FINAL STATEMENT OF REASONS

In October, 1999 the California State Legislature passed AB394 (Kuehl, Chapter 945, Statutes of 1999) adding section 1276.4 to the Health and Safety Code (HSC). This section was later amended by AB 1760 (Kuehl, Chapter 148, Statutes of 2000). The section requires the California Department of Health Services (Department/CDHS) to develop minimum, specific, numerical licensed nurse–to-patient ratios for specified units of general acute care hospitals. CDHS determined that the requirements listed in this section are the minimum necessary to protect the public health and safety. CDHS's policy decisions remediate the hospitals with the leanest staffing, effectively raising the bar for the standard of acceptable staffing.

In its preamble to the legislation, the Legislature "finds and declares all of the following:

a) Health care services are becoming complex and it is increasingly difficult for patients to access integrated services.
b) Quality of patient care is jeopardized because of staffing changes implemented in response to managed care.
c) To ensure the adequate protection of patients in acute care settings, it is essential that qualified registered nurses and other licensed nurses be accessible and available to meet the needs of patients.
d) The basic principles of staffing in the acute care setting should be based on the patients' care needs, the severity of condition, services needed, and the complexity surrounding those services."

The Legislature clearly believed that the quality of patient care was related to the number of licensed nurses at the bedside, and wished to ensure a minimum, adequate number. When Governor Davis signed the bill on October 10, 1999, he accompanied the measure with a "sign message" which read, in part, "Registered nurses are a critical component in guaranteeing patient safety and the highest quality health care. Over the past several years many hospitals, in response to managed care reimbursement contracts, have cut costs by reducing their licensed nursing staff. In some cases, the ratio of licensed nurses to patients has resulted in an erosion in the quality of patient care." (Exhibit A)

The CDHS considered proposing regulations requiring staffing ratios for registered nurses in acute care hospitals in 1992. However, upon further consideration, the Department instead opted for regulations requiring that hospitals have a patient classification system (PCS) in place. The PCS was intended to assure that the number of nursing staff was aligned to the health care needs of the patients, while allowing the provider maximum flexibility for the efficient use of staff. The Department spent more than four years working with key statewide nursing and hospital organizations, including the California Nurses Association and the California Healthcare Association, to develop the final regulations which became effective on January 1, 1997.

California's hospitals are currently required (22 CCR, 70053.2 and 70217) to use a PCS for determining the staffing needs of individual units. PCS are defined as systems that include:

(1) A method to predict nursing care requirements of individual patients.

(2) An established method by which the amount of nursing care needed for each category of patient is validated for each unit and for each shift.

(3) An established method to discern trends and patterns of nursing care delivery by each unit, each shift, and each level of licensed and unlicensed staff.

(4) A mechanism by which the accuracy of the nursing care validation method described in (2) above can be tested. This method will address the amount of nursing care needed by patient category and pattern of care delivery on an annual basis, or more frequently, if warranted by the changes in patient populations, skill mix of the staff, or patient care delivery model.

(5) A method to determine staff resource allocations based on nursing care requirements for each shift and each unit.

(6) A method by which the hospital validates the reliability of the patient classification system for each unit and for each shift.

(7) A written staffing plan must be developed by the administrator of nursing service or a designee, based on patient care needs determined by the patient classification system. The staffing plan must be developed and implemented for each patient care unit and must specify patient care requirements and the staffing levels for registered nurses and other licensed and unlicensed personnel.

(8) The plan must include the following:

(a) Staffing requirements as determined by the patient classification system described above for each unit, documented on a day-to-day, shift-by-shift basis.

(b) The actual staff and staff mix provided, documented on a day-to-day, shift-by-shift basis.

(c) The variance between required and actual staffing patterns, documented on a day-to-day, shift-by-shift basis.

(d) The staffing plan must be retained for the time period between licensing surveys, which includes the Consolidated Accreditation and Licensing Survey (CALS) Process.

(8) The reliability of the patient classification system for validating staffing requirements must be reviewed at least annually by a committee appointed by the nursing administrator to determine whether or not the system accurately measures patient care needs.

(9) At least half of the members of the review committee must be registered nurses who provide direct patient care.

(10) If the review reveals that adjustments are necessary in the patient classification system in order to assure accuracy in measuring patient care needs, such adjustments must be implemented within thirty (30) days of that determination.

(11) Hospitals must develop and document a process by which all interested staff may provide input about the patient classification system, the system's required revisions, and the overall staffing plan.

These PCS requirements will not change with the addition of the minimum nurse-to-patient ratios required by HSC 1276.4.

There have been no studies to date to determine the effectiveness of the PCS. However, it was the perception of some working nurses, and the labor organizations that represent them, that the PCS does not always accurately reflect the patients' needs for increased staffing. Consequently, the Legislature passed, and the Governor signed, AB 394 (Kuehl, Chapter 945, Statutes of 1999) requiring the establishment of minimum numerical licensed nurse-to-patient ratios.

Acute care hospitals in California are surveyed routinely using the Consolidated Accreditation and Licensing Survey (CALS) process once every three years. In addition, surveyors make unannounced visits to hospitals to conduct investigations into complaints that are received at the Licensing and Certification Program's District Offices. HSC 1276.4 does not change the number nor frequency of surveys, and neither do these proposed regulations. The survey process will be changed only in that surveyors may add the additional step of verifying compliance with the ratios. Currently, acute care hospital CALS surveys include an evaluation of the hospital's compliance with all staffing requirements imposed under 22 CCR 70053.2 and 70217 for the PCS whenever survey findings suggest that such an evaluation is appropriate.

It is the Department's intent that the minimum staffing ratios set at 22 CCR 70217(a) will co-exist with the existing PCS regulations at 70053.2 and the current 70217(a), proposed to be 70217(b). HSC 1276.4 adds a needed refinement to the existing PCS requirements. The establishment of minimum nurse-to-patient ratios will set the baseline licensed staffing requirement for every unit type. The proposed minimum ratios will increase the number of licensed nurses on the 5-25% of hospital shifts with the leanest staffing statewide as soon as the regulations go into effect. In 2005 and 2008, the ratios for medical/surgical, step-down, specialty, and telemetry units will change to further enrich staffing in those units. The PCS will remain in place to indicate the needed increases beyond minimum licensed staffing as patient acuity increases.

Subacute Units and Transitional Inpatient Care Units:

HSC 1276.4(a) lists those units that are intended to be included in the definition of "hospital unit". Included in that listing are "subacute care units and transitional inpatient care units". CDHS proposes not to address those units in these regulations. Subacute and Transitional Inpatient Care are not supplemental services nor licensed bed categories under general acute care hospital licensing regulations. They exist at 22 CCR sections 51215.4(e), 51215.5(e), and 51215.8(t) as Medi-Cal contracted reimbursement categories. Some general acute care hospitals and skilled nursing facilities contract with

Medi-Cal to provide these services, and are consequently reimbursed at rates which are lower than the acute care rate but higher than a general skilled nursing service rate. These services are provided in certified skilled nursing beds and reimbursed as skilled nursing facility level of care. Along with the set rates, required staffing for this skilled nursing facility level of care is expressed in regulation as "nursing hours per patient day" (NHPPD). The NHPPD are not readily convertible to "whole person" ratios, and so CDHS did not attempt to make a numerical conversion. These regulations do not propose to replace current staffing requirements, which are in place in regulation and in contracts and are well understood by the Medi-Cal Program as well as the contracted provider community. The reimbursement category of "Transitional Inpatient Care Unit" was eliminated by statute (AB 2877, Ch. 93, Statutes of 2000), with a sunset date of January 1, 2002. Staffing regulations governing Subacute Units will be included in a subsequent CDHS regulation package.

The Workforce Debate:

The ongoing public health debate, and the resultant tension between labor organizations representing nurses and provider organizations representing hospitals, centers on the numbers, cost, and availability of nurses to provide safe and professional care for patients. Many nurses now believe that staffing levels in acute care hospitals are unsafe for patients, and continuing to decline. In a recently published study, two-thirds of nurses in the United States reported that they believe that staffing in their hospitals is inadequate to provide high-quality care, and 45% stated that the quality of care in their hospitals had deteriorated in the last year (Exhibit B). Physicians agree, with 64% rating nurse staffing levels at their hospitals as "fair" or "poor" (Exhibit C). Patients and their families are also concerned with the paucity of nursing staff at hospitals as evidenced by the growing trend of hiring private duty nurses when a loved one needs hospitalization (Exhibit D).

From December 7, 2000 through January 19, 2001, a national nursing survey was posted at www.nursingworld.org, the website for the American Nurses' Association (ANA). The survey was promoted in the ANA's media outlets, including *The American Nurse* and *The American Journal of Nursing.* Nearly 7300 nurses took part in the study, which found the following: 75% reported that the quality of nursing care had declined in their work setting, a decline which 69% blamed on inadequate staffing. 56% noted a reduction of the time available for registered nurses to provide direct care. One of the most telling statistics was that 41% of RNs polled would not recommend that a family member receive care in the hospitals in which they work. 55% of nurses surveyed also reported that they would not recommend the nursing profession as a career for their friends or children. (Exhibit E and Exhibit F).

These results continued the trend found in a previous study conducted for the American Journal of Nursing by Boston College School of Nursing's Assistant

Professor Judith Shindul-Rothschild, RN, PhD. That study, based on a survey of 7500 RNs found that 60% noted a reduction in the number of registered nurses providing direct care, with 40% reporting substitution of unlicensed personnel for registered nurses. The study also found disturbing increases in unexpected patient readmissions, complications, medication errors, wound infections, patient injuries and patient deaths. 36% of RNs in this study would not recommend that a family member receive care in the hospitals in which they work (Exhibits G and H).

The findings of a recent 20-hospital study (Exhibit I) found substantial variation in nurse-to-patient ratios for inpatient AIDS care. The study concluded that higher nurse-to-patient ratios are strongly associated with lower mortality. The researchers estimated that, holding all other factors constant, an additional nurse per patient day cut the likelihood of dying within 30 days of admission by more than half. Another recent study found that hospitals that had the richest nurse-to-patient ratios had significantly shorter overall lengths of stay, as well as fewer ICU days (Exhibits V and V-1).

