together to address the operations of hospital units. Several reports suggest that health care organizations could foster collaborative relationships by identifying negative interpersonal behaviors, such as the use of foul language and rudeness, and including those behaviors in performance evaluations of all hospital staff. Poor communication or rude behavior between physicians and nurses can lead to intimidation that inhibits clarification of orders or procedures that have a direct impact on patients' safety.[34] The literature further suggests that if hospital management paid more attention to improving working conditions for nurses, making these jobs more competitive with other professions, it would likely reduce efforts to impose severe workload restrictions, such as nurse-patient ratios.

[33] Health care's human crisis: The American nursing shortage. 2002 Robert Wood Johnson Foundation. Health care at the crossroads. Strategies for addressing the evolving nursing crisis. Joint Commission on the Accreditation of Healthcare Organizations. Aug 2002. Keeping patients safe: transforming the work environment of nurses. 2004. Crossing the Quality Chasm: A New Health System for the 21st Century. 2001. To Err is Human: Building a Safer Health System. 1999. Institute of Medicine. National Academy Press.

[34] Rosenstein, A., Nurse-Physician Relationships: Impact on Nurse Satisfaction and Retention," *American Journal of Nursing*. June 2002. 102(6).

12 What unintended consequences might result from implementing nursing ratios?

It is worth noting that hospital care redesign of the 1990's led to RN staff reductions which led to a decline in nursing school admissions and thus a diminished supply of nurses. Unintended consequences of any new policy should be thoroughly explored. Hospitals could respond to mandated RN staffing ratios by taking any of the following actions:

- Reduce beds in units or close units
- Refuse admissions including emergency room admissions
- Reduce other nursing and support staff including CNAs, LPNs, housekeeping and transport staff, thus increasing an inappropriate workload of RNs and diminishing job satisfaction
- Reduce RN staff if the hospital unit currently employs RNs above the minimum ratio
- Reassign nursing staff in administrative or policy decision making positions in favor of assignment to patient care in order to comply with ratio requirements
- Defer investment in medical technology due to increases in personnel and benefit costs
- Attract RNs from local hospitals to meet quotas, thus engaging in 'bidding wars' without increasing overall supply. In this scenario larger, financially robust hospitals would likely be better positioned to meet their ratio requirements than would small rural hospitals.

13 What are current standards?

There are no national standards that define minimum nurse staffing levels; hospitals develop their staffing plans based on a combination of factors including patient acuity, skill mix of clinical staff, patient census, etc. Hospitals and software firms have developed a variety of tools to determine patient acuity and predict nurse staffing levels. These patient classification systems (PCS) are ostensibly used to evaluate the needs of the patient, estimate the nursing hours required to care for the patient, and collect longitudinal data. Researchers and clinicians note that PCSs are time-consuming and often inaccurate due to the variation and the general unpredictable nature of patients' needs.[35]

In recent years a number of organizations have been working to identify specific nurse-sensitive indicators - conditions, particularly influenced by nurses, that take into account the experience, skill level, skill mix, as well as the numbers of nurses – to gauge patient safety.

Below are summaries of several national and state initiatives.

[35] Seago, J. Nurse staffing, models of care delivery, and intervention. In: Shojania K, et al, eds. *Making Health Care Safer: A critical Analysis of Patient Safety Practices.* Evidence Report/Technology Assessment No. 43. Rockville, MD: AHRQ. Spetz, J., et.al. Minimum nurse staffing ratios in California Acute Care Hospitals. 2000. California Workforce Initiative.

National Initiatives

American Nurses Association (ANA)

The American Nurses Association has actively studied the issue of standards of nurse staffing. Rather than recommending minimum staffing levels, this organization has formulated the following nine principles:[36]

I. Patient Care Unit Related
   a. Appropriate staffing levels for a patient care unit reflect analysis of individual and aggregate patient needs.
   b. There is a critical need to either retire or seriously question the usefulness of the concept of (total) nursing hours per patient day.
   c. Unit functions necessary to support delivery of quality patient care must also be considered in determining staffing levels.

II. Staff Related
   a. The specific needs of various patient populations should determine the appropriate clinical competencies required of the nurse practicing in that area.
   b. Registered nurses must have nursing management support and representation at both the operational level and the executive level.
   c. Clinical support from experienced RNs should be readily available to those RNs with less proficiency.

III. Institutional/Organization Related
   a. Organizational policy should reflect an organizational climate that values registered nurses and other employees as strategic assets and exhibit a true commitment to filling budgeted positions in a timely manner.
   b. All institutions should have documented competencies for nursing staff including agency or supplemental and traveling RNs for those activities that they have been authorized to perform.
   c. Organizational policies should recognize the myriad needs of both patients and nursing staff.

Since the mid 1990s the ANA has focused its attention on collecting and disseminating hospital data and promoting the use of nursing report cards and nursing quality indicators.[37] They have determined that the following 10 indicators are most sensitive to nursing care and staffing levels:

- Mix of RNs, LPNs, and unlicensed staff caring for patients in acute care settings
- Total nursing care (productive) hours provided per patient day
- Patient satisfaction with pain management
- Patient satisfaction with educational information
- Patient satisfaction with overall care
- Patient satisfaction with nursing care

[36] Principles for Nurse Staffing, American Nurses Association., Website accessed May 2004: http://www.nursingworld.org/readroom/stffprnc.htm.

[37] National Database of Nursing Quality Indicators, American Nurses Association: http://nursingworld.org/quality/ndnqi.pdf.

- Nosocomial infection rate
- Pressure ulcers
- Patient falls
- Nurse staff satisfaction

Joint Commission of Accreditation of Healthcare Organizations (JCAHO)

In *Health Care at the Crossroads*, the Joint Commission of Accreditation of Healthcare Organizations noted that nurse-patient ratios do not address skill mix in relation to patient acuity, ancillary support staff, and nurse competency.[38] However, due to the evidence of correlations of nursing staff levels to patient outcomes, this organization convened a group of 100 experts to develop Staffing Effectiveness Standards designed to assist hospitals to determine optimal staffing levels based on their own evidence and experience. As a condition of accreditation, hospitals are required to select at least two of the measures to assess and monitor its patient outcomes against its own mix of RNs, LPNs, CNAs, technical, and other health care staff.

The JCAHO auditors evaluate selected indicators during each hospital's regular review process. The process includes an evaluation of the rationale for the indicator selection, available data to support the evaluation, findings from the analysis, and action plans for addressing needs, if evident in the findings. Each hospital is required to select two human resource indicators and two clinical indicators on which to be evaluated. Two of the four indicators may be developed by the hospital and the remaining two must be selected from the following lists:

Human Resource	**Clinical Indicators**
Nursing care hours per patient day	Adverse drug events
On-call or per diem use	Family complaints
Overtime	Injuries to patients
Sick time	Length of stay
Staff injuries on the job	Patient complaints
Staff satisfaction	Patient falls
Staff turnover rate	Pneumonias
Staff vacancy rate	Postoperative infections
Staffing compared to staffing plan	Shock/cardiac arrests
	Skin breakdowns
	Upper gastrointestinal bleeding
	Urinary tract infections

The standards, implemented for less than two years, have not produced any impact analyses to date. A limitation of this method may be that, because each hospital can choose two measures from its own methods in addition to the two from the JCHAO list, it may be difficult to compare outcomes across hospitals.

[38] Health care at the crossroads: strategies for addressing the evolving nursing crisis. Aug 2002. Joint Commission on the Accreditation of Healthcare Organizations.

National Quality Forum

The National Quality Forum (NQF) is a voluntary, consensus standard-setting organization established in 1999 to develop and implement a national strategy for health care quality measurement and reporting. The forum's Core Measures for Nursing Care Performance project set out to "…establish consensus on a set of evidence-based measures for evaluating the performance of all nursing in acute care hospitals…to improve nursing care and patient outcomes."

The NQF engaged more than 200 stakeholders in the year-long process. The effort, funded by the Robert Wood Johnson Foundation, resulted in the release in January 2004 of 15 indicators intended to measure nursing performance and patient outcomes.[39] The selection and implementation of the measures is voluntary.

The nurse-sensitive indicators are as follows:

- Skill mix
- Nursing care hours per patient day
- Practice environment scale - Nursing Work Index
- Voluntary staff turnover
- Failure to rescue
- Pressure ulcer prevalence
- Falls prevalence
- Falls with injury
- Restraint prevalence
- Central line catheter-associated blood stream infection rate for ICU and high risk nursery patients (HRN)
- Ventilator-associated pneumonia for ICU and HRN patients
- Urinary catheter-associated UTI in ICU and HRN patients
- Smoking cessation counseling – AMI patients
- Smoking cessation counseling - heart failure patients
- Smoking cessation counseling - pneumonia patients

The practice environment scale of the nursing work index is a 31 item tool designed to capture all aspects of nursing workplace concerns. The following subscales are included in the tool: a) participation in hospital affairs, b) nurse foundation for quality of care, c) nurse manager ability, leadership, and support of nurses, d) staffing, and e) resource adequacy and collegial nurse-physician relations.

