STATE OF CALIFORNIA
OFFICE OF ADMINISTRATIVE LAW

AGENCY: BOARD OF LICENSED VOCATIONAL NURSES AND PSYCHIATRIC TECHNICIANS	)	DECISION OF DISAPPROVAL OF REGULATORY ACTION (Gov. Code Section 11349.3)
ACTION: Amend sections 2542, 2542.1, 2547, and 2547.1 of Title 16 of the California Code of Regulations	)	OAL File No. 02-0228-09S

BACKGROUND

The Board of Licensed Vocational Nurses and Psychiatric Technicians ("Board") proposed regulatory amendments that would have permitted a licensed vocational nurse ("LVN") with a Board-certification in intravenous therapy to administer intravenous medications in hemodialysis, pheresis and blood bank settings under certain conditions. The regulations were submitted to the Office of Administrative Law ("OAL") for review on February 28, 2002, and disapproved on April 12, 2002.

DECISION

OAL notified the Board of Vocational Nursing and Psychiatric Technicians (Board) that OAL had disapproved the above regulatory action because it did not comply with the following standards of the Administrative Procedure Act ("APA").

I. AUTHORITY/CONSISTENCY. The proposed regulations enlarge the scope of practice of the LVN and appear to be inconsistent with the Vocational Nursing Practice Act.

II. CLARITY. Proposed sections 2542.1(b)(5) and 2547.1(b)(5) include the term "immediate vicinity," which is not defined in regulation or statute and is susceptible to differing interpretations by affected persons.

III. MISSING OR DEFECTIVE DOCUMENTS. The micro-cassette recording of the public hearing included in the rulemaking file is mostly inaudible, and there is no transcript or minutes in the file.

DISCUSSION

I. AUTHORITY / CONSISTENCY.

The proposed amendments would allow an LVN to administer medicine to a patient through intravenous fluid, provided certain conditions intended to protect the patient are satisfied. The question presented is whether the Board has exceeded its authority by adopting a regulation that expands the scope of practice of LVNs beyond recognized limits and thereby conflicts with other provisions of law.

Government Code section 11342.1 provides:

> "Each regulation adopted, to be effective, shall be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law."

Government Code section 11342.2 provides:

> "Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute."

Government Code section 11349.1, subdivision (a), paragraphs (2) and (4) require OAL to review each regulation for compliance with the APA "authority" and "consistency" standards. "Authority," as defined by Government Code section 11349(b) "means the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation." "Consistency," as defined in Government Code section 11349(d) "means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law."

The Board cited as authority for this rulemaking action section 2854 and, as reference, section 2860.5 of the Business and Professions Code. Section 2854 provides:

> "The board may adopt, amend, or repeal such rules and regulations as may be reasonably necessary to enable it to carry into effect the provisions of this chapter. Such rules and regulations shall be adopted in accordance with the provisions of the [APA]."

Section 2860.5 provides, in pertinent part:

> "A licensed vocational nurse when directed by a physician and surgeon may do all of the following:
> (a) Administer medications by hypodermic injection.
> (b) Withdraw blood from a patient, . . .
> (c) Start and superimpose intravenous fluids if all of the following additional conditions exist:
> (1) The nurse has satisfactorily completed a prescribed course of instruction approved by the board or has demonstrated competence to the satisfaction of the board.
> (2) The procedure is performed in an organized health care system in accordance with the written standardized procedures adopted by the organized health care system as formulated by a committee which includes representatives of the medical, nursing, and administrative staffs. . . ." [Emphasis added.]

Standard of Review

An administrative agency may not exercise its rulemaking power so as to alter, extend, limit, or enlarge the provisions of the statute that is being administered (First Industrial Loan Co. v. Daugherty (1945) 26 Cal.2d 545, 550). OAL's review of administrative regulations for compliance with the authority standard also relies upon section 14 of title 1 of the California Code of Regulations ("CCR") which provides:

> "In reviewing a regulation for compliance with the 'authority' and 'reference' requirements of Government Code section 11349.1, OAL shall apply the following standards and presumptions: . . . .
>
> "(c) Review of 'Notes.' In reviewing 'notes,' OAL shall use the same analytical approach employed by the California Supreme Court and the California Court of Appeal, as evidenced in published opinions of those courts.
>
> > "(1) For purposes of this analysis, an agency's interpretation of its regulatory power, as indicated by the proposed citations to 'authority' or 'reference' or any supporting documents contained in the rulemaking record, shall be conclusive unless:
> >
> > > "(A) the agency's interpretation alters, amends or enlarges the scope of the power conferred upon it; or
> > >
> > > "(B) a public comment challenges the agency's 'authority'; . . . ."

The above-mentioned presumption of authority does not stand in this regulatory action because the Board's interpretation appears to enlarge the scope of the power conferred upon it, and because public comments challenge the Board's authority to adopt this rule. (See, for example, the comments of the California Nurses Association; the Board of Registered Nursing; and the American Nurses Association, California.)

In 1975, the Board adopted section 2542 of title 16 of the CCR, to establish limits on the scope of intravenous therapy. The regulation's long-standing definition of "intravenous fluids," includes only "fluid solutions of electrolytes, nutrients, vitamins, blood and blood products." In this rulemaking action, the Board has proposed expanding its concept of "intravenous