In October of 2002 Linda Aiken, PhD, RN et. al. published a study in the Journal of the American Medical Association entitled "Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction". The study was designed to determine the association, if any, between nurse-to-patient ratios and risk-adjusted patient mortality and failure-to-rescue within 30 days of admission, as well as nurse-reported job dissatisfaction and job-related burnout (Exhibit V-2). ("Failure-to-rescue" refers to the licensed nurse's failure to respond quickly and intervene effectively when patients (in this study, post-surgical patients) begin to develop signs and symptoms of serious complications. Failure to rescue, then, results in increased patient mortality.) The likelihood of failure-to-rescue was expressed as odds ratios (ORs), after patient and hospital characteristics were controlled for. The study concluded that the OR of failure-to-rescue was sizeable and significant, indicating that the odds of patient mortality increased by 7% for every additional patient in an average nurse's workload and that the difference from 4 to 6 and from 4 to 8 patients per nurse would be accompanied by 14% and 31% increases in patient mortality, respectively. The study concluded, "If the staffing ratio in all hospitals was 8 patients per nurse rather than 6 patients per nurse, we would expect 2.6 additional deaths per 1000 patients and 9.5 additional deaths per 1000 patients with complications....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. Our major point is that there are detectable differences in risk-adjusted mortality and failure-to-rescue rates across hospitals with different registered nurse staffing ratios." The study also showed that nurses who worked in hospitals with the highest nurse-to-patient ratios were more than twice as likely as nurses who worked at lower ratios to report burnout and job dissatisfaction, and four times as likely to report that they intended to leave their current jobs within one year. If that increase in stated intentions truly

resulted in resignations, given the high (and steadily increasing) cost of replacing nursing staff, then improving staffing may not only prevent patient deaths but may also improve staff retention and decrease hospital costs.

The positive impact of changes in workload on the nursing workforce was recently demonstrated in the state of Victoria, Australia. After intense lobbying and political pressure from the Australian Nurses Association, the Victorian Ministry for Health, which is responsible for the operation of acute care hospitals there, adopted the union-backed nurse-to-patient ratios effective December 1, 2000. For medical/surgical units, those ratios varied from 1:4 to 1:6, with more patients permitted on the night shift; for emergency departments the ratio was 1:3 at all times, and the triage and charge nurses were not counted in the ratios. The Victorian government also committed to--and funded--re-entry and refresher programs for nurses who wished to return to the workforce, as well as a vigorous advertising recruitment campaign. In addition, Victoria mandated a 12.5% pay increase over three years, paid study leave, and financial rewards based on education. The results were impressive. In 1999, Victoria's hospitals had approximately 20,000 full-time equivalent nursing positions, with 1300 of those positions vacant. By October, 2001, there were an additional 2650 full-time equivalent nurses employed in Victoria's hospitals—half filling the vacancies and the other half to staff up to meet the ratios (Exhibits J, K, and L).

Public Input:

There is intense interest in these new regulations among nurses in California. Between the time that the enabling law was passed and the initial draft regulations were made public, the Department received over 3800 postcards, telephone calls, and e-mails from individual working nurses expressing their thoughts on the ratios. There have been organized town hall meetings and rallies around the State, attended by nurses as well as hospital administrative staff, which CDHS staff also attended in order to hear firsthand the personal testimony of working nurses. CDHS also established a dedicated e-mail address to facilitate public input on the ratios before the public comment period began.

The Department received four formal proposals for setting the ratios in each unit. They came from three labor organizations: the California Nurses' Association (CNA), Service Employees International Union (SEIU) Nurse Alliance, and United Nurses' Associations of California (UNAC) of the American Federation of State, County, and Municipal Employees (AFSCME). CDHS also received a formal staffing ratio proposal from the California Healthcare Association (CHA), which is the provider organization representing more than 400, or greater than 85%, of acute care hospitals statewide.

Proposals: L&C Summaries and Assessments:

CNA Proposal:
The CNA proposed the adoption of the following ratios:

Critical Care Unit/ICU	1:2
Burn Unit	1:2
Neonatal ICU	1:2
Labor and Delivery	1:1
Postpartum	1:5
Well Baby Nursery	1:5
Postanesthesia Service	1:2
Emergency Department	1:3
Operating Room	1:1
Pediatric Unit	1:3
Stepdown Care Unit	1:3
Specialty Care Unit	1:3
Telemetry Unit	1:3
General Medical/Surgical Unit	1:3
Subacute/Transitional Care	1:4
Behavioral/Psychiatric Unit	1:4

The CNA process used a panel of 25 of their nurse-members to assign patients to one of seven "virtual units" based on about 500 All Patient Refined – Diagnostic Related Groups (APRDRG) scales. Within each APR-DRG, they calculated the Severity of Illness class using OSHPD hospital discharge data from 1993-1998. Once APRDRGs were assigned to "presumptive (or virtual) units", average acuity was calculated within that unit. The average acuity of the ICU was used as a common numerator, with the other units' calculated acuity indicator taken in turn as the denominator, and the quotient multiplied by two (because 1:2 is the mandated minimum staffing ratio in ICUs). The product was then designated as the "middle range staffing ratio" for that unit.

The conceptual framework of the CNA proposal rests on a series of assumptions, among them that appropriate staffing requirements increase linearly with severity of illness, that patients can reliably be assigned to one of seven presumptive units, that "severity subclass assignments" can be used as a metric for acuity across APRDRGs as well as within them, etc. There is also the problem of the "floor effect". That is, the APRDRG scale (severity of illness score) is a range from 1-4. Given the mean ICU severity of 2.21, no unit could have a mean acuity ratio less than 0.55 (2.21/4=0.55) or greater than 2.21 (2.21/1=2.21). The 0.55 is not a problem, because rounded up it will give a ratio of 1:1 (0.55 X 2=1.1). However, 2.21/1 X 2=4.42; that is, a ratio of 1:4.42. Therefore, the finding that all acute care units require a ratio of at least 1:4 was predetermined by the 1-4 range that was used. (See Exhibit M for complete proposal).

In summary, the CNA took a very innovative approach to ascertaining what the ratios should be. They studied a massive amount of information and made an attempt to generate scientifically sound ratios. However, a number of concerns about the way that the study was conducted and the appropriateness of the data relied upon, as well as CDHS's determination to conduct its own study, precluded the use of the CNA proposal as submitted.

A University of California (UC) research team was contracted by CDHS to assist in the development of the on-site hospital survey (described on page 15) study tool and the analysis of the data it produced. That research team also reviewed the CNA study. Their review concluded that flaws in the assumptions driving the [CNA] analysis limited the extent to which the results can be applied to policy-making. The UC review can be found in Exhibit N.

SEIU Proposal:

The SEIU proposed the adoption of the following ratios:

Critical care Unit/ICU	1:2 (+1RT^:4 Vents#)
Burn Unit	1:2 (+1RT^:4 Vents#)
Neonatal ICU	1:2 (+1RT^:2 Vents#)
Labor and Delivery	1:2
Antepartum	1:3
Postpartum	1:3 couplets
Well Baby Nursery	1:6
Postanesthesia Service	1:2 Adults; 1:1 Peds
Emergency Department (ED)	1:3
ED-Critical Care	1:2
ED-Trauma	1:1
Operating Room	1:1RN+1LVN/1Tech
Pediatric Unit	1:3
Stepdown Care Unit	1:3
Telemetry Unit	1:3
General Medical/Surgical Unit	1:4
Subacute/Transitional Care	1:5
Behavioral/Psychiatric Unit	1:2/1:3/1:5 (by acuity)

^RT= Respiratory Therapist
#Vents= Ventilator-Dependent Patients

SEIU represents over 100,000 health care workers employed in many different classifications within acute care hospitals throughout California. Their process was to organize their member nurses into committees, one committee for each hospital unit. Each committee was comprised of 6-10 RNs and LVNs who were convened by conference call three to five times to deliberate on and

draft the proposed ratios. The final proposal was based on a consensus of committee members, and was ratified by assemblies of SEIU's membership around the State, at which a large number of workers from many hospitals and many classifications voted. SEIU also conducted a limited search of academic literature, and provided CDHS with the results of that search in the form of an annotated bibliography. (For SEIU's complete proposal, please see Exhibit O, dated 01/13/00, with follow-up letter dated 07/13/01).

SEIU's fundamental premise is that staffing a hospital is a team effort. SEIU encouraged CDHS to look at all categories of hospital workers, because they stated that focusing on the single profession of nursing undermines the quality of care and distorts the nature of the work that must be done. Also, they were concerned that focusing only on nursing would be inimical to the interests of the members they represent.

The SEIU proposal is very task based, i.e., it is based upon "those things which every nurse on every shift must do, what every nurse will always do for at least some patients, and what every nurse will often do for some patients". The length of time the listed tasks should take, in the opinion of the nurse-members on the Committee, dictates the number of nurses needed for each patient.

SEIU also proposed a number of improvements to the PCS, as well as unannounced inspections and re-inspections of hospitals by CDHS enforcement staff.

In summary, SEIU's proposal represents a tremendous mobilization of their membership and an effort to make their proposal truly representative of the wishes of their membership. Their approach is democratic, creative, and instructive. Since their membership is very large and divergent in the health care services they provide, their proposal has merit and has received careful consideration by the Department.

It is important to note, however, that they make no claim that their method is based on objective data. The proposals are not supported by a claim that they are representative of current practice, nor are they based on any claim of "best practice". For these reasons, and because the Department desired to conduct its own study, we did not adopt the proposal as submitted.

UNAC Proposal:
The UNAC proposed the adoption of the following ratios:

Critical Care Unit/ICU	1:2
Burn Unit	1:2
Neonatal ICU	1:2
Labor and Delivery	1:2
Postpartum	1:3 couplets
Well Baby Nursery	1:6

Postanesthesia Service	1:2
Emergency Department (ED)	1:3
ED-Critical Care	1:2
Operating Room	1:1
Pediatric Unit	1:3
Stepdown Care Unit	1:3
Specialty Care Unit	1:3
Telemetry Unit	1:3
Oncology Unit	1:4
General Medical/Surgical Unit	1:4
Subacute/Transitional Care	1:5
Behavioral/Psychiatric Unit	1:5

UNAC represents over 10,000 health care workers throughout Southern California, including several bargaining units comprised entirely of RNs. UNAC's recommendation to CDHS originated from a meeting of union's leadership, who are themselves working nurses and other types of health care professionals elected by their peers. UNAC also did a study of the California Code of Regulations, Title 22, and compared their proposals to those requirements already in regulations. (For the entire UNAC proposal, please see Exhibit P).

A fundamental premise of the UNAC proposal is that safe and adequate staffing can be based on a reasonable assessment of the anecdotal reports of the day-to-day experiences of its members. It is also important to note that all of UNAC's proposed ratios address RN-to-patient ratios only. In units where LVNs may, in the judgment of CDHS, be utilized, they request that CDHS establish a precise, closely-defined skill mix.

UNAC's leadership has provided CDHS with their perspective as leaders of a labor organization. As they represent a large and diverse corps of health care workers in non-profit, for-profit, district, and Federal hospitals, their proposals merited and received careful attention and regard.

However, because UNAC's proposal represents the judgment of its elected leadership with no direct input from its membership, and because no justification is provided for the proposals (other than the best professional judgment of that leadership), combined with CDHS's desire to conduct a study of its own, the proposal was not adopted as submitted.