[39] National Quality Forum website: http://www.qualityforum.org/prnursingcarevcsFINAL1-30-04.pdf and http://www.qualityforum.org/txNCappCspecsotherFINAL.pdf.

Institute of Medicine

Keeping Patients Safe is the third report in the Institute of Medicine's (IOM) quality series following *To Err is Human* and *Crossing the Quality Chasm*.[40] A committee of 18 nurses, physicians, and policy makers spent more than one year reviewing the literature and current practices relating to nurse staffing and patient safety. The result of their effort is a report and a series of recommendations that form a comprehensive, systems-based approach, designed to improve patient safety by promoting a culture of safety, a culture of nurse retention, and the use of evidence-based management systems. The committee addresses the recommendations to health care organizations, federal and state governments, and professional organizations. A complete set of the recommendations can be found in Appendix C.

The section of the recommendations that addresses staffing issues is as follows:

Recommendation 5-2. Hospitals and nursing homes should employ nurse staffing practices that identify needed nurse staffing for each patient care unit per shift. These practices should:

- Incorporate estimates of patient volume that count admissions, discharges, and "less than full-day" patients in addition to a census of patients at a point in time.
- Involve direct-care nursing staff in determining and evaluating the approaches used to determine appropriate unit staffing levels for each shift.
- Provide for staffing "elasticity" or "slack" within each shift's scheduling to accommodate unpredicted variations in patient volume and acuity and resulting workload. Methods used to provide slack should give preference to scheduling excess staff and creating cross-trained float pools within the HCO. Use of nurses from external agencies should be avoided.
- Empower nursing unit staff to regulate unit work flow and set criteria for unit closures to new admissions and transfers as nursing workload and staffing necessitate.
- Involve direct-care nursing staff in identifying the causes of nursing staff turnover and in developing methods to improve nursing staff retention.

The report warns against taking a piecemeal approach to address only one aspect of the entire recommendation series. The committee notes the "unavailability, incompleteness, and unreliability of nurse staffing data in the US and the weaknesses of tools for measuring nursing workload and predicting hospital staffing needs." One recommendation calls for standardized staffing data at the unit level to be collected and maintained by a federal agency for use by states to assist with the development of staffing standards.

Members of the committee conducted an exhaustive review of the literature relating to staffing and nurse-patient ratios and found a lack of evidence to substantiate the efficacy of this method for staff planning in all but one category. They found that there is sufficient evidence to support a requirement of one licensed nurse for every two patients in hospital intensive care units (ICU). For other units in acute hospitals, the report suggests that a combination of the following three approaches together would likely produce safe staffing levels: a regulatory approach, market place/consumer driven approach, and improved internal hospital staffing practices.

[40] Ibid.

Staffing and Patient Safety Initiatives in Other States

California

During the past five years bills requiring minimum nurse-patient ratios have been proposed in 23 states.[41] California, with one of the lowest nurse per capita rates in the country (544 per 100,000 of the population compared to Maine's 1,025 per 100,000), passed legislation requiring minimum staffing ratios in 1999. It remains the only state to do so. California had previously mandated the use of patient classification systems (PCS) to manage staffing plans. PCSs are continuing in place in addition to the implementation of the new nursing ratios legislation. Data from California's Office of Statewide Health Planning and Development (OSHPD) provided a baseline and 15 year history of nurse staffing levels in the state. The requirements of Assembly Bill 394 are included in Table 2 below.

Approval of the bill was preceded by several years of lobbying and negotiations. Initial negotiations included proposals by the California Hospital Association of one licensed nurse (RN or LPN) to 10 patients with the California Nurses Association lobbying for one RN for every three patients in the medical surgical units.[42] The final bill called for a ratio of one licensed nurse to five patients in these units. The bill requires hospitals to have brought the majority of the units into compliance by July 2003 with phase-in for all units expected to be completed by 2008. In May 2004, a lawsuit by a California hospital coalition argued that the ratio requirements should not be in effect when nurses are on meal or rest breaks; the lawsuit was rejected.

Nurses, hospital associations, state and national policy makers are divided on whether this legislation will improve quality, patient safety, or nursing job satisfaction and are taking a wait and see approach.[43] Researchers are carefully monitoring the effects of the ratios; the results of their findings will be instructive as they become available in the future. Under California law, a nurse is defined as an RN, a licensed vocational nurse (LVN), and in psychiatric units only, a licensed psychiatric technician (LPT).[44] The chart below illustrates California's ratios compared to those proposed under LD 616; in the Maine proposal a nurse is defined as a direct-care registered nurse.

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41 AZ, CO, CT, FL, HI, IL, IA, IN, KY, MA, ME, MO, MT, NJ, NM, OH, OR, PA, RI, TN, VA, VT, WV. Coffman JM, Seago JA, Spetz J. Minimum nurse-to-patient ratios in acute care hospitals in California. *Health Affairs.* 2002; 21(5):53-64 and also American Nurses Association Government Affairs website: http://nursingworld.org/gova/state/intro htm.

42 Ibid.

43 Ibid.

44 Summary of the Law: Implementation of California's Nurse Ratio Law, California Healthcare Association, Website accessed June 2004: http://www.calhealth.org.

Table 2: Minimum Nurse-to-Patient Ratios Required by California and Proposed in LD 616

Hospital Unit	California AB 394 Nurse-to-Patient Ratio	Maine's LD 616 Proposed RN-to-Patient Ratio
Behavioral Health & Psychiatric Units	1:6	1:4
Emergency Departments (RN only)	1:4	1:2
Triage (RN only)	1:1	1:1
Radio (RN only)	1:1	--
Trauma	1:1	1:1
Critical Care	1:2	1:2
General Medical/Surgical	1:6, on 1/1/05 1:5	1:4
ICU/CCU/NICU	1:2	1:2
Labor & Delivery	1:2	1:1
Ante-partum (Not Active Labor)	1:4	1:2
Postpartum (mothers only)	1:6	1:6
Well-Baby Nursery	1:8	1:6
Couplets (mothers & babies)	1:4	1:4
Combined Labor & Delivery	1:3	--
Mixed Units	1:6, on 1/1/05 1:5	1:6
Neonatal ICU (RN only)	1:2	1:2
Operating Room (RN only)	1:1	1:1
Pediatrics	1:4	1:4
Post anesthesia Care Unit	1:2	1:2
Specialty Care (Oncology & Dialysis)	1:5, on 1/1/08 1:4	--
Step-Down Unit	1:4, on 1/1/08 1:3	1:3
Telemetry Unit	1:5, on 1/1/08 1:4	1:4
Burn unit		1:2
Observational and Outpatient		1:4
Transitional and Rehabilitation		1:5
Non-critical/stable		1:3
Any unit not specified above		1:3

New Jersey

In 2002, the New Jersey legislature approved regulations requiring all hospitals to collect the following nurse-sensitive indicators:[45]

- Patient injury rate
- Medication process errors
- Maintenance of skin integrity
- Nosocomial infection rates
- Hospital-wide patient satisfaction with overall care, including nursing care
- Nursing turnover rate
- Patient satisfaction with pain management and
- Mix of RNs, LPNs, and unlicensed staff caring for patients.

In addition to the use of nurse-sensitive indicators, New Jersey hospitals are required to have nurse staffing plans based on skill mix, patient acuity, and projected length of stay, among other factors. Contingency staffing plans must have procedures to close beds if nurse staffing levels fall below those identified in the nurse staffing plans. Despite these regulations, the state has two bills currently pending in the legislature, one for mandated nurse-patient ratios and one that calls for public disclosure of actual nursing levels.

New York

The New York State Assembly is currently considering multiple bills relating to nurse staffing. Bill S1094 calls for the commissioner of health of that state to develop staffing formulas at the hospital unit level. Formulas would be based on census, acuity, skill mix of personnel on the unit, intensity on each shift, equipment needs and environmental concerns, most of which would be subject to public disclosure. Another bill calls for nurse-patient ratios to be implemented, the creation of a nursing committee to advise the commissioner, and protections for nurses to refuse work if they deem that patient safety is jeopardized.