CHA Proposal:
The CHA proposed the adoption of the following ratios:

Critical Care Unit/ICU	1:2
Burn Unit	1:2
Neonatal ICU	1:2
Labor and Delivery	1:3

Postpartum	1:4 couplets
Well Baby Nursery	1:8
Postanesthia Service	1:3
Emergency Department	1:6
Operating Room	1:1
Pediatric Unit	1:6
Stepdown Care Unit	1:6
Telemetry Unit	1:10
Oncology Unit	1:10
General Medical/Surgical Unit	1:10
Subacute/Transitional Care	1:12
Behavioral/Psychiatric Unit	1:12

CHA, together with the Association of California Nurse Leaders, convened a statewide taskforce to identify what they believed were clinically appropriate staffing ratios for all major patient care units. (Please see letter from CHA dated 08/17/00, Exhibit Q). They did that by evaluating their own and other hospital's units functioning with various ratios. They consulted with designers of patient acuity systems, and developed standardized definitions to bring enhanced clarity to communications. They sent the taskforce's proposal to all California hospital chief executive officers and chief nursing officers for input and approval. The CHA's final proposal represented the majority's view. (For the complete proposal, please see Exhibit R).

CHA's essential premises include the observation that there are currently no academic or empirical studies that define nurse-to-patient ratios that are appropriate for improving the quality of patient care in the various hospital units. CHA suggested, therefore, that CDHS delay implementation of AB 394 until there are credible, evidence-based studies upon which to base the regulations. CHA also suggested in other communications with CHDS that nurse-to-patient ratios may negatively impact the quality of care if they cause the utilization of higher percentages of nurses at the expense of a "milieu rich in clinical diversity". They argued, on behalf of their membership, that hospitals cannot afford to hire more nurses because of the extreme fiscal constraints caused by seismic retrofitting, Health Insurance Portability and Accountability Act (HIPPA) implementation, etc., in concert with the fiscal pressure of managed care. They further posited that, even if hospitals somehow were able to afford to hire more nurses, there aren't enough nurses available due to the nursing shortage. They stated that, if hospitals cannot comply with the mandated ratios, hospitals will be forced to close units and suspend services, thus limiting, and possibly denying, access to care for many Californians. Closures and suspensions in services could, in turn, cause lengthy patient transports, delays in start of care, and, potentially, increased morbidity and mortality.

CHA's proposal represents the considered judgment of the leadership of the State's largest provider group. Their concerns about limiting access to care

are especially relevant, and CDHS has carefully evaluated the possibility that care and services could be diminished or denied if the proposed ratios were unreasonable. CHA's caution about imposing ratios that will place heavy and unnecessary burdens on the fiscal reserves of providers deserved and received thoughtful and deliberate consideration.

However, given the statutory mandate, CDHS did not have the option of declining to implement the ratios, notwithstanding the nursing shortage and the hospitals' financial concerns. However, the Department did evaluate the multitude of factors effecting acute care, and is working toward facilitating compliance with the staffing ratios while easing any undue fiscal burdens by providing maximum flexibility for hospitals within the bounds of patient health and safety. CDHS also chose to phase-in the richer ratios for Medical/Surgical units for one year, and for Step-down, Telemetry, and Specialty Care units for four years in order to allow providers time to develop a strategy for compliance, for the recruitment of additional nurses, and for the education and training of additional classes of nursing students.

In response to the concern raised by many providers that meeting the mandated ratios would not be possible in light of California's nursing shortage, on January 23, 2002 Governor Davis announced his Nurse Workforce Initiative (See Press Release 02:033, Exhibit S), a $60 million effort to address the nursing shortage in California. The Initiative includes funding for expanded training and preceptorship positions in hospitals, community colleges, and the California State University (CSU) system; five regional workforce collaboratives to train 2,400 new licensed nurses; a plan for upgraded training opportunities for health care workers' career ladders; and a statewide media recruitment campaign, among other provisions. In addition, the 2001-2002 and 2002-2003 budgets include $4 million for 1,000 additional student nurse training program seats at community colleges across the State. The Governor and his Administration are committed to increasing the number of licensed nurses available to provide patient care in California.

In summary, the four proposals outlined above reflect the interests of the submitting organizations and their best recommendations, but do not present an adequately supported, documented basis for their specific proposed ratios. CDHS chose to take into consideration all of these perspectives in reaching a broader, more objective consensus of workable, reasonable standards that would improve nurse staffing levels and quality of care to patients.

Current Status of Ratios in Regulation:

In California, the nurse-to-patient ratio of 1:2 was set for intensive care units in 1975 at 22 CCR 70495 (e). An Institute of Medicine study in 1996 (Exhibit T) concluded that there was insufficient evidence that mandating a specific ratio in hospital nursing units resulted in quality improvements for

patients, nursing staff, or institutions. More recent studies, however, are providing a link between the staffing level in ICUs and improved outcomes. In Maryland, where there is no specific minimum nurse-to-patient staffing ratio in ICUs, a study was conducted in 1997 to test if different staffing practices had an impact on the recovery of patients who were critically ill after abdominal aortic surgery. That study determined that in hospitals where the ratio of ICU nurses to patients was 1:3 or greater, the patients had a significantly higher rate of medical complications compared with patients in ICUs where nurses cared for 2 or fewer patients (Exhibit U). In addition, a previous study by the same principal investigator demonstrated that when ICU nurses cared for more than 2 patients, the mean number of days those patients remained in the ICU increased by 49% (Exhibit V). These new studies now provide some evidence-based validation for the California standard.

The public health depends on the availability of adequately staffed acute care hospitals. CDHS L&C has experienced a steadily increasing volume of complaints about patient care in acute care hospitals. L&C received 3348 such complaints in 2000, which represents a 30% increase in volume over the 1995 level. This may reflect that the quality of care is declining; it certainly suggests increasing consumer dissatisfaction with the care received.

A search of health-related literature, conducted by a team of researchers from the UC system under contract with CDHS, identified 2870 articles of potential interest for developing appropriate ratios. Of these, 456 were selected for retrieval based on established inclusion criteria. (For a detailed description of the criteria and methodology, please refer to Exhibit W). 419 of the 456 articles were subsequently rejected for not reporting key information, leaving 37 articles for analysis. The results of the analysis are detailed in the evidence tables in Section I of the "Hospital Nursing Staff Ratios and Quality of Care" study (Exhibit W). Essentially, there was no hard, scientific evidence in the literature indicating the number of patients nurses can safely and effectively handle while providing quality patient care.

Additionally, standardized nurse-to-patient ratios have not been mandated or required in any other state. Therefore, there is no experience with specific nurse-to-patient ratios from which to determine with certainty the exact number of nurses needed based strictly upon the number of patients to be provided care. The mandate in California is to set a minimum level, allowing hospitals to more specifically identify the nursing care needed based upon the hospitals' patient classification system. Faced with the lack of research and the lack of any other State's experience in setting ratios, CDHS decided to conduct a study to determine how acute care hospitals were currently staffing their units with licensed nurses.

Description of the Process:

The first step was to collect data concerning the current level of staffing in California hospitals. The Department began by utilizing the data collected by the Office of Statewide Health Planning and Development (OSHPD).

OSHPD collects data annually from all acute care hospitals in the State. They collect a number of items, including an inventory of provided services, number of beds, expenses by classification and cost center, productive hours per patient day by employee classification and cost center, and numbers of patient admissions and discharges. California's OSHPD collects, by far, more comprehensive data about hospital usage and staffing than any other state in the nation.

For purposes of developing staffing minimums, however, there are some serious limitations to the OSHPD data. The most important limitations are:

1) "Productive Hours per Patient Day" (PHPD) for nurses includes many hours not spent at the bedside. In fact, "productive nursing hours" includes all hours worked by the nurse (i. e., all hours not spent as vacation or sick leave). During those hours, nurses may be engaged in other activities, including continuing professional education, quality assurance, management, etc. Thus, PHPD are likely to overestimate the actual amount of bedside care, and the magnitude of the discrepancy may vary from hospital to hospital.

2) The "patient day" that the hospitals report is the sum of the patients in the hospital at a specified time each day. In other words, the average "patient day" is assumed to be 24 hours. For any given hospital, this may or may not be true. Assuming a standard census time of midnight, hospitals that tend to admit patients very soon after midnight (e. g. through the Emergency Department) and discharge them the next day before midnight will appear to have a lower daily census overall (and thus have fewer patient days) than hospitals that admit patients late in the afternoon or evening (just before the census is taken). All else being equal, the hospitals that admit a number of patients after midnight and discharge patients before midnight the next day would appear to have richer nurse-to-patient ratios than is actually the case.

3) The additional work required to admit and discharge patients is not captured by PHPD. Previous studies have shown that medical resource use is greatest during the first few days of hospitalization (Exhibit X). Therefore, two hospitals with the same daily census—one with high patient turnover and one with low patient turnover—could experience very different staffing demands.

4) Not all patient days are alike. Patients differ in terms of severity of illness, acuity, and care requirements. The PHPD metric does not

adjust for patient severity. Therefore, two hospitals with the same census but different overall acuity in their patient populations could require very different staffing patterns.

5) Not all nurses are alike. When nurses are "floated" out of their specialty area, they may not perform with the same level of competence, and may not have the same work output, as nurses trained for that area. For example, an RN assigned to the labor and delivery unit who is floated to a medical/surgical unit may not be as productive as the regular medical/surgical unit staff. Similarly, hospitals that have a high use of registry nurses may not attain a high level of work output, because those nurses are constantly learning to work in new environments. Therefore, hospitals that regularly float their own staff to different units and/or have a high use of registry staff may have higher staffing needs than hospitals with more stable staffing patterns.

6) PHPD reflects average staffing across a 24 hour period, and does not portray fluctuations due to day/night scheduling patterns, absenteeism, and other circumstances, both foreseen and unforeseen.

Even with these limitations, however, PHPD is the best available metric for estimating current nurse staffing levels in California using administrative data.

In order to get a clearer picture of nurse staffing in California's acute care hospitals, the administrative data needed to be supplemented by clinical data. Toward that end, the Department again partnered with the UC research team to gather empirical, real-world data about our health care workforce.

Design of the On-Site Study:

CDHS worked with the UC research team to develop a stratified sample of California's 495 hospitals. The hospitals were sorted into six categories: academic medical centers, Kaiser, small and rural, other public, other private, and state facilities. (Kaiser hospitals were given a separate category because OSHPD does not collect hospital-specific data on the Kaiser organization as it does on other hospitals. Instead, the Kaiser hospital system is permitted to report in the aggregate, in conformance with HSC 128760(f).)

Within each of the six categories, the number of hospitals that would yield a statistically valid and representative sample was determined by the contracted statistician and epidemiologist. Ultimately, the number of hospitals to be visited for each category was: Ten (10) academic medical centers (all), ten (10) Kaiser hospitals, twenty (20) small and rural hospitals, ten (10) other public, thirty (30) other private, and ten (10) state facilities (all), for a total of 90 hospitals statewide. CDHS chose seventeen (17) experienced facility surveyor registered nurses to

administer the study. All were from Licensing and Certification's headquarters staff, so that staff performing the study would not be the same surveyors who were in an enforcement role in the field. This also minimized impact on the field staff and allowed easier logistics for travel planning, etc.

CDHS utilized its registered nursing staff to work with the research team to develop a study tool to capture the way that hospitals are actually staffing their units. The tool, after numerous reiterations and refinements, consisted of three segments: the Cover Sheet, the Unit Inventory and the Unit List and Selection Form, and the Nurse Staffing Study Form. (Exhibit Y).

The Cover Sheet was designed to gather basic information about the hospital, the date and time the study began and ended, the name and contact information about the hospital administrator, the name of the PCS in use at that hospital, etc.

The Unit Inventory and the Unit List and Selection Form were designed to sort the hospital's units into categories of unit types. So that the study would maintain internal consistency, a script was developed that was read to the hospital's administrative staff, which included definitions of each unit type. Hospital administration then determined whether or not their facility had a unit (or units) meeting the stated description. The name(s) and location(s) of the units, as well as contact information for the unit, was recorded on the form.

The Nurse Staffing Study Form was used on the individual units. Information related to the shift that was currently in progress was gathered, as well as information on the previous 24 hours, including patient census, numbers of discharges and admissions, the number of licensed and unlicensed staff on duty, and the nursing care model in use. Questions were included that gathered demographic information about nurses in order to get a snapshot of their education, employment status, and years of practice. That information would serve to confirm or refute earlier studies of nursing and provide CDHS with a picture of the current nursing workforce.

On every unit, the form called for shift-specific data for the seven days preceding the date of the study visit (a maximum of twenty-one shifts in all). For each shift, the numbers of RNs, LVNs, Unlicensed Assistive Personnel, and patients were documented. Because the date of the study varied over the course of the three weeks it was being conducted around the State, the "previous seven day" shift information reflected a variety of dates. In addition, the same information was requested for ten (10) specific dates during the first three (3) months of 2001. The dates were chosen in advance by the research team to include all days of the week, including weekends and holidays. That first-quarter data produced information about the same shift on the same date at all of the hospitals in the study.

Before the tool was finalized, CDHS used the draft tool to conduct a field pre-test at four (4) hospitals representing four different strata. The results of the pre-test led to further refinements to the tool.

After the tool was finalized, CDHS developed a lesson plan to teach the nurse surveyors about the new law, the purpose of the study, and the design and use of the tool. The nurse surveyors were brought together for an intensive, one-day training session, given by CDHS. A representative of the UC research team was also on hand during the training to answer technical questions about the selection of the sample and the design of the tool. The nurse surveyors were also given instructions and contact information so that appropriate CDHS staff could be reached as needed for consultation while the studies were progressing in the field.

The one-day training was conducted, and the field studies commenced the following day.

The Study Process:

Prior to implementation, the University of California Davis Medical Center's Committee for the Protection of Human Participants approved this study. All visits were conducted between April 30, and May 18, 2001. All of the visits were unannounced. The surveyors introduced themselves to Administration as soon as they arrived, and then explained the purpose of the visit. They began the unit inventory and proceeded through the study protocol, first with hospital administration and then with the nurse managers and staff nurses on each of the selected units.

All of the information collected was reviewed by CDHS to ensure that it was correct and complete. Subsequently, all data was entered and electronically submitted to the UC researchers for analysis.

The study provided the Department with a portrait of nurse staffing as it is currently occurring in general acute care hospital units. It included shift by shift retrospective data for the week preceding the study, as well as staffing information for the ten randomly selected 24-hour periods over the first three months of 2001. Table 3a on the next page gives a broad look at the number of patients per licensed nurse in each unit type over the standard percentile rankings for all hospitals visited.

Table 3a. Patients per licensed nurse by survey nursing unit type, weighted estimates[1] for all hospitals and shifts.

Survey Unit Type	Number of Hospitals	Number of Shifts	Patients per Licensed Nurse						
			5%ile	10%ile	25%ile	Median	75%ile	90%ile	95%ile
Labor and Delivery Only	39	39	0.55	0.56	0.86	1	1.33	1.8	2
Postpartum Only	37	1650	2	2.67	4	5.07	6.38	7.67	8.67
Combined Post-partum/ Labor and Delivery	13	499	0.67	1	1.5	2.25	3.17	4	4.5
Stepdown Only	20	780	1.6	2	2.33	2.83	3.4	4	4
Telemetry Only	21	956	2.56	2.83	3.71	4.5	5.6	6.8	8.25
Combined Stepdown/Telemetry	18	793	2	2.5	2.67	3.36	4	4.62	5
Medical Only	14	726	3.17	3.71	4.4	5	5.8	7	8
Surgical Only	21	920	2.44	2.89	3.6	4.57	5.67	7.33	8.5
Combined Medical/Surgical	40	1781	3	3.5	4.3	5.14	6	7.5	8
Emergency	71	71	0	0.33	0.5	1	1.6	2	2.86
Pediatric	31	1320	1	1.5	2.5	3.4	4.5	5.5	6
Oncology	13	550	2.5	2.91	3.75	4.5	5.33	6.2	7.5
Psychiatric (Acute Care Hospitals)	20	979	2	2.5	3.5	4.5	6	11	15
Sub-Acute/Transitional	8	343	3.67	4.4	5.5	7.25	10.75	13.33	15
Postanesthesia	68	68	0	0	0	0.8	1.82	2.5	3.43
Mixed	47	2040	1	1.67	3.67	5	6	7.5	8

[1] These estimates are based on the actual number of licensed nurses, and the actual number of beds or gurneys occupied by patients, at the beginning of the sampled shift.

For an in-depth discussion of the study process, forms, and procedures, please see Exhibit Z, included as a document relied upon for the development of the regulations.

In summary, CDHS responded to the mandate to establish these nurse-to-patient ratio regulations by performing an extensive literature search, soliciting the recommendations of professional organizations representing physicians and nurses, having discussions with other states and countries about their experiences with acute care staffing, and extracting the information that could be obtained about nurse staffing from the OSHPD data. CDHS also solicited input from professional nurses on its own staff, as well as the perspectives of the major stakeholders before the proposed ratio regulations were drafted. Because none of the sources of information provided CDHS with hard scientific evidence of the optimal nurse staffing ratio for each individual unit, and in order to supplement the other sources of information empirically, CDHS conducted an on-site hospital study. The purpose of the study was to discover the level of nurse staffing practiced in hospitals in the absence of these proposed ratio regulations. It also gave CDHS the opportunity to estimate the FTE and fiscal deficits that may occur with various ratio proposals, and provided a foundation for the required study evaluating the effect of these regulations five years after adoption. The Aiken study (Exhibit V-2) has recently provided validation that increasing the amount of nurse staffing in acute care hospitals has the effect of decreasing patient mortality and improving both patient and workforce outcomes.

Section 70217(a). Nursing Service Staff.

The Department proposes to adopt this section to define the nurse-to-patient ratios mandated by AB 394 (Kuehl, Chapter 945, Statutes of 1999). Proposed regulations require that hospitals provide staffing by licensed nurses, which includes registered nurses and licensed vocational nurses within the scope of their licensure, in accordance with specific nurse-to-patient ratios. Under California law, the term "licensed nurses" includes both registered nurses and licensed vocational nurses. This is specified in the regulations so that the general public will clearly understand the term as used in this regulation.

The Department clarified that the phrase "licensed nurse" includes "licensed psychiatric technicians in psychiatric units only." This change means that the general provisions of this section that apply to licensed nurses, would also apply to licensed psychiatric technicians assigned to provide care within their scope of practice in psychiatric units for the purposes of the licensed nurse to patient ratios.

The Department added the descriptors "licensed," "registered," "licensed vocational" or "licensed psychiatric technician" throughout this section to more clearly specify which licensing category is required in the regulation.

In order to clarify that a hospital cannot reduce overall staffing by assigning licensed nurses to duties customarily and appropriately performed by unlicensed staff, it is stated that staffing for care not requiring a licensed nurse is not included within these ratios and shall be determined pursuant to the patient classification system. At 22 CCR 70053.2 and 70217(b), the PCS is defined as a system that is established to determine the amount of nursing care needed by each unit, on each shift, and for each level of licensed and unlicensed staff. Setting a minimum level of staffing for licensed nurses is not intended to alter the current requirement of the PCS to determine needed staffing levels for licensed and unlicensed staff.

HSC 1276.4 (e) requires that a nurse must be oriented to a specific clinical area "sufficient to provide competent care to patients in that area, and has demonstrated current competence in providing care in that area." The statutory requirement is repeated in regulation in response to requests made in many public comments. It is necessary to include all licensed nurses in the requirement for current competency in order to ensure patient safety in licensed hospitals. It is also necessary to include licensed psychiatric technicians in psychiatric units only as licensed nurses to ensure that the general requirements for current competency to licensed nurses are applied to licensed psychiatric technicians as well. Pursuant to HSC 1276.4 (d) and (f), hospitals are already required by regulation to establish and implement policies and procedures which set competency standards for nursing staff performance in the delivery of patient care. See 22 CCR 70016, 70016.1, 70213(c), and 70719.

"During one shift" is being changed to "at any one time" for clarity in all the subsections of 70217(a) dealing with individual hospital unit types. This was done in response to many public comments. "Assigned" is being defined in regulation in response to the requests of many public comments. The prohibition of averaging, which was contained in the statement of reasons for the original proposed regulations, is being explicitly stated in regulation in response to the requests of many public comments.

Only licensed nurses providing direct patient care are included in the ratios because the intent of the statute is to ensure that nurses are "accessible and available to meet the needs of the patient". While nurse administrators, nurse managers, and nurse supervisors have vital supportive, supervisory, and oversight responsibilities, it is not their role to be readily accessible and available to directly meet the needs of the patients when they are functioning in their administrative or supervisory positions. However, as those nurses do not have their own patient assignment, they may relieve staff nurses during the staff nurses' breaks, meals, and other routine, expected absences from the unit as long as they have demonstrated to the hospital in which they are currently working their current competency for the unit on which they will be present to provide direct patient care.

The ratios are the same minimum standard for every shift. They represent the leanest staffing the Department believes is compatible with safe and quality patient care in the acute care setting. Because of the pressures of managed care and the increasing complexity of acute care services, people who are hospitalized now tend to require more intense and sophisticated care for fewer days. When combined with the flexible shift scheduling in hospitals (i.e. eight, ten and twelve hour shifts may be available on the same unit), it is no longer feasible to reduce nursing staff during evening, night, or weekend hours. Therefore, these ratios represent the leanest staffing permitted on any shift.

The ratios represent the maximum number of patients assigned to any one nurse at any one time. It is CDHS' intent not to permit averaging the numbers of patients and nurses during a single shift, nor averaging over time. This prohibition of averaging is consistent with the way existing ICU and NICU nurse-to-patient ratios have been interpreted and enforced since they were put in place over 26 years ago. The 1:2 ratio in those units has historically been interpreted to mean that an individual nurse in an ICU may not have a patient assignment that exceeds two patients at any time. To deviate from that interpretation of the ratios in the new regulations would cause enormous confusion for both providers and working nurses.