Oregon

In 2001 the Oregon legislature passed a bill requiring hospitals to develop and implement staffing plans and an internal review process to ensure their efficacy. Further, the legislation requires the Oregon Department of Human Services to conduct annual, random, unannounced audits of at least 7% of licensed hospitals in the state (five hospitals).[46] The audits verify that each hospital has a system in place to develop and manage nurse staff levels. Specifically, the audits verify compliance with each hospital's nursing staffing plan, individual unit staffing plans, and staffing guidelines for each unit. Auditors compare the daily staffing or payroll reports for each unit to the plan to verify the actual staff who worked and the number of hours they worked. Supporting documentation is also reviewed including staffing policies, nursing staff committee meeting minutes, reports of inadequate staffing filed by clinical staff, job descriptions, and verification of current licensure/certification.

Quality assurance data and nurse-sensitive outcome data are reviewed in this annual audit process. Oregon defines nurse-sensitive outcome data as: infection control, decubitus ulcers,

[45] New Jersey Hospital Licensing Standards, Subchapter 17., Nurse Staffing 8:43G-17.1.
[46] Oregon House Bill 2800, Oregon Revised Statutes (ORS) 441.160 – 441.192.

medication errors, and patient satisfaction surveys. The legislation requires public disclosure of the annual report of the audit findings, allows for civil penalties where appropriate, and provides whistle-blower protection.

Texas

In 2002 Texas enacted legislation mandating hospitals to adopt and enforce nursing staffing plans based on nurse-sensitive outcome measures.[47] The plans are developed by hospital committees comprised of one-third practicing RNs. Plans may be at the unit level or another basis appropriate to the hospital. Staffing plans are reviewed and adjusted at least annually and the committee uses one of each of the following three types of measures to develop or adjust the plans:

1) *nursing sensitive patient outcomes*: patient falls, adverse drug events, injuries to patients, skin breakdown, pneumonia, infection rates, upper gastrointestinal bleeding, shock, cardiac arrest, length of stay, or patient readmissions;

2) *nursing-sensitive operational outcomes*: work related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

3) *nursing sensitive validated patient complaints:* those related to staffing levels.

The data are considered confidential to the hospitals and are not subject to state reporting requirements or public disclosure.

Washington State

Washington state's bill 2712 calls for a task force to essentially develop a plan to implement the recommendations in the Institute of Medicine's *Keeping Patients Safe* report. (This report is discussed above in this paper and the recommendations can be found in Appendix C). The costs of the task force are funded from nurse license fees. This bill has passed debate and is currently in the rules committee.

Other enacted legislation

Other approaches recently enacted in legislation by states to address nurse staffing or improve patient safety include:

- Nevada recently enacted legislation to conduct a study on nurse staffing,
- Florida passed a bill to establish a two-year pilot requiring implementation of staffing standards in one type of hospital unit, a sub-acute pediatric transition care center,
- Kentucky requires all hospitals to create a staffing method that provides a skill mix for all personnel,
- Connecticut enacted legislation to establish broad standard measurement of clinical performance in all hospitals.[48]

[47] Title 25 Texas Administrative Code, Chapter 133, Hospital Licensing. Website accessed June 2004: http://www.tdh.state.tx.us/hfc/hnew%5F133.pdf

[48] http://www.dph.state.ct.us/Agency_News/PA02125%20Quality%20Health%20Report.pdf

Unsuccessful legislative actions

In 2003, of the 14 states that considered legislation involving nurse staffing policy changes, no legislation was enacted.[49] Some of the attributes of these bills included:

- Task forces to monitor and disclose nurse staffing levels
- Annual staffing plans that include a system for determining staffing levels based on patient acuity
- Daily staffing requirements
- Setting maximum hours for nurses
- Publicly disclose mandated and actual staffing levels
- Provide access to unannounced inspections

Pending Federal legislation

A bill establishing direct care registered nurse-patient ratios was introduced in May 2004 in the House of Representatives. HR 4316, *The Nurse Staffing Standards for Patient Safety and Quality Care Act of 2004*, would require minimum RN-patient ratios in 18 types of units including a 1:4 ratio in medical/surgical units and a 1:1 ratio in trauma emergency units. The bill is currently in the Ways and Means and the Energy and Commerce committees.

[49] CO, FL, HI, IA, IL, MA MO, NV, NJ, NY, PA, RI, VT, WA. American Nurses Association, Government Affairs website: http://nursingworld.org/gova/state/intro htm.

14 What are alternative approaches to nurse staffing ratios?

There are a number of strategies, culled from other organizations' approaches and states' activities, from which Maine could choose singularly or in combination, to improve patient safety in areas where the adequacy of nurse staffing levels is inherent:

1. Quality Indicators

Current Maine policy requires hospitals to maintain 'two clinical indicators relative to staffing effectiveness and the effectiveness of nursing;' the results of the indicators are reported annually to each hospital's board (Chapter X., I.2.). Each hospital may select any two indicators on which to be reviewed - internal, 'home grown' measures or evidenced-based, nationally-accepted indicators. It is conceivable that a hospital could select an indicator in which it already has a high performance level, thereby rendering the exercise useless. Unless a standard set of accepted quality indicators is utilized, hospitals miss an opportunity to examine outcomes relative to their peers and target improvements in identified areas and the State misses an opportunity to review the effects of the current policy and understand the extent to which problems exist, relative to these indicators.

The Maine legislature could expand the number of indicators and require that the same indicators are used in all Maine hospitals. Findings from these indicators could be submitted to a state entity, such as the Maine Health Data Organization, or the State's mandatory reporting system, for the purpose of tracking patient safety statewide, by type of unit. As shown earlier in this paper, there is an increasing interest in using quality indicators that are nurse-sensitive as a method to track and improve patient outcomes while taking into account variations in nurse staffing. Implicit in these patient outcomes is the level of nursing skills and experience, the mix of clinical skills in the unit, and other elements that contribute to good patient care. Using patient outcome indicators that are sensitive to nursing skills can highlight variation at a unit level, hospital level, and across similar units in similar hospitals. Variances above the mean would point to deficiencies in the system to be corrected. One such deficiency might be an insufficient number of experienced nursing staff.

The table below shows the nurse-sensitive indicators promoted by the following organizations and used by the following states: American Nurses Association, Joint Commission of Accreditation of Healthcare Organizations, National Quality Forum, New Jersey, Oregon, and Texas.

Table 3: Use of Nursing-Sensitive Indicators

	ANA	JCAHO	NQF	NJ	OR	TX
I. Human Resources						
Nursing care hrs per patient day	•	•	•			•
On-call or per diem use		•				•
Overtime		•				•
Sick time		•				•
Skill mix	•		•	•		
Staff injuries on the job		•				•
Staff satisfaction	•	•				
Staff turnover rate		•	•	•		•
Staff vacancy rate		•				•
Planned vs. actual staffing		•				
Practice environment scale			▪			
II. Clinical Indicators						
Adverse drug events/process errors		•		•	•	•
Failure to rescue			•			
Family complaints		•				
Length of stay/Readmissions		•				•
Patient complaints/satisfaction*	•	•		▪	▪	•
Patient falls/injuries	•	•	•	▪		•
Pneumonias¥		•	•			•
Infections±	•	•	•	•	•	•
Restraint prevalence			•			
Shock/cardiac arrests		▪				•
Skin breakdowns/ulcers	•	•	•	•	•	•
Smoking cessation counseling∞			•			
Upper gastrointestinal bleeding		•				•
Urinary tract infectionsμ		•	•			

* The ANA uses four patient satisfaction indicators. New Jersey uses two.
¥ The NQF measures specify ventilator-associated pneumonia for ICU and HRN patients.
± The ANA specifies nosocomial infections, JCAHO specifies post-operative infections. The NQF measure specifies central line-associated blood stream infection rate for ICU and HRN patients.
∞ NQF specifies three separate smoking cessation measures, one each for patients with AMI, heart failure and pneumonia.
μ The NQF measure specifies UTIs associated with urinary catheters for ICU and HRN patients.

2. Public Disclosure

Require public disclosure of nurse staffing plans or of actual nurse staffing levels by hospital unit. This strategy has been proposed in many states; the *Keeping Patients Safe* report recommends that staffing information at the unit level be made available to the public routinely.

3. Report De-identified Quality Improvement Data

Maine hospitals are currently required to convene Quality Improvement Committees to review quality assurance/quality improvement findings (Chapter 112, subchapter 9, T.). They are also required to generate interventions designed to improve deficiencies and audit the interventions for effectiveness and report findings quarterly, according to their institutional plan. Two of the required indicators in these regulations, nosocomial infections and adverse drug events, are also nurse-sensitive indicators. De-identified data from these indicators could be reported to a state agency, such as the Maine Health Data Organization, or included in the mandatory reporting system for sentinel events, for the purpose of tracking patient safety statewide, by type of unit.

4. Nurse Participation

Current policy requires that direct care nursing staff "…are allowed an opportunity to provide input into staffing plans…at a minimum, annually." This requirement could be expanded to appoint direct care nurses to staff plan development committees and/or to have more frequent opportunities for input into their workload, such as quarterly, rather than annually.

5. Pilot Test Use of Staffing Ratios

Pilot test a nurse staffing ratio in a type of unit, *e.g.*, in intensive care units in Maine hospitals for a period of time and review effects on patient outcomes and on consequences of the ratio implementation.

6. Task Force

Similar to the approach in Washington state, a task force could be charged with assessing the extent to which the IOM recommendations in the *Keeping Patients Safe* report could be implemented in Maine hospitals.

7. Commission an Independent Survey

Commission an independent survey of nurses to understand the extent to which a culture of safety exists. Findings would shed light on the level of fear or comfort with reporting medical errors, the presence of training or analysis in error detection, and the extent to which medical errors are intercepted by nurses.

8. Review Findings of Complaints and Non-compliance

Maine enacted comprehensive improvements to nurse staffing policy less than two years ago (Chapter 112, subchapter 10). The Department of Health and Human Services monitors these improvements during each hospital's regular licensing review, conducted annually for non-JCAHO accredited hospitals and every three years for JCAHO-accredited hospitals.

To gauge the effectiveness of current regulations and assess the extent to which problems related to nurse staffing exist, periodic analyses of deficiencies could be conducted and reported. Together with findings from patient and staff complaints, such reports might reveal whether there are recurring problems with compliance and whether further refinement of nurse staffing regulations is needed.

15 Summary

The primary questions of this review are: *Are minimum nurse staffing ratios an effective way to improve patient safety in Maine hospitals? What is the most effective approach for addressing patient safety with regard to nurse staffing and how will we know if it is working?*

Mandated nurse-patient ratio legislation was proposed with the goal of improving the safety of patients in Maine hospitals. There is ample evidence, at a national level, that improvements in hospital patient safety should be made. Absent Maine-specific adverse outcomes data, there is no evidence that Maine's patient safety needs are different from those of the nation's. Nor is there any indication of where Maine should focus its patient safety improvement efforts. In the near future patient safety data will be available as a result of Maine's mandatory reporting of sentinel events and from AHRQ's patient safety indicator project. Together these data sources will provide both an understanding of the extent of patient safety issues in Maine and direction for targeting future improvement initiatives.

Implementing nurse patient ratios is one approach to improving patient safety that is favored by some, but not all, professional nursing associations. It would require the implementation of a very specific and detailed staffing system, applied to all hospitals, that may have unintended consequences. For example, it is not clear that hospitals would react to RN hiring requirements by simply reducing other essential hospital staff, thus having the effect of placing more demands on the RN staff. Other consequences include the possible closure of units, entirely or intermittently, as staffing needs fluctuate and transferring nurses or reducing nurses' hours if patient censuses per unit are low.

Evidence in the literature suggests that a greater number of patient care staff is positively associated with better patient outcomes at the hospital level. There is no evidence that specific unit-level ratios improve patient outcomes, other than in ICUs, where the IOM proposes a ratio of 1:2. Indeed, the recent Institute of Medicine committee convened to study nurse staffing issues came to this conclusion after more than a year of study and recommended that more research be conducted in this area. Influencing factors, including experience of the nursing staff, complexity of nursing services, communication and cooperation among hospital staff, effect of quality improvement technology at the hospital and unit level, all affect patient safety and cannot be controlled through nurse-patient ratios.

California is the only state that has implemented nurse-patient ratios at a unit level. Policymakers throughout the states are monitoring outcomes from that experiment and we can anticipate 'lessons learned' reports from researchers in the coming years. However, the utility of these reports may be limited by the considerable differences between Maine's proposal and California's implementation. California's legislation generally allowed both LPNs and RNs to satisfy staffing requirements, the populations and rurality of the two states vary greatly, and Maine's hospital service system is not comparable to California's in which one major health care system (Kaiser Permanente) has a high penetration rate.

Following a 2001 study of nurse staffing issues the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) implemented its Staffing Effectiveness Standards which are

now a part of their regular hospital evaluations and include both human resource and clinical indicators.

The American Nurses Association recommends the utility of such indicators and other states are using similar nurse-sensitive indicators to gauge patient safety as it relates to nurse staffing. Oregon's legislation requires annual unannounced audits of hospitals to review outcomes of four indicators and each hospital's nurse staffing plan, unit plans, implementation, procedures, and complaints. Texas requires that hospitals develop their nursing plans by committee comprised of direct care RNs and the committee selects three nursing-sensitive indicators to gauge patient safety. New Jersey mandates the use of eight nurse-sensitive indicators in addition to comprehensive staffing plans. Many states have pending legislation requiring hospitals to publicly disclose their unit-level staffing plans; the IOM recommends routine disclosure to the public of unit and hospital level staffing.

Expanded use of nurse-sensitive indicators has the advantage of assessing patient outcomes regardless of each hospital's mix of patient care staff. It accommodates variation in skill level mix of LPNs, RNs, and other clinical staff and hospital environment factors such as communication, organization, and management. Policy makers and hospitals should be cautioned, however, on the use of outcomes data from these measures. Poor findings from these indicators, such as high rates of hospital acquired infections, while being *nurse*-sensitive, most likely will point to systems problems in need of correction. In the culture of safety recommended by the IOM, adverse events are investigated to understand the root cause and determine where and how the system broke down and then to take corrective actions to restructure systems so that the error does not recur. Unless a hospital encourages a culture of safety, blaming, obfuscation of facts or concealing the root cause of the error may occur, thus increasing the likelihood that the error will be repeated.

The recent IOM report warns against a piecemeal approach to improving patient safety. With respect to nurse staffing levels, it recommends that nurses be responsible for setting and regulating workflow at the unit level. However, this is one in a complex set of recommendations that is designed to address nurse professional development, nurse retention, a safety culture, data needs, and evidence-based management. Its multi-pronged approach recommends structural, cultural, and systemic changes to be put in place at a national and health care organizational level. Many of these recommendations cannot be legislated; they are dependent on each hospital's commitment, resources, and management style and may take time to implement.

16 Conclusion

A previous section of this review highlights a number of approaches that states can take to address the issue of nurse staffing as it relates to patient safety. However, given the critical nature of medical error findings, the emerging nurse workforce shortage in Maine, and the continued interest of the public and concerned organizations, any approach without built-in reporting and reviewing requirements may result in re-visiting this issue in the future.

The Maine legislature has already taken important steps to implement improvements in nurse staffing regulations. Monitoring current nursing regulations and other patient safety-related

regulations, such as the mandatory reporting requirement of sentinel events and the hospital quality management process, will provide insights into next steps. Regardless of the approach, it will require state leadership to implement and to act on findings in a deliberate, concerted, and coordinated manner. The State has many organizational resources that are currently engaged in patient safety or health care workforce issues including the Maine Quality Forum, the Performance Indicator Committee of the MQF, the Commission to Study Maine Hospitals, the Maine Health Data Organization, and the Health Care Workforce Leadership Council. Maine is not alone in this process; the state has the advantage of borrowing from successful strategies used in other states, learning from experiments being conducted in other states, and capitalizing on findings from a number of reputable, national organizations that have already conducted substantive analyses on this issue.

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Appendix B-a

LD 616:An Act to Provide Safe Staffing Levels for Patients and To Retain Registered Nurses

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1832 is enacted to read:

§1832. Hospital staffing

Staffing in all hospitals licensed under this chapter is subject to the provisions of this section.

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Acuity-based patient classification system" or "system" means a standardized set of criteria based on scientific data that acts as a measurement instrument that is used to predict registered nursing care requirements for individual patients based on the severity of patient illness, the need for specialized equipment and technology, the intensity of required nursing interventions and the complexity of clinical nursing judgment required to design, implement and evaluate the patient's nursing care plan consistent with professional standards. The system calculates, in a manner that can be readily understood and used, the number of direct-care registered nurses and the skill mix of nursing personnel required on a daily basis for each patient.

B. "Direct-care registered nurse" means a registered nurse who has accepted direct responsibility for carrying out medical regimens, nursing and other bedside care for patients.