Additionally, if CDHS were to permit averaging (as an alternative approach), there would effectively be no limit on the number of patients who could be assigned to one nurse at any given time. For example, a medical/surgical unit with four bedside nurses and 24 patients would be in compliance with an *average* ratio of 1:6 during that shift. However, if acuity dictated that three of those patients receive 1:1 care, then one nurse could theoretically become responsible for the care of the remaining twenty-one patients.

As an example of averaging over time, the same 24 bed unit could be staffed with 6 nurses on day shift, 4 nurses on evening shift, and 2 nurses on the night shift. In that scenario, the unit would be in compliance with an *average* ratio of 1:6 over the 24 hour period. The actual care provided, however, would be 1:4 on day shift, 1:6 on evening shift, and 1:12 on night shift. While facilities always have the option of increasing staffing above the minimum required levels as in the day shift example above (and indeed the obligation to increase staffing in response to patient acuity according to the PCS) the regulations are written to prevent, at any time, the assignment of fewer nurses to care for patients than the minimum level specified in these regulations.

The Department believes that such situations would not conform to the Legislature's intent, nor the Governor's message when he signed the bill into law. Most importantly, it would not provide the needed safeguard for patients in

California's acute care hospitals to be cared for by adequate numbers of nursing staff.

Existing regulations at 22 CCR 70465(e) and 70495(e) permit licensed vocational nurses (LVNs) to constitute up to 50 percent of licensed nurses. CDHS has no evidence that the quality of care has been negatively impacted by allowing the 50/50 percent skill mix of RNs and LVNs. This provision clarifies that, unless RNs are required (as in intensive care newborn nursery service in existing section 22 CCR 70485 in current regulations, in the roles of triage or trauma nurse, or if the PCS indicates a need for that level of skill) the nurse staffing on a unit may include up to 50% LVNs.

The standard at 22 CCR 70485 for RNs will remain in effect because subdivision (i) of HSC 1276.4 mandates that existing ratios may be augmented but not replaced. The 50% limitation has been a long-standing requirement necessary to ensure that RNs make up at least half of the nurses available to patients in the acute respiratory care, intensive care, and coronary care settings. The roles and function of the RN and the LVN are clearly described in their respective scopes of practice (as set forth in the Business and Professions Code sections 2725 and 2859 et. seq.) The OSHPD data reports of California hospitals demonstrate that in critical care units LVNs make up only 3% of nursing staff, and LVNs constitute only 17% of acute care staffing overall. Therefore, the 50% limit provides basic assurance that sufficient RNs will be available, but leaves room for needed flexibility for hospitals to determine how to best meet patients' nursing care needs based on fluctuating patient acuity and on skill mix. This change clarifies that licensed vocational nurses shall not care for patients when the hospital's patient classification system requires registered nurses, nor may they function in the roles of triage and trauma nurse. Triage nurses assess, screen, and sort patients so that the patients with the most emergent needs are handled in order of priority. Because triage by definition includes obtaining a brief history and performing a rapid physical assessment, and because patient assessment is reserved to the registered nurse scope of practice (Business and Professions Code (B&PC) 2725(b)(4), only registered nurses may function in the role of triage nurse. Likewise, because trauma nurses require advanced skills and abilities in addition to the ability to provide the patient with swift and ongoing assessment, only registered nurses may function in the role of trauma nurse.

Nothing in these regulations prohibits a licensed nurse from providing care within his or her scope of practice to a patient assigned to another nurse. The Department recognizes the existence of some overlapping functions between registered nurses and licensed vocational nurses, and intends to permit the sharing of those functions for the most efficient, effective delivery of patient care.

CDHS believes it is sound health policy to permit LVNs to provide nursing care within their scope of practice where RNs are not required. Permitting LVNs to constitute up to 50% of licensed nurses on units also makes the nursing

workforce more closely resemble California's diverse population, ethnically and racially. The RN workforce in California remains overwhelmingly female and white: in 1996, fully 84% of RNs were white, with only 3% African American, 8% Asian/Pacific Islander, 4% of Hispanic origin, and less than 1% Native American. That same year, the LVN workforce was 73% white, 18% African American, 3% Asian, 5% of Hispanic origin, and 1% Native American (Exhibit Z-1). According to the report prepared by the National Advisory Council on Nurse Education and Practice published in April, 2000 entitled "A National Agenda for Nursing Workforce: Racial/Ethnic Diversity", a culturally, ethnically, and racially diverse nursing workforce is essential to meet the health care needs of patients. Minority nurses are significant for their contribution to the provision of healthcare services and models of care that are more congruent with the unique needs of minority populations. They "raise the bar" of cultural competence for the entire workforce (Exhibit Z-2).

"Assist" is being defined in the proposed regulation in response to the requests of many public comments. This clarifies that it is not CDHS' intent to prohibit nurses from providing care to patients who are not assigned to that nurse, nor is it a violation of these proposed regulations when nurses provide such care so long as the tasks performed are specific and time-limited. Such tasks might include administering medications, performing assessments, assisting with personal care, providing discharge instructions, and other nursing tasks.

When LVNs are assigned to patients, it will be necessary for an RN to perform duties for those patients that are outside the scope of practice of the LVN. Likewise, although the LVN may have a patient assignment, he or she may be required to perform duties for patients that are assigned to an RN. These proposed regulations are intended to allow hospitals flexibility with regard to assignments as they utilize the PCS to determine the care needed, to be provided by RNs, LVNs, and unlicensed staff. This clarification is necessary to ensure that hospitals retain reasonable flexibility in choosing staffing models as directed by Governor Davis in his sign message (Exhibit A), to accommodate scope of practice issues, and to clarify that team nursing is not prohibited by these regulations.

<u>70217(a)(1)</u>

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments.

"Critical care unit" is defined in the new law at HSC 1276.4(c). The decision was made to specify the critical care units by name to add clarity to the regulation. Those units which are currently defined in regulations as intensive care units may also properly be referred to as critical care units. It is CDHS'

intent that the phrases "intensive care units" and "critical care units" may be used interchangeably.

"Intensive care newborn nursery service" was added to the list of critical care units to clarify that it is included as a critical care unit. Intensive care units are mandated at 22 CCR 70495 to have a minimum nurse-to-patient ratio of 1:2 or fewer at all times. Similarly, acute respiratory units (section 70405), coronary care service units (section 70465), and intensive care newborn nursery units (section 70485) all require a minimum ratio of 1:2. These provisions are long-standing requirements that have not been, and are not now, disputed. Neither providers nor their representative organizations have suggested that the 1:2 ratio is too rich for those unit types. In fact, with the increasing sophistication and complexity of medical technology allowing patients' lives to be saved and maintained which previously would have been lost, the 1:2 ratio standard has become the minimum ratio for critical care units, with many patients in those units requiring staffing at 1:1 and even 2:1. Additionally, HSC 1276.4 (i) prohibits replacing existing ratios for the intensive care units, neonatal intensive care units, or the operating room. Burn centers are currently staffed at 1:2 as the standard of practice in California. This regulation clarifies that the Department considers burn units to be critical care units, and sets the nurse staffing ratio in conformance with other intensive care units for the health and safety of patients admitted to the burn unit setting. Including all nurse staffing ratios in this section, as well as existing ratios that are now designated as "critical care", is necessary for clarity, convenience, and organizational purposes.

70217(a)(2)

This provision makes explicit the requirement for a registered nurse (RNs) to function as the circulating assistant in the surgical service operating room (For the meaning of "surgical service operating room", please see 22 CCR, section 70223, Surgical Service General Requirements). Current regulations at 22 CCR section 70225(d) require, "There shall be registered nurses, licensed vocational nurses, and operating room technicians in the appropriate ratio to ensure that at all times a registered nurse is available to serve as the circulating assistant whenever a licensed vocational nurse or operating room technician is serving as scrub assistant." Current regulation, therefore, leaves open the possibility of a licensed vocational nurse or other personnel serving as circulating assistant if a registered nurse were serving as scrub assistant. That situation is not sensible, not safe, and not congruent with current practice as evidenced by both the analysis of the OSHPD data and the CDHS on-site study. DHS proposes to repeal section 70225(d) in this regulation package to eliminate conflicting language.

The circulating assistant is responsible for managing the nursing care within the operating room, observing the surgical team from a broad perspective, assisting the team to create and maintain a safe, comfortable environment for the

patient, and coordinating the activities of each member of the surgical team (Exhibit AA). The function of the registered nurse in that role is the accepted community standard of practice. The use of RNs as circulating assistants was specifically approved by the National Association of Perioperative Registered Nurses, as ratified at their Congress in March, 2001 (Exhibit BB). The most critical period of care for surgical patients occurs in the operating room. The instability inherent in the patients' condition while undergoing surgery necessitates the registered nurse level of skill for ongoing assessment and evaluation, while assisting the surgical team. The ongoing assessment includes minute-by-minute vigilance and availability for immediate response to emergent patient changes on the part of the circulating registered nurse. Because of the close scrutiny each patient requires, there must be one circulating registered nurse assigned to each patient-occupied operating room. For these reasons, the term "circulating assistant" was changed to "circulating nurse". This change was requested by many public comments.

The role of the scrub assistant is to assist the surgeon by handing on instruments, sponges, and other items needed during the surgical procedure, while maintaining the sterile field (Exhibit AA). This duty can be safely performed by registered nurses, licensed vocational nurses, or specially trained surgical assistants. The role of the perioperative circulating registered nurse, on the other hand, is to oversee the surgical patient's care and to be immediately available to respond to emergencies as the circulating nurse. Because each role is distinct and both are crucial to the care the patient receives while undergoing surgery, one circulating registered nurse and one scrub assistant are needed for every patient-occupied operating room. The requirement was further clarified to reflect this, and to clarify that the roles may not be combined with the other licensed professionals such as physicians who are assisting in the performance of the surgery.

70217(a)(3)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The nurse-to-patient ratio for labor and delivery units is proposed to be 1:2 or fewer at all times. This is based on the patients' need for critical care during the end of labor and through the delivery process. The 1:2 ratio conforms to the ratios for the other critical care units in the hospital. Both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, representing the specialty's physicians (Exhibit CC), as well as the Association of Women's Health, Obstetric, and Neonatal Nurses representing the specialty's nurses, (Exhibit DD) recommend a minimum nurse-to-patient ratio of 1:2 for patients in labor. The Department relied upon both of these documents in

developing the proposed regulations. Staffing of labor and delivery suites at 1:2 is already the standard of practice in California's hospitals, as evidenced by both the analysis of the OSHPD data and the CDHS on-site study. Analysis of the CDHS' on-site study data revealed that, for 95% of hospital shifts statewide, labor and delivery units are currently staffed at 1:2 or richer.