2. Minimum staffing ratios. The minimum staffing ratios for general, acute and specialty hospitals are established in this subsection for direct-care registered nurses as follows:

A. For an intensive care unit, one nurse to every 2 patients;

B. For a critical care unit, one nurse to every 2 patients;

C. For a neonatal intensive care unit, one nurse to every 2 patients;

D. For a burn unit, one nurse to every 2 patients;

E. For a step-down, intermediate care unit, one nurse to every 3 patients;

F. For an operating room while under anesthesia, one nurse to every patient; and post anesthesia, one nurse to every 2 patients;

G. For a post-anesthesia care unit while still under anesthesia, one nurse to every patient; and post anesthesia, one nurse to every 2 patients;

H. For an emergency department, one nurse to every 2 patients; in emergency critical care, one nurse to every patient; and in emergency trauma, one nurse to every patient. In an emergency department, triage, radio or specialty registered nurses do not count in calculation of nurse staffing;

I. For labor and delivery in active labor, one nurse to every patient; in immediate postpartum, one nurse to every 2 patients; in postpartum and well-baby nursery, one nurse to every 6 patients; and in immediate-care nursery, one nurse to every 4 patients;

J. For pediatrics, psychiatrics, medical-surgical, telemetry, observational and outpatient units, one nurse to every 4 patients;

K. For a transitional care and rehabilitation unit, one nurse to every 5 patients; and

L. For specialty care of non-critical, stable-condition patients and any unit not listed above, one nurse to every 3 patients.

Additional direct-care registered nurses must be added and the ratio adjusted to ensure staffing in accordance with acuity-based patient classification systems.

3. Restriction. The following activities are prohibited.

A. A hospital may not directly assign any unlicensed personnel to perform registered-nurse functions in lieu of care delivered by a licensed registered nurse.

B. Unlicensed personnel may not perform tasks that require the clinical assessment, judgment and skill of a licensed registered nurse, including, without limitation, nursing activities that require nursing assessment and judgment during implementation; physical, psychological and social assessment that require nursing judgment, intervention, referral or follow-up; formulation of a plan of nursing care and evaluation of the patient's response to the care provided; and administration of medications.

C. A hospital may not impose mandatory overtime requirements to meet the staffing ratios imposed in subsection 2.

4. Consumer protection. A hospital subject to this section shall daily post in a conspicuous place visible to the public the ratio of registered nursing staff to patients on each unit. A hospital subject to this section shall give to each patient admitted to the hospital for inpatient care a toll-free telephone number for the Bureau of Medical Services, Division of Licensing and Certification to report inadequate staffing or care.

5. Enforcement. A hospital that violates the provisions of this section is subject to enforcement action by the department, including suspension or revocation of license to operate, and is subject to a fine not to exceed $25,000 per violation.

6. Rules. The department shall adopt rules to implement this section. By November 1, 2004 the department shall adopt rules for establishing an acuity-based patient classification system in hospitals. Rules adopted pursuant to this section are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill imposes minimum staffing requirements for nurse-to-patient staffing on all hospitals with an increase of nurses required based on the acuity of the patients. The bill directs the Department of Human Services to adopt rules, which are classified as major substantive rules, for establishing an acuity-based patient classification system in hospitals.

Appendix B-b

Chapter 112: Regulations for the Licensure of General and Specialty Hospitals in the State of Maine, Subchapter 10

(All items in bold indicate regulations effective 10/1/02.)

CHAPTER X: NURSING SERVICES

X.A. The hospital shall have an organized nursing service integrated with other services and/ or departments of the hospital, directed and staffed in a manner to ensure that the nursing needs of all the patients are met twenty-four (24) hours a day, seven (7) days a week. Nursing Services representatives shall be included in the planning and policy setting processes that impact patient care.

X.B. Administration

Nursing Services must be directed by a Nurse Executive or a Director of Nursing, who is a registered professional nurse, currently licensed in the State of Maine, qualified by advanced education or management experience. The Nurse Executive must be employed full-time and the administrative and patient care responsibilities must be clearly delineated. The Nurse Executive must be responsible for the monitoring, provision and evaluation of nursing care consistent with acceptable standards of practice, nursing service objectives and nursing policies and procedures.

X.B.1. Nursing care policies, procedures and standards of care must be written, must be consistent with professionally recognized current nursing practice, and must be in accordance with the Rules and Regulations of the Maine State Board of Nursing in the State of Maine.

X.B.2. Written nursing administrative policies and procedures must provide the nursing staff direction to meet their responsibilities and achieve projected goals.

X.B.3. Nursing procedure manuals must be available to the nursing staff and to other services and departments of the hospital.

X.B.4. The nursing policies, procedures, and standards must be reviewed and revised as necessary and new policies must be developed as needed.

X.C. Staffing

There must be a system in place to determine staffing requirements, which reflects the needs of the patients. The system must meet, at a minimum, the following:

X.C.2. The staffing plan must be based on the following:

a. Number of patients on the unit;

b. Unit core staffing;
c. Unit core staff-mix;
d. Care needs of the patients including, but not limited, to acuity. Some examples of care needs of patients may be geography of the unit and the impact of technology.

X.C.3. Criteria for increasing or decreasing staff on the unit may not be based solely on hours per day. Modifications in staffing must include specific criteria upon which the staffing may be increased or decreased dependent on patient needs.

X.C.4. All staffing plans must include contingency provisions for instances when the hospital/patient care unit is unable to meet the care needs of patients. Contingency plans are required for all areas where direct care is provided in the hospital. Policies and procedures will be established which establish mechanisms for deployment of personnel to meet patient needs when specific areas are unable to do so.

X.C.5. The system must include a process whereby all direct care nursing staff will be allowed an opportunity to provide input into staffing plans. This opportunity must be provided, at a minimum, annually.

X.C.6. All registered professional and licensed practical nurses and certified nursing assistants shall provide patient care within the scope of their licensure/ certification. The individual's knowledge, competence, and experience must be appropriate for his/her assigned responsibilities.

X.C.7. All nursing personnel shall provide patient care under the direction of a registered professional nurse in accordance with the Board of Nursing regulations.

X.C.8. A registered professional nurse shall assign the nursing care of each patient to other nursing personnel in accordance with patient needs.

X.D. Licensure

There must be a procedure to ensure that hospital nursing personnel for whom licensure/registration is required hold current licensure with the Maine State Board of Nursing or registration on the Maine Registry of Certified Nursing Assistants.

X.E. Organizational Plan

Nursing Service must have a current written organizational plan that delineates functional structure and mechanisms for cooperative planning, decision-making and communication among nursing units.

X.E.1. The plan shall be an integral part of the overall hospital organizational plan and shall be reviewed and revised as necessary.

X.E.2. The plan shall indicate the lines of communication within Nursing Services and should define the relationships of nursing services to other departments of the hospital.

X.E.3. Job descriptions for each position in Nursing Services must delineate the functions, responsibilities and qualifications.

X.E.4. Orientation of new personnel, including per diem and temporary nurse agency staff, must be defined and documented.

X.E.5. If the hospital provides clinical facilities for the education and training of nursing students, there must be a written agreement that defines the role and responsibility of both the nursing service and the educational institution.

X.E.6. Competencies and training must be documented for all permanent staff on an annual basis. A mechanism must be in place to evaluate the competencies and training of per diem, float, and temporary staff.

X.E.7. The hospital has a mechanism to disseminate/communicate policy and procedural changes to all direct care nursing staff in a timely manner.

X.F. Meetings

Committees shall be formally organized to discuss issues arising regarding the nursing care of patients. Meetings must be held on a regular basis and minutes must be maintained.

X.G. Medications/Transfusions

Blood transfusions, intravenous fluids and intravenous medications must be administered only by those licensed personnel who have evidence of education and supervised clinical practice in performing these procedures in accordance with the Rules and Regulations of the Maine State Board of Nursing.

X.H. Documentation

Nursing Services must provide nursing care for each patient consistent with all assessments planning implementation and evaluation, documented in the medical record.

X.H.1. There must be a nursing care plan. It must be incorporated within the patient's record. It may be incorporated within the patient's multidisciplinary plan of care.

X.H.2. Patient progress notes written by nursing personnel must be pertinent, accurate and concise and must reflect the patient's progress as it relates to the overall plan of care.

X.H.3. The patient's record must contain a discharge plan and summary documented by nursing personnel.

X.I. Quality Management

Nursing Services, with input from direct care nursing staff, must have a quality improvement/quality assurance plan in place to continually monitor and evaluate the nursing care provided. The plan must identify issues and potential issues, propose and implement recommendations for improvements and reevaluate to determine if further improvement is possible/needed.

X.I.1. The Nursing Services quality improvement/quality assurance plan must be an integral part of the hospital-wide quality management program.

X.I.2. The Nursing Services Quality Improvement/Quality Assurance Plan must include at least two (2) clinical screening indicators relative to staffing effectiveness, and the effectiveness of nursing.

XI.3. The data collected and analyzed from the selected clinical screening indicators is used to identify potential staffing effectiveness issues.

X.I.4. Evidence of action must be taken, as appropriate, in response to analyzed data.

X.I.5. Nursing Services must report, at least annually, to the Governing Board on the aggregation and analysis of data related to the effectiveness of staffing and any actions taken to improve staffing.

Appendix B-c

Recommendations from: *Keeping Patients Safe: Transforming the Work Environment of Nurses, a report from the Institute of Medicine*

Recommendations are numbered according to the chapter of the IOM report in which they appear.

Recommendation 4-1.5. Health care organizations (HCOs) should acquire nurse leaders for all levels of management (e.g., at the organization-wide and patient care unit levels) who will:

- Participate in executive decisions within the HCO.
- Represent nursing staff to organization management and facilitate their mutual trust.
- Achieve effective communication between nursing and other clinical leadership.
- Facilitate input of direct-care nursing staff into operational decision making and the design of work processes and work flow.
- Be provided with organizational resources to support the acquisition, management, and dissemination to nursing staff of the knowledge needed to support their clinical decision making and actions.

Recommendation 4-2. Leaders of HCOs should take action to identify and minimize the potential adverse effects of their decisions on patient safety by:

- Educating board members and senior, midlevel, and line managers about the link between management practices and safety.
- Emphasizing safety to the same extent as productivity and financial goals in internal management planning and reports and in public reports to stakeholders.

Recommendation 4-3. HCOs should employ management structures and processes throughout the organization that:

- Provide ongoing vigilance in balancing efficiency and safety.
- Demonstrate trust in workers and promote trust by workers.
- Actively manage the process of change.
- Engage workers in nonhierarchical decision making and in the design of work processes and work flow.
- Establish the organization as a “learning organization”.

Recommendation 4-4. Professional associations, philanthropic organizations and other organizational leaders within the health care industry should sponsor collaboratives that incorporate multiple academic and other research-based organizations to support HCOs in the identification and adoption of evidence-based management.

Recommendation 5-1. The U.S. Department of Health and Human Services (DHHS) should update existing regulations established in 1990 that specify minimum standards for registered and licensed nurse staffing in nursing homes. Updated minimum standards should:

- Require the presence of at least one RN within the facility at all times.
- Specify staffing levels that increase as the number of patients increase, and that are based on the findings and recommendations of the DHHS report to Congress, Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes Phase II Final Report.
- Address staffing levels for nurse assistants, who provide the majority of patient care.

Recommendation 5-2. Hospitals and nursing homes should employ nurse staffing practices that identify needed nurse staffing for each patient care unit per shift. These practices should:

- Incorporate estimates of patient volume that count admissions, discharges, and "less than full-day" patients in addition to a census of patients at a point in time.
- Involve direct-care nursing staff in determining and evaluating the approaches used to determine appropriate unit staffing levels for each shift.
- Provide for staffing "elasticity" or "slack" within each shift's scheduling to accommodate unpredicted variations in patient volume and acuity and resulting workload. Methods used to provide slack should give preference to scheduling excess staff and creating cross-trained float pools within the HCO. Use of nurses from external agencies should be avoided.
- Empower nursing unit staff to regulate unit work flow and set criteria for unit closures to new admissions and transfers as nursing workload and staffing necessitate.
- Involve direct-care nursing staff in identifying the causes of nursing staff turnover and in developing methods to improve nursing staff retention.

Recommendation 5-3. Hospitals and nursing homes should perform ongoing evaluation of the effectiveness of their nurse staffing practices with respect to patient safety, and increase internal over-sight of their staffing methods, levels, and effects on patient safety whenever staffing falls below the following levels for a 24-hour day:

- In hospital ICUs-one licensed nurse for every 2 patients (12 hours of licensed nursing staff per patient day).
- In nursing homes, for long-stay residents – one RN for every 32 patients (0.75 hours per resident day), one licensed nurse for every 18 patients (1.3 hours per resident day), and one nurse assistant for every 8.5 patients (2.8 hours per resident day).

Recommendation 5-4. DHHS should implement a nationwide, publicly accessible system for collecting and managing valid and reliable staffing and turnover data from hospitals and nursing homes. Information on individual hospital and nursing home staffing at the level of individual nursing units and the facility in the aggregate should be disclosed routinely to the public.

- Federal and state nursing home report cards should include standardized, case mix adjusted information on the average hours per patient day of RN, licensed, and nurse assistant care provided to residents and a comparison with federal and state standards.
- During the next 3 years, public and private sponsors of the new hospital report card to be located on the federal government website should undertake an initiative - in collaboration with experts in acute hospital care, nurse staffing, and consumer information - to develop, test, and implement measures of hospital nurse staffing levels for the public.

Recommendation 5-5. HCOs should dedicate budgetary resources equal to a defined percentage of nursing payroll to support nursing staff in their ongoing acquisition and maintenance of knowledge and skills. Theses resources should be sufficient for and used to implement policies and practices that:

- Assign experienced nursing staff to precept nurses newly practicing in a clinical are to address knowledge and skill gaps.
- Annually ensure that each licensed nurse and nurse assistant has an individualized plan and resources for educational development within health care.
- Provide education and training of staff as new technology or changes in the workplace are introduced.
- Provide decision support technology identified with the active involvement of direct-care nursing staff to enable point of care learning.

- Disseminate to individual staff organizational learning as captured in clinical tools, algorithms, and pathways.

Recommendation 5-6. HCOs should take action to support interdisciplinary collaboration by adopting such interdisciplinary practice mechanisms as interdisciplinary rounds, and by providing ongoing formal education and training in interdisciplinary collaboration for all health care providers on a regularly scheduled, continuous basis (e.g. monthly, quarterly, or semiannually).

Recommendation 6-1.
To reduce error-producing fatigue, state regulatory bodies should prohibit nursing staff from providing patient care in any combination of scheduled shifts, mandatory overtime, or voluntary overtime in excess of 12 hours in any given 24-hour period and in excess of 60 hours per 7 day period. To this end:

- HCOs and labor organizations representing nursing staff should establish policies and practices designed to prevent nurses who provide direct patient care from working longer than 12 hours in a 24-hour period and in excess of 60 hours per 7-day period.
- Schools of nursing, state boards of nursing, and HCOs should educate nurses about the threats to patient safety caused by fatigue.

Recommendation 6-2. HCOs should provide nursing leadership with resources that enable them to design the nursing work environment and care processes to reduce errors. These efforts must directly involve direct-care nurses throughout all phases of the work design and should concentrate on errors associated with:

- Surveillance of patient health status.
- Patient transfers and other patient hand-offs.
- Complex patient care processes.
- Non-value-added activities performed by nurses, such as locating and obtaining supplies, looking for personnel, completing redundant and unnecessary documentation, and compensating for poor communication systems.

Recommendation 6-3. HCOs should address hand washing and medication administration among their first work design initiatives.

Recommendation 6-4. Regulators; leaders in health care; and experts in nursing, law, informatics, and related disciplines should jointly convene to identify strategies for safely reducing the burden associated with patient and work-related documentation.

Recommendation 7-1. HCO boards of directors, managerial leadership, and labor partners should create and sustain cultures of safety by implementing the recommendations presented previously and by:

- Specifying short- and long-term safety objectives.
- Continuously reviewing success in meeting these objectives and providing feedback at all levels.
- Conducting an annual, confidential survey of nursing and other health care workers to assess the extent to which a culture of safety exists.
- Instituting a de-identified, fair, and just reporting system for errors and near misses.
- Engaging in ongoing employee training in error detection, analysis, and reduction.
- Implementing procedures for analyzing errors and providing feedback to direct-care workers.
- Instituting rewards and incentives for error reduction.

Recommendation 7-2. The National Council of State Boards of Nursing, in consultation with patient safety experts and health care leaders, should undertake an initiative to design uniform processes across states for better distinguishing human errors from willful negligence and intentional misconduct, along

with guidelines for their application by state boards of nursing and other state regulatory bodies having authority over nursing.

Recommendation 7-3. Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by HCOs for internal use or shared with others solely for purposes of improving safety and quality.

Recommendation 8-1. Federal agencies and private foundations should support research in the following areas to provide HCOs with the additional information they need to continue to strengthen nurse work environments for patient safety:

- Studies and development of methods to better describe, both qualitatively and quantitatively, the work nurses perform in different care settings.
- Descriptive studies of nursing-related errors.
- Design, application, and evaluation (including financial costs and savings) of safer and more efficient work processes and workspace, including the application of information technology.
- Development and testing of a standardized approach to measuring patient acuity.
- Determination of safe staffing levels within different types of nursing units.
- Development and testing of methods to help night shift workers compensate for fatigue.
- Research on the effects of successive work days and sustained work hours on patient safety.
- Development and evaluation of models of collaborative care, including care by teams.