For the purpose of caring for antepartum patients who are not in active labor in these units, CDHS has determined that the ratio shall be 1:4 or fewer at all times. This would maintain the 1:8 maximum total patient ratio in perinatal units and be congruent with the postpartum requirement for 1:4 mother/baby couplet care. This is appropriate because each mother and fetus requires assessment, care, evaluation, possibly intervention, and documentation. An antepartum ratio of 1:4 would allow for the detection of and intervention for unexpected maternal-fetal problems that may become apparent.

70217(a)(4)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The nurse-to-patient ratios in the postpartum unit of the perinatal area is proposed to be 1:4 mother/baby couplets (1:8 total patients), and, in the event of multiple births, would never exceed a total of eight (mothers plus infants) per nurse. In those units where care of recovering mothers is staffed separately from the newborn nursery areas, the nurse-to-patient ratio is proposed to be 1:6. According to the analysis of CDHS' on-site study, between 90-95% of hospital shifts statewide have perinatal units staffed at 1:8 total patients, while 75% are staffed at approximately 1:6 total patients.

In *Guidelines for Perinatal Care* (Exhibit CC), both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, representing the specialty's physicians, recommend a nurse-to-patient ratio of 1:6 for postpartum patients without complications and 1:4 for normal mother-newborn couplet care. That publication states, "The most current scientific information, professional opinions, and clinical practices have been assembled and received in the formulation of the information in this manual..." The Association of Women's Health, Obstetric, and Neonatal Nurses, representing the specialty's nurses, agrees that those are the appropriate ratios (Exhibit DD). The Department relied upon these documents in developing the proposed regulations.

There was also a non-substantive grammatical correction from "nurses' "to "nurse's".

70217(a)(5)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

In a combined Labor/Delivery/Postpartum area of the perinatal service, the minimum nurse-to-patient ratio is proposed to be 1:2 or fewer at all times when a nurse is caring exclusively for women in active labor. When a nurse is caring exclusively for antepartum women who are not in active labor, the proposed ratio shall be 1:4 or fewer at all times. When a nurse is caring exclusively for postpartum women, the minimum nurse-to-patient ratio is proposed to be 1:6 total patients. When a nurse is caring exclusively for mother/infant couplets, the minimum nurse-to-patient ratio is proposed to be 1:4 couplets (1:8 total patients). In those facilities that combine perinatal services into one single unit for staffing purposes, a minimum nurse-to-patient ratio of 1:3 allows a nurse to care for two women in active labor, and to continue to care for both patients in the event that one of the laboring women delivered her infant while the other patient remained in labor. According to the analysis of CDHS' on-site study data, approximately 75% of hospital shifts statewide currently meet or exceed the 1:3 minimum ratio for combined Labor/Delivery/Postpartum units.

The ratios in 70217(a)(3) and (4) apply equally when the labor and delivery suites and the postpartum areas are combined into Labor/Delivery/Postpartum areas. The only unique circumstance addressed for these units is the possibility, because of the nature of the unit, that a nurse might temporarily care for one woman in active labor and also a newly delivered mother and infant.

Also, the sentence structure was changed to enhance clarity and at the request of many public comments.

70217(a)(6)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations. The word "unit" was added because current regulations at 22 CCR 70537(c) and 70543(a) differentiate between the pediatric service and the pediatric unit. These proposed pediatric ratios would only apply to those hospitals that have a pediatric unit. Other hospitals which admit pediatric patients but do not have pediatric units would admit the pediatric patients to a mixed unit, and that ratio in concert with the PCS would dictate the appropriate staffing level.

The nurse-to-patient ratio in pediatric service units is proposed to be 1:4 or fewer at any time. According to the CDHS on-site study, at the 75th percentile, where 25% of hospital shifts have leaner staffing, the ratio is 1:4.5. When compared with the OSHPD data, however, at the 75th percentile, the ratio is 1:3.8. Because of the margin for error in both approaches, staffing in the pediatric service of hospitals is probably very close to 1:4 at the 75th percentile. This regulation will enrich staffing for the leanest one-quarter of pediatric hospital shifts in California.

Because of their immaturity and their dependency, hospitalized children and youth require significantly more nursing attention than adult patients. The need is greatest where dependency is greatest: for infants and pre-school children. The American Academy of Pediatrics supports a minimum nurse-to-patient ratio of 1:4 in pediatric units (Exhibit EE). The Department relied upon this document in developing the proposed regulations.

70217(a)(7)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The nurse-to-patient ratio in a postanesthesia recovery unit (PACUs) of the anesthesia service is proposed to be 1:2 or fewer at all times. Compared with the CDHS on-site study, 25% of hospital shifts in California staff PACUs at 1:1.8; the leanest 10% staff PACUs at 1:2.5, so the ratio of 1:2 would increase staffing at the leanest 10-25% of hospitals statewide. This 1:2 ratio is consistent with the staffing requirements for critical care units in the hospital. Multiple physiological systems, notably the neurological and pulmonary systems, are compromised with the administration of anesthesia and remain unstable until the patient is recovered successfully. CDHS concurs with the California Society of Anesthesiologists which wrote as Commenter #1633, "The CSA supports the proposed DHS nurse-to-patient ratio of 1:2 or fewer for patients in the postanesthesia recovery unit. The most critical phase for a patient recovering from anesthesia whether it is general, regional, or intravenous, is the immediate period following surgery and anesthesia, before they are transitioned to an inpatient setting or discharged to a lower level of care." The American Society of PeriAnesthesia Nurses, representing the nurses in that specialty, has set standards of practice which require a minimum of one nurse for every two patients during the immediate postanesthesia period, defined as the time from the patient's admission to the PACU until they are transitioned to an inpatient setting or discharged to a lower level of care (Exhibit FF). In addition, the PeriAnesthesia Nurses Association of California concurs that 1:2 is the appropriate ratio (Exhibit GG), as does the California Society of Anesthesiologists, representing the specialty's physicians (Exhibit HH). The

Department relied upon these documents in developing the proposed regulations. The phrase "regardless of the type of anesthesia the patient received" was added to the proposed regulations for clarity and in response to the requests of many public comments.

70217(a)(8)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations for the nurse staffing requirement for basic and comprehensive emergency medical services. The word "registered" was added to "nurse assigned to triage" for clarity.

The methodology for determining appropriate nurse-to-patient ratios in Emergency Departments (EDs) is problematic for several reasons, including the great variation in patient acuity and visit frequency that an individual ED can experience over a 24 hour period. In addition, different EDs can vary greatly from one to the next in the acuity and intensity of care required for the different patient populations they serve. EDs can also be severely impacted by trauma and critical care admissions, both medical and psychiatric. In order to make the most efficient use of its resources, staffing formulae for EDs are typically calculated on an hour-to-hour basis, with the beginning and end of staff shifts staggered so that there is peak staff availability when patient volume is highest. These idiosyncratic staffing patterns necessitated creating a multifaceted regulation for nurse-to-patient ratios in EDs.

In a hospital providing basic emergency medical services or comprehensive emergency medical services, the nurse-to-patient ratio is proposed to be 1:4 or fewer at all times. This represents the median ratio between critical care units (1:2) and medical/surgical units (1:6), and is the same ratio as that applied to step-down units. This is appropriate because, while not all ED patients are critical, they all arrive in a potentially unstable condition. Most patients do not arrive with a clear diagnosis of condition, and ED evaluation and treatment usually demands multiple tasks to be done quickly, and often simultaneously.

Critical care patients in the ED deserve the same standard of care they would receive in a critical care unit, and therefore the same minimum 1:2 nurse-to-patient ratio. For trauma patients, the most critical cohort of the critical care patients, the maximum number of patients one nurse shall care for is proposed to be one. That will provide those patients a greater intensity of care than patients requiring regular critical or intensive care. In the ED, as in all other units, these are minimum standards only, with the number of licensed nurses increasing as patient acuity increases based on the PCS.

CDHS has added definitions for "critical care patient" and "critical trauma patient" as requested by many public comments. "Critical care patient " is defined as a patient who meets the criteria the hospital is currently using for admission to its own critical care units, and states that a patient who meets that criteria should logically receive a consistent level of nurse staffing, regardless of the patient's temporary placement in an area outside of a critical care unit. The definition of "critical trauma patient" is provided for clarity because it more precisely defines the CDHS intent than the previous reference to HSC 1798.160, and a clearer definition was requested by many public comments. Providing the definition of "critical trauma patient" was necessary so that a distinction could be made between those trauma patients who would not require enriched ED staffing above 1:4 and those trauma patients whose injuries are so severe that the enriched staffing to 1:2 is necessary for the provision of critical trauma care. HSC 1798.160 did not actually define "critical trauma patient"; rather, it defined "trauma case" as "any injured person...who has been found to require transportation to a trauma facility." CDHS intended to include all critical trauma patients at general acute care hospitals in the enriched staffing ratios, not just those patients who were transported to a trauma facility. Therefore, the definition was changed.

The word "Local" was added to the "Emergency Medical Services Agency" to be consistent with the way those agencies are referred to in HSC 1797.58. The word "Local" was mistakenly omitted in the initial proposed regulations.

The positions of triage nurse and base radio nurse in the ED require an immediate, focused, and often continuous response, and, therefore, must be staffed by registered nurses assigned to those roles and not otherwise counted in the minimum ratios. However, nothing in these regulations should be construed to prohibit the triage and base radio nurse from assisting by performing nursing tasks when there are no patients awaiting triage and no calls on the base radio. This is permitted as long as the registered nurses remain immediately available to resume their roles as triage nurse and base radio responder. The nursing tasks that they may assume, therefore, must be ones that can be readily put aside when they need to resume their primary assignment, without endangering a patient. The proposed regulations further clarify that either a licensed physician or a registered nurse may respond to calls on the base radio, and that these proposed regulations apply only when the base radio responder is a registered nurse.

For hospitals which do not function as a "base hospital" as defined in section 1797.58 of the Health and Safety Code, but offer basic or comprehensive emergency medical services, then, a minimum of two nurses (one triage nurse plus one treatment nurse) would be needed in the emergency room whenever a patient is present.

The above ratios, including the exception of triage and radio nurses from a patient assignment, are the minimum nurse-to-patient ratios acceptable to the California Chapter of the American College of Emergency Physicians (CAL/ACEP), which represents over 2000 medical practitioners in that specialty (Exhibit II). The California Medical Association has also endorsed these ratios (Exhibit JJ). In addition, this is the intensity of care standard acceptable to the Emergency Nurses' Association California State Council, representing the specialty's nurses (Exhibit KK). The Department relied upon these documents in developing the proposed regulations.

70217(a)(9)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The nurse-to-patient ratio in a step-down unit is proposed to be 1:4 or fewer at all times. A step-down unit is defined as a unit for the monitoring and care of patients with moderate or potentially severe physiologic instability, requiring technical support but not necessarily life support; a unit reserved for those patients requiring less care than standard intensive care, but more than that which is available from standard medical/surgical care. This definition was added to clarify the confusion expressed by some commenters that step-down care was equivalent to sub-acute care.

This is the way the unit is defined by the American College of Critical Care Medicine, which refers to these units as "Intermediate Care Units" (Exhibit LL). These same units are also sometimes called "Progressive Care Units". The regulations refer to these units as "Step-down Units" for the sake of clarity, because the term "Intermediate Care" is defined at 22 CCR 70038 as beds "designated for patients requiring skilled nursing and supportive care on a less than continuous basis." Intermediate Care Service requirements reflecting that level of care, which is a lower level of care than the skilled nursing level of care, are further explicated at 22 CCR 70501 and 70503. The units, then, are referred to as "step-down units" so that the public will be able to clearly understand which type of unit is governed by this regulation.

The 1:4 ratio represents the median ratio between the ratio required in intensive or critical care units (1:2) and the ratio required in medical/surgical units (1:6), which is appropriate for the median level of care between the two units. The ratio required for medical/surgical units is proposed to change from 1:6 to 1:5 in the year 2005. CDHS now proposes to phase-in a change to require a ratio of 1:3 in step-down units in the year 2008. This is clinically appropriate because of increased patient acuity and the required level of care in stepdown units. Enriched staffing is needed to address this increased patient fragility and

complexity of care and treatment. In addition to needing many of the extra nursing interventions that are required in Telemetry and other specialty units, patients in step-down units are much more medically fragile. This requires ongoing assessment to detect any change in condition. A change of condition in such a medically fragile patient can be the cause of more immediate and serious consequences than such a change has for patients in other unit types. These patients are literally just a step away from needing intensive care. CDHS proposes to delay the phase-in until 2008 because both critical care and stepdown-qualified nurses are the rarest in the nursing workforce and require advanced education, training, and certification. The additional time will allow for increasing the numbers of these specialized nurses. The analysis of CDHS's on-site staffing study showed that 95% of shifts in step-down units statewide are currently staffing at 1:4, with 50-75% already staffing at 1:3.

"Technical support" was defined in the original proposed regulations as "...specialized equipment and/or personnel providing for invasive monitoring, telemetry, and mechanical ventilation, for the immediate amelioration or remediation of severe pathology...." That sentence has been changed in this version to read, "....specialized equipment and/or personnel providing for the invasive monitoring, telemetry, or mechanical ventilation, for the immediate amelioration or remediation of severe pathology..." to clarify CDHS' intent that any one of those treatments for the severe pathology would be defined as technical support. All three treatment types do not need to be in use in order for the term "technical support" to apply.

"Artificial life support" is defined as a system that uses medical technology to aid, support, or replace a vital function of the body that has been seriously damaged. Patients requiring artificial life support could, depending on their acuity, be found in critical care units or on these step-down units. Patients who are stable and are on artificial life support long term may also be appropriately located on subacute units. "Artificial life support" and "technical support" are defined in the regulation in order to differentiate the types of equipment and nursing care that would commonly be required by patients in stepdown units, and, by extension, the degree of illness or impairment experienced by patients in this unit type. The term "technical support" is used in Exhibit LL in describing equipment found in a step-down unit. "Artificial life support" is defined in Exhibit MM.

70217(a)(10)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The nurse-to-patient ratio in telemetry units is proposed to be 1:5 or fewer at all times. The ratio required for medical/surgical units is proposed to change from 1:6 to 1:5 in the year 2005. CDHS now proposes to phase-in a change to require a ratio of 1:4 in telemetry units in the year 2008. This is clinically appropriate because of increased patient acuity and the required level of care. This care requires more nursing hours at the bedside to perform all the tasks required on medical/surgical units plus additional nursing tasks, including the reading and interpreting of the electronic monitor output. Phasing in the ratio in the year 2008 is also appropriate because most nursing programs can be completed in approximately three years. This phase-in in 2008 allows for another class of nursing students to graduate and become licensed before the phase-in to the richer ratios occurs.

"Telemetry unit" was defined in the original proposed regulations as a unit designated for the electronic monitoring, recording, retrieval, and display of cardiac electrical signals (Position statement of the American College of Cardiology, Exhibit NN). The final proposed definition was expanded in response to the requests of many public comments to improve clarity. The new proposed definition was supplied by commenter number 1826. The definition was expanded because the original language was so broad as to be confusing operationally. Many patients require monitoring of cardiac signals, including women in active labor, babies in utero, intensive care patients, surgical patients, and others. The added language will minimize confusion. It limits telemetry patients to those who are in stable condition, thus distinguishing them from step-down and ICU patients. It further defines a telemetry unit as dedicated to patients having or suspected of having a cardiac condition or disease requiring specific monitoring and care. This definition is consistent with existing practice, is more precise, and will minimize confusion.

Cardiac monitoring, which in the past was reserved to critical care units, is now used routinely in non-critical care settings to improve patient care and provide a more accurate and continuous assessment of cardiac function for those patients whose underlying disease state, e.g. conduction disturbances or arrthymias, makes monitoring appropriate. This ratio is necessary because patients on telemetry require licensed nurses to be readily available to expeditiously detect and treat the irregularities that the monitor identifies. The CDHS' on-site study data showed that 50% of hospital shifts in telemetry units are currently staffed at 1:4.5, and 75% at 1:5.6. This proposed ratio would, therefore, increase staffing for telemetry unit shifts in the more than 25% of shifts with the leanest staffing. When the ratio shifts to 1:4, it will enrich staffing for more than 50% of shifts on telemetry units statewide. This is necessary because the expanded use of telemetry reflects the prevalence of heart disease in the United States. Even with the use of telemetry and other technological assessment advances, heart disease remains the leading cause of death in America in the year 2000 (Exhibit OO). Concern for the care provided in these units was heightened by a survey of telemetry care conducted by the American

Association of Critical Care Nurses in May, 1998. In response to the survey question, "Which of the following describes your usual way of handling increased acuity and/or inadequate staffing?", fully 64% responded that they simply "work with less staff" (Exhibit PP). The Department relied upon these documents in developing the proposed regulations.

The original proposed regulations required, for every ten or fewer telemetry patients, a minimum of one additional person to monitor the telemetry screens. This requirement has been removed from these proposed regulations because the equipment used by telemetry units to monitor patients is very variable. Some hospitals use telemetry equipment for which the requirement would have been appropriate, but many do not, because of newer technology. Some newer systems show twenty or more cardiac monitor tracings on the same monitor screen. Some facilities are using telemetry equipment that communicates with a paging device worn by the nurse to alert her to the patient whose cardiac rhythm and/or rate has changed; some even display the identified problematic tracing. For this reason, and because CDHS is sure that technology will continue to change and further improve clinicians' ability to monitor cardiac activity, a uniform requirement for monitoring the tracings that would be suitable for all hospitals regardless of the equipment in use was not appropriate. Instead, the above enrichment of the staffing requirements for nursing staff on these units is proposed.

The definition of "telemetry unit" was re-worded for clarity and in response to the requests of many public comments. The statement that the "telemetry unit monitoring" shall not include fetal monitoring nor fetal surveillance was made in response to the requests of many public comments, and for clarification.

70217(a)(11)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The nurse-to-patient ratio in medical, surgical, and combined medical/surgical units is proposed to be 1:6 or fewer at all times. This ratio is also proposed to apply to those medical/surgical units that serve diverse patient populations and age groups. These units, which for purposes of the CDHS on-site study were identified as "mixed units", were found to contain patients with diseases, injuries, acuity levels, and care needs that closely approximated patients in more traditional medical/surgical units. The PCS will continue to coexist with the minimum ratio in these mixed units to require an increase in nurse staffing in response to increased patient acuity and/or the needs of the specific patient population, e.g. pediatric patients. The words "who require care appropriate to a medical/surgical unit" were added to clarify that mixed and

medical/surgical units provide the same level of care and that the care level is necessitated by the patients' needs.

"Specialty care units" was added as a non-substantive change to the unit types which would contain patients who required more care and observation and a more specialized type of care than is appropriate in a medical/surgical unit. This is a non-substantive change because the words, "Services provided in these units are more specialized to meet the needs of patients with the specific condition or disease process than that which is required on medical/surgical units, and is not otherwise covered by subdivision (a)" already exists at 70217(a)(12). This addition was necessary to clarify that CDHS' intent in setting the minimum staffing ratio richer in specialty care units was to accommodate the additional care needs, specialized monitoring, use of specialized equipment and medications, etc., for those patients requiring specialty care. Those units containing patients who need the same amount and type of nursing care as patients in medical/surgical units should be deemed by facilities to be medical/surgical units regardless of their name (see discussion about proposed 70217(a)(14).

The words "who require care appropriate to a medical/surgical unit" were added to the last sentence in this regulation to emphasize that, whether the diagnoses and ages of the patients in these units were diverse or similar, it is the level and type of nursing care provided on the unit that determines the staffing level that is needed on that unit.

According to OSHPD's data, 75% of California's hospital shifts are already staffed at a level of 1:5.6 or richer for medical/surgical units. The CDHS's on-site study of hospitals statewide confirmed staffing in those unit types at 1:6 for 75% of all medical/surgical and mixed unit shifts. CDHS decided to set the starting point for the minimum ratios at this level, to improve staffing on those shifts in the leanest 25TH percentile. This is necessary because, due to the need for cost containment and the pressures of managed care, patients admitted to acute inpatient beds are sicker, and have a shorter length of stay, than ever before (Exhibits QQ and RR). Also, medical/surgical units are the inpatient setting where, by far, the largest majority of patients receive care. Setting this minimum standard for care in these units should significantly improve health care delivery statewide.

Commencing January 1, 2005, the nurse-to-patient ratio in medical, surgical, and combined medical/surgical units is proposed to change to 1:5 or fewer at all times. CDHS has decided to increase staffing on these unit shifts incrementally, by a later phase-in of this lower ratio. This is being done for both practical and clinical reasons.

In a practical sense, because these are the most common and largest unit types in acute care hospitals and in light of the current nursing shortage, this will

allow providers additional time to build up their pool of nurse staffing resources. It will give the provider community adequate lead time to develop a strategy for complying with the minimum standards before they are mandated. It allows time for providers to look ahead and plan their budgets accordingly. It also puts providers, along with the Medi-Cal program, on notice so that they can make any needed adjustments.

Clinically, CDHS believes it is important to enrich staffing in medical, surgical, and combined medical/surgical units because those are the settings where the majority of acute care patients receive care. Thus, increasing staffing in this unit type will increase the nursing care received by the greatest number of patients. Any improved outcomes that result from the increase in staffing (patient, workforce, or institutional) would, therefore, benefit the greatest number of patients, nurses, and hospitals.

There is no independent, empirical information about appropriate staffing levels in medical, surgical, and combined medical/surgical units. We will, therefore, in compliance with the new law, review the patient, workforce, and institutional effects of these regulations, and report to the Legislature in five years regarding any proposed changes.

70217(a)(12)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

Specialty care units, those units which are organized, operated, and maintained to provide care for a specific medical condition or a specific patient population, are very varied, depending on the hospital, its location, its size, and the patient population it serves.