Appendix B-d

List of Terms and Acronyms

AMI. Acute myocardial infarction; heart attack.

CNA. Certified nurse assistant

Decubitus Ulcers. Bed sores.

Failure to Rescue. The death of a patient with a life-threatening complication for which early identification by nurses and medical and nursing interventions can influence the risk of death.

HCO. Health care organizations.

HRN. High risk nursery.

ICU. Intensive care unit.

IOM. Institute of Medicine.

JCAHO. Joint Commission on Accreditation of Health Care Organizations; an organization responsible for reviewing and accrediting hospitals.

LPN. Licensed practical nurse.

LVN. Licensed vocational nurse.

NICU. Neonatal intensive care unit for newborns.

Nosocomial Infections. Infections acquired during a hospital stay.

PCS. Patient classification system, a system to measure the acuity of patients and predict nurse staffing

RN. Registered nurse.

Traveling Nurse. A nurse hired from an agency on a temporary basis.

UTI. Urinary tract infections.

Appendix C: Maine Quality Forum Provider Group

Robert Armstrong	Central Maine Healthcare Corporation
Ronald Bailyn, MD	Portland Psychiatric Services
Bruce Bates, DO	College of Osteopathic Medicine
Leslie Brancato, MSW	Community Counseling Center
Keith Burnham, RPh	Parkview Adventist Medical Center
David Douglass, OD	Northeast Eye Center
Jeffrey Dow, DMD	Maine Dental Association
Philip Elkin, MD, Chair	Peninsula Primary Care, Blue Hill
Holly Gartmayer, MBA, BSN	Harrington Family Health Center
Joel Johnson, RN	Central & Western Maine Regional PHO
Douglas Jorgensen, DO	Jorgensen Consulting,
Jane Kirschling, RN, DNS	Organization of Maine Nursing Executives
Patricia Leavitt, MS, FNP	Executive Director, Leavitt's Mill Health Center
Marc Malon, DC, FICC	Malon Chiropractic Centre
David Marks, PhD	Maine Psychological Association
Shawn McGlew, PA-C	Downeast Association of Physicians Assistants
Karen Mosher, PhD	Kennebec Valley Mental Health Center
Christopher Pingitore, DPM	Maine Foot & Ankle Society
Nancy Quick, PhD	University of New England
Patricia Roy, RN, MSN	Central Maine Medical Center
Saundra Scott-Adams	Visiting Nurses of Aroostook
Stephen Sears, MD, MPH, FACP	MaineGeneral Medical Center
Marie Vienneau, RN, BSN	Millinocket Regional Hospital

Appendix D: CMS/NQF National Voluntary Consensus Standards for Nurse-Sensitive Indicators

Framework Category	Measure	Source of Measure	Numerator	Denominator	Exclusions
Patient-centered Outcome Measures	1. Death among surgical inpatients with treatable serious complications (failure to rescue)[1]	Needleman et al. for the Agency for Healthcare Research and Quality (AHRQ)[2,3]	Surgical inpatients with complications of care whose discharge status is death	Major surgical discharges[4] with complications of care: sepsis (ICD-9-CM codes 038, 790.7), pneumonia (ICD-9-CM codes 507.0, 997.3, 514, 482, 485, 486), GI bleeding (ICD-9-CM codes 531.00-531.31,531.9,532.00-532.31, 532.9, 533.00-533.31,533.9, 534.00-534.31, 534.9, 535.01, 535.4, 578.9, 530.82), shock/cardiac arrest (ICD-9-CM codes 427.5, 785.5, 785.50, 785.51, 785.59, 799.1, 93.93, 99.60, 99.63), DVT/PE (ICD-9-CM codes 451.81, 451.11, 451.19, 415.11, 415.1, 453.8)	Exclusions as noted for each complication of care[5]: • Sepsis excluding sepsis as a primary diagnosis, AIDS and immunocompromised states, LOS < 3 days, infection related admission • Pneumonia excluding any primary diagnosis of pneumonia, any secondary diagnosis of ICD-9-CM 480, 481, 483, 484, 487, MDC4 (respiratory system), AIDS and immunocompromised states • GI Bleeding excluding primary GI bleed as a primary diagnosis, MDC 6 (digestive tract), MDC 7 (hepatobiliary tract and pancreas), primary diagnosis of anemia due to blood loss, trauma, burn, alcoholism • Shock/cardiac arrest excluding shock as primary diagnosis, MDC 4 (respiratory), MDC 5 (cardiac), hemorrhage or trauma as a primary diagnosis • DVT/PE excluding DVT/PE as a primary diagnosis and pregnancy related PE

Framework Category	Measure	Source of Measure	Numerator	Denominator	Exclusions
	2. Pressure ulcer prevalence	CalNOC[6]	Inpatients with National Pressure Ulcer Advisory Panel (NPUAP) – Stage II or greater (II-IV + eschar) hospital-acquired pressure ulcers[7]	Inpatients in the prevalence study[8,9,10] NOTE: Quarterly reporting is recommended by measure developer	• Patients less than 16 years of age • Skin breakdown due to arterial occlusion, venous insufficiency, diabetes neuropathy, or incontinence dermatitis is not reported in the numerator • Pressure ulcers present on admission (community-acquired): o Pressure ulcers discovered/ documented on first day of hospitalization o If the prevalence study is done on day 1 of patient's hospital stay and the patient's ulcer is already present o If the prevalence study is done on day 2 of patient's hospital stay and the patient's Stage II+ ulcer is already present
	3. Falls prevalence[11]	ANA-NDNQI	Number of inpatient falls[12] x 1,000	Total number of inpatient days[9, 13] NOTE: Quarterly reporting is recommended by measure developer	• None
	4. Falls with injury	ANA-NDNQI	Number of inpatient falls[12] with injuries[14] x 1,000	Total number of inpatient days[9, 13] NOTE: Quarterly reporting is recommended by measure developer	• None
	5. Restraint prevalence (vest and limb only)	CalNOC[6]	Inpatients that have vest restraint and/or limb restraint (upper or lower or both)[15] on the day of the prevalence study	Inpatients in the prevalence study[8,9,10]	• Patients less than 16 years of age

Framework Category	Measure	Source of Measure	Numerator	Denominator	Exclusions
	6. Urinary catheter-associated UTI for intensive care unit (ICU) patients[11]	Centers for Disease Control and Prevention (CDC)	Number of indwelling urinary catheter-associated UTIs (defined by CDC case definitions of symptomatic UTI or asymptomatic bacteriuria, excludes other infections of the urinary tract[16,17]) x 1,000	Number of indwelling urinary catheter days for ICU patients ▪Reported by type of ICU (coronary, cardiothoracic, medical, medical-surgical (major teaching and all others), neurosurgical, pediatric, surgical, trauma, burn, and respiratory)	• None
	7. Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients[11]	CDC	Number of central line-associated blood stream infections (laboratory-confirmed bloodstream infection or clinical sepsis) x 1,000[16, 17] Number of umbilical and central line-associated blood stream infections (laboratory-confirmed bloodstream infection or clinical sepsis) x 1,00016, 17	Number of central line-days for ICU patients ▪Reported by type of ICU (coronary, cardiothoracic, medical, medical-surgical (major teaching and all others), neurosurgical, pediatric, surgical, trauma, burn, and respiratory) Number of central-line days for HRN patients ▪Reported for HRNs by birth weight category (≤1,000, 1,001-1,500, 1,501-2,500, and >2,500g)	• None
	8. Ventilator-associated pneumonia for ICU and HRN patients[11]	CDC	Number of ventilator-associated pneumonias x 1,000[16, 17] Number of ventilator-associated pneumonias x 1,000[16, 17]	Number of ventilator-days for ICU patients ▪Reported by type of ICU (coronary, cardiothoracic, medical, medical-surgical (major teaching and all others), neurosurgical, pediatric, surgical, trauma, burn, and respiratory) Number of ventilator days for HRN patients ▪Reported for HRNs by birth weight category (≤1,000, 1,001-1,500, 1,501-2,500, and >2,500g)	• None

Framework Category	Measure	Source of Measure	Numerator	Denominator	Exclusions
Nurse-centered Intervention Measures	9. Smoking cessation counseling for AMI[11]	Centers for Medicare and Medicaid Services (CMS)-Quality Improvement Organizations (QIO) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (ORYX)	Inpatients who receive smoking cessation advice or counseling given during hospitalization	AMI inpatients (principle diagnosis ICD-9-CM code of 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.71, 410.81, 410.91) with a history of smoking cigarettes anytime during the year prior to hospital arrival	• < 18 years of age • Transferred to another acute care hospital • Expired • Left against medical advice • Discharged to hospice
	10. Smoking cessation counseling for HF[11]	CMS-QIO and JCAHO (ORYX)	Inpatients who receive smoking cessation advice or counseling given during hospitalization	HF inpatients (principal diagnosis ICD-9-CM code of 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9) with a history of smoking cigarettes anytime during the year prior to hospital arrival	• < 18 years of age • Transferred to another acute care hospital • Expired • Left against medical advice • Discharged to hospice
	11. Smoking cessation counseling for pneumonia[11]	CMS and JCAHO (ORYX)	Inpatients who receive smoking cessation advice or counseling given during hospitalization	Pneumonia inpatients (principal diagnosis ICD-9-CM code of 480.0-483.8, 485-486, or 487.0; or a principal diagnosis code of sepsis (038.xx) or 518.81[18] (respiratory failure), and a secondary diagnosis code of pneumonia) with a history of smoking cigarettes anytime during the year prior to hospital arrival	• < 18 years of age • Transferred to another acute care hospital • Expired • Left against medical advice • Discharged to hospice • No working diagnosis of pneumonia on admission • Receiving comfort measures only

Framework Category	Measure	Source of Measure	Numerator	Denominator	Exclusions
System-centered Measures	12. Skill mix (RN, LVN/LPN, UAP, and contract)	ANA-NDNQI[19]	Number of productive hours[20] worked by RN nursing staff (employee and contract)[21] with patient care responsibilities[22] Number of productive hours[20] worked by LVN/LPN staff (employee and contract)[21] with patient care responsibilities[22] Number of productive hours[20] worked by UAP staff (employee and contract)[21] with patient care responsibilities[22] Number of productive hours[20] worked by contract staff[21] (RN, LVN/LPN, and UAP) with patient care responsibilities[22]	Total number of productive hours worked by nursing staff (RN, LVN/ LPN, and UAP) with direct patient care responsibilities (employee and contract)[9, 13]	• None
	13. Nursing care hours per patient day (RN, LPN, and UAP)	ANA-NDNQI[19]	Number of productive hours[20] worked by RN nursing staff (employee and contract)[21] with direct patient care responsibilities[22] Number of productive20 hours worked by nursing staff (RN, LVN/LPN, and UAP)21 with direct patient care responsibilities (employee and contract)22	Inpatient days[9, 13]	• None

Framework Category	Measure	Source of Measure	Numerator	Denominator	Exclusions
	14. Practice Environmnt Scale—Nursing Work Index (composite and five subscales)	Literature[23,24,25]	Composite score = mean of all subscales[26] Subscales = mean of all items comprising each subscale: • Nurse participation in hospital affairs (items: 5, 6, 11, 15, 17, 21, 23, 27, 28) • Nursing foundations for quality of care • (items: 4, 14, 18, 19, 22, 25, 26, 29, 30, 31) • Nurse manager ability, leadership, and support of nurses (items: 3, 7, 10, 13, 20) • Staffing and resource adequacy (items: 1, 8, 9, 12) • Collegial nurse-physician relations • (items: 2, 16, 24)	Staff RNs NOTE: Random sample with a minimum response of 30 completed surveys (all items completed) is consistent with the NQF-endorsed consensus standard[27,28]	• None
	15. Voluntary turnover	VHA Inc.	Number of voluntary uncontrolled separations during the month for RNs and advanced practice nurses Number of voluntary uncontrolled separations during the month for LPNs and nurse assistants/aides	Number of employees (full-time plus part-time) on last day of the month for RNs and advanced practice nurses Number of voluntary uncontrolled separations during the month for LPNs and nurse assistants/aides	• Separation due to death, illness, pregnancy, relocation, retirement, performance or discipline, cutbacks due to mergers, cyclical layoffs, permanent reductions in force. • Per diem, consultants, temporary, agency, non-salaried physicians, students in training.

[1] Patient level factors that contribute to the risk of acquiring particular in-hospital complications are used in a logistic regression model to predict each patient's probability. See Table 1. for the risk adjustment coefficients as provided by Needleman J et al.

[2] Needleman J, Buerhaus PI, Mattke S, Stewart M, Zelevinsky K. Nurse Staffing and Patient Outcomes in Hospitals. Final Report, US Department of Health and Human Services, Health Resources and Services Administration, February 28, 2001. Contract No. 230-99-0021.

[3] AHRQ has agreed to provide ongoing support through its Quality Indicators Software, specifically the Patient Safety Indicator (PSI) module. Review of measure specifications and risk adjustment will be undertaken annually.

[4] Risk pools were constructed based on the DRG codes found in Table 2.

[5] See Table 3 for exclusion codes for each complication of care.

[6] VANOD and MilNOD initiatives are also using this measure.

[7] NPUAP/AHCPR classification (any lesion caused by unrelieved pressure resulting in damage of underlying tissue); In Pressure Ulcers in Adults: Prediction and Prevention. Clinical Practice Guideline Number 3. AHCPR Pub. No. 92-0047: May 1992.

[8] CalNOC unit stratification: medical, surgical, medical-surgical combined (units with a mix of patients receiving acute medical and surgical care), critical care, step down (units that provide care to patients requiring a higher level of care than provided on an acute unit, yet not sufficiently intensive to require admission to an ICU; examples include progressive care, telemetry, and intermediate care); reported as three strata (med-surg combined, critical care, step down).

[9] Stratified by hospital size: under 100, 100-199, 200-299, 300-399, 400-499, 500 or more.

[10] This measure is derived from data collected during a quarterly one-day prevalence study on all patients in each unit on the day of the study.

[11] NQF-endorsed Hospital Care Performance Measure.

[12] Falls are defined as patients who experience an unplanned descent to the floor.

[13] ANA-NDNQI unit stratification: medical, surgical, medical-surgical combined (units with a mix of patients receiving acute medical and surgical care), critical care, step down (units that provide care to patients requiring a higher level of care than provided on an acute unit, yet not sufficiently intensive to require admission to an ICU; examples include progressive care, telemetry, and intermediate care); reported as five strata (medical, surgical, med-surg combined, critical care, step down).

[14] Level of injury is defined as minor (results in application of a dressing, ice, cleaning of a wound, limb elevation, or topical medication), moderate (results in suturing, steri-strips, fracture, or splinting), major (results in surgery, casting, or traction), and death (results in death as a result of the fall).

[15] Any manual method of 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.

[16] Definition for infections are given in: Garner JS, et al. CDC Definitions for Noscomial Infections. In: Olmsted, RN, ed. APIC Infection Control and Applied Epidemiology: Principles and Practice. St. Louis: Mosby, 1996: pp. A1-A20. Available at www.apic.org/pdf/cdcdefs.pdf.

[17] Personal communication, Linda McKibbin, MD, MPH, Medical Officer, CDC/NCID, Division of Healthcare Quality Promotion/Prevention and Evaluation Branch, October 21, 2002.

[18] Principal diagnosis code 518.84 (acute & chronic respiratory failure) can be added to 518.81.

[19] This measure is also a CalNOC measure, however, because the CalNOC unit stratification differs (3 strata reported) from the ANA-NDNQI stratification (5 strata reported) , a single version has been endorsed.

[20] Productive hours is defined as the actual direct hours, not budgeted or scheduled hours. Productive hours excludes vacation, medical leave, orientation, education, and committee time.

[21] Employees are the persons who are employed directly by the facility and are on the hospital payroll; contracted/agency staff includes temporary nursing staff who are: not employed by the facility but are hired on a contractual basis to fill staffing needs for a designated shift or for a short-term contracted basis, or registry staff from outside the facility, or traveling nurse staff contracted to the facility for a designated period of time.

[22] Patient care responsibilities = patient centered nursing activities carried out by unit-based staff in the presence of the patient (e.g., medication administration, nursing treatments, nursing rounds, admission/transfer/discharge, patient teaching, patient communication) and nursing activities that occur away from the patient that are patient related (e.g., coordination of patient care, documentation time, treatment planning).

[23] Kramer M, Hafner LP. Shared values: impact on staff nurse job satisfaction and perceived productivity. Nursing Research. 1989;38:172-177.

[24] Aiken LH, Patrician P. Measuring organizational traits of hospitals: the revised nursing work index. Nursing Research. 2000;49:146-153.

[25] Lake ET. Development of the practice environment scale of the Nursing Work Index. Res Nurs Health. 2002;25:176-188.

[26] See Table 4 for the full instrument, subscales, and scoring instructions.

[27] National Quality Forum. A Comprehensive Framework for Hospital Care Performance Evaluation. Washington, DC: National Quality Forum; 2003.

[28] While NQF's endorsed standard for minimum sample size is 30, the measure developer acknowledges that a smaller number of completed surveys (i.e., minimum of 15- 25) retains the instrument's validity