Specialty care units are often found in large, urban hospitals and academic medical centers serving unique patient cohorts. While "specialty care unit" is not currently a supplemental service nor a licensing term, this is the generally understood meaning of the term. The specific specialties served by these units run the gamut from orthopedics to HIV/AIDS to metabolic transplants, and require more specialized skills and comprehensive care than is normally available in medical/surgical units. Minimum staffing, of course, will vary according to the needs of the patients, and will increase in response to the PCS. The most commonly found specialty care unit in California's hospitals is the oncology unit, and, therefore, that is the unit type that was included in the DHS on-site study.

The minimum safe nurse-to-patient ratio in specialty care units is proposed to be 1:5 or fewer at all times. The ratio required for medical/surgical units is proposed to change from 1:6 to 1:5 in the year 2005. CDHS now proposes to phase-in a change to require a ratio of 1:4 in specialty care units in the year 2008. This is clinically appropriate because of patient acuity and the required level of care. This care results in more nursing hours at the bedside to perform all the tasks accomplished on medical/surgical units plus additional nursing tasks, including the administration, continual monitoring, and patient assessment of response to medications which can cause life-threatening adverse reactions and must be precisely administered to avoid toxicity. Phasing in the ratio in the year 2008 is also appropriate because most nursing programs can be completed in approximately three years. This phase-in in 2008 allows for another class of nursing students to graduate and become licensed before the phase-in to the richer ratios occurs.

These ratios provide sufficient staffing in recognition of the greater specialization and intensity of care provided. According to the CDHS on-site study results for shifts on oncology units statewide, 75% currently staff at a ratio of 1:5 or richer. When the ratio shifts to 1:4, it will enrich staffing for more than 50% of shifts on specialty care units statewide. (There is no data available from OSHPD for this unit type.) In a recent study of oncology nurses working in the inpatient setting (Exhibit SS), the oncology nurses reported that five was the maximum number of patients for whom they could provide safe, appropriate care.

The words "defined as" were added to the definition of specialty care units to conform this subsection with the definitions of the other subsections. The word "available" was deleted and the word "required" was added to clarify and emphasize that the care that is provided is necessitated by the needs of the patients and is not merely an option.

70217(a)(13)

"At any time" is being changed to "at all times" for consistency with the provisions in current regulations and in response to the request of many public comments. The word "licensed" was added to "nurse" for clarity and consistency with other proposed regulations.

The severity of psychiatric disorders, like the severity of physiologic disorders, varies in acuity. Therefore, the same minimum ratio as is used for general medical, surgical, and medical/surgical units, which serves the widest variety of patient diagnoses, should apply to psychiatric units. The nurse-to-patient ratio for psychiatric units in general acute care hospitals, then, is proposed to be 1:6 or fewer at all times.

According to the data that OSHPD collects, 75% of the psychiatric units in California currently staff at 1:6.2 or richer. This was confirmed by the CDHS on-

site study, which also found that shifts in those units were staffed at 1:6 or richer. The 1:6 ratio is also supported by the California Chapter of the American Psychiatric Nurses Association (Exhibit TT), representing over 310 professional psychiatric nurses in California. The Department relied upon this information in developing the proposed regulations.

Currently, in Acute Psychiatric Hospitals, Psychiatric Technicians (PTs) are equivalent to Licensed Vocational Nurses (LVNs) for the purpose of provision of patient care. For psychiatric units in general acute care hospitals, PTs are counted in the ratios in the same manner as LVNs. This is appropriate because PTs and LVNs receive the same number of hours of training as preparation for licensure, with PTs spending a greater proportion of their time in the psychiatric specialty than the more generalist LVNs. Both PTs and LVNs also share the same governing Board, the Board of Vocational Nurses and Psychiatric Technicians, within the Department of Consumer Affairs.

PTs, like LVNs, practice under the direction of a physician, psychologist, registered nurse, or other professional personnel, and are not independent practitioners. Of the 1530 required curricular hours for PT licensure, fully 756 are dedicated to the study of mental disorders and developmental disabilities. PTs are the primary direct care providers for patients in the acute psychiatric setting, and therefore should logically be counted in the ratios as licensed staff for acute psychiatric units.

The Department clarified that hospitals may use licensed psychiatric technicians as a licensed nurse category, only in the psychiatric units of the hospital.

70217(a)(14)

This provision was added to allow providers maximum flexibility in the naming of their units. Some hospitals give units names that are perceived to be less troubling for patients and their families than the regulated unit names. For example, Intensive Care Newborn Nurseries may be named the "Special Care Nursery", and an Oncology Unit may be called the "Camellia Care Unit", etc. This provision ensures that, while providers may use unit names that they believe will be best received by the population they serve, the use of those names does not affect nor avoid the requirement to comply with the staffing regulations that are based on the type of care provided, and not merely the name of the unit.

70217(b)

The phrase, "In addition to the requirements of subdivision (a)" was added here to make clear the Department's intent that the ratios are minimums only, and will co-exist with PCS, which will dictate increased staffing when patients' needs warrant it, based on assessments on each shift. A non-substantive

capitalization change was made to the filing order to correct a typographical error in the post-hearing change availability.

The language added repeats the statutory language defining the elements of basic principles of staffing in general acute care hospitals. It is being repeated in response to the requests of many public comments, including the Board of Registered Nursing (commenter #1754) which believed it was needed for clarity. It also clearly describes the legislative intent for the nexus between the proposed ratio regulations and the patient classification systems. It is necessary to emphasize that the proposed licensed nurse-to-patient ratios are a required minimum staffing standard, and additional nursing staff above this minimum is required when such additional nursing staff is dictated by the hospital's patient classification system.

70217(c)

The statement, "In no case shall the staffing level for licensed nurses fall below the requirements of subsection (a)" was added to require that the staffing plan that is developed and implemented for each unit be based first on the PCS, using the ratios only to designate the minimum safe staffing level.

Subsection (c)(4) was redesignated to (d)(1) and modified slightly for correct grammar in a modified regulation structure. Additional language was added to propose an additional requirement for recordkeeping for all shifts and for all units. Hospitals are already required to retain a record of the staffing requirements determined by the patient classification system, the actual staff and staff mix provided, and the variance between the two, documented on a day-to-day, shift-by-shift basis. Each licensed nurse's assignment and licensed psychiatric technician's assignment is also documented every shift. This proposed regulation will require the hospitals to retain the documented licensed nurses' and licensed psychiatric technicians' actual assignments, ensuring that the specific nursing personnel will be linked to the specific patients. These records shall be retained by the hospital for a minimum of one year.

This is necessary because, without this new provision, it would be impossible for CDHS or the public to know retrospectively whether the facility complied with these proposed regulations and would therefore make enforcement of these proposed regulations virtually impossible. Therefore, this recordkeeping requirement is necessary for the health and safety of California's citizens. HSC 1278 states that, "Any officer, employee, or agent of the state department may, upon presentation of proper identification, enter and inspect any building or premises at any reasonable time ***to secure compliance with, or to prevent a violation of, any provision of this chapter."*** (Emphasis added.) Without this requirement, agents of the state department would only know in the aggregate the numbers of patients and nurses on each shift, and could calculate the average staffing, but would be unable to assess whether a violation occurred,

or prevent a violation of these proposed regulations which implement and make specific HSC 1276.4. For example, if CHDS received a complaint about inadequate staffing on a shift of a psychiatric unit, an investigation for compliance would be necessary. Without this requirement the only information that would be available would be that which is already required by the PCS at subsections 1-3: the numbers of staff required, the number of staff provided, etc., and the nurse-to-patient staffing could appear to be adequate on average. However, if one or more of the patients had required 1:1 staffing, then the staffing ratio would be non-compliant, but would have appeared appropriate under current recordkeeping requirements. This requirement will enable CDHS to secure compliance with provisions of this chapter, in accord with statute. Although this recordkeeping is an expansion of existing record keeping requirements, it will not add any significant cost to providers, including State-run facilities. It will not significantly add costs to Medi-Cal, nor will it have a significant, statewide adverse economic impact directly effecting businesses in the State of California.

Subsections (d) through (q) were redesignated to maintain alphabetical order.

70217(i)

The phrase "except as described in subsection (a) above" was added to clarify that the nurse administrator may have a patient care assignment if that nurse administrator has demonstrated current competence to the hospital in providing care on a particular unit. This may be for the duration of a shift, or for the purpose of relieving staff nurses during breaks, meals, and other routine, expected absences from the unit as described in subsection (a).

70217(q)

This provision was added to clarify that the Department expects hospitals to plan for routine fluctuations in patient census. This planning should include, but not be limited to, an evaluation of the number of patients in other areas of the hospital waiting for an inpatient bed, consideration of how many patients are customarily admitted to individual units on a day-to-day, shift-by-shift basis based on historical information for that type of unit, the season of the year, day of the week, and time of day, etc. The PCS projects needed staff for the upcoming shift and hospitals have systems in place that indicate how additional staff will be obtained when needed. Hospitals commonly use such systems as the maintenance of a pool of on-call employees, providing part-time employees with additional work hours, and the use of nurse registries to augment staffing above scheduled staff. 22 CCR currently requires that each patient's nursing care needs must be determined by the PCS, and documented on a day-to-day, shift-by-shift basis.

In the event of a change in patient census that could not reasonably have been foreseen by the hospital, this states the Department's intent to give the

hospital needed flexibility while the hospital makes prompt, diligent efforts to return each unit to the minimum required staffing ratios. The requirement cannot be more specific because the broad range of circumstances that could befall a hospital are beyond the Department's ability to anticipate. The timing and the appropriateness of the response may vary according to the circumstances and the nature of the unanticipated changes. These changes could include such diverse events as earthquakes and other natural disasters, instances of bioterrorism, and other healthcare emergencies. CDHS' meaning of "healthcare emergencies" is defined for the sake of clarity and in response to the requests of many public comments. The use of this definition was suggested by commenter number 1826. Also, this is the definition used by the Industrial Welfare Commission in a recent overtime wage order effecting acute care facilities.

70225(d)

This regulation is being repealed, and staffing in the surgical service operating room will be addressed at section 70217(a)(2). Please see that section for a discussion of the reasons for the repeal.

70455(a)

The Department made a change without regulatory effect to Section 70455(a).

70455 (e)

This proposed requirement is added to cause the minimum requirements for comprehensive emergency medical service staff to conform to the current minimum requirements for basic emergency medical service staff. Current regulations at 22 CCR 70415(d) require that there shall be a minimum of one registered nurse on duty in basic emergency departments at all times, but there is no such requirement for comprehensive emergency departments. Basic emergency departments provide more limited services than those provided in comprehensive emergency departments. This proposed regulation will conform the minimum standard for nurse staffing at the more comprehensive level of care to the minimum standard in current regulation at the more limited level of care. Nurse staffing requirements for the comprehensive level of care will then be consistent with the requirements for the basic level of care. While this language is being added for consistency, it does not create a new requirement for nurse staffing in these units, because these units are already required to have a registered nurse on duty assigned to triage patients at all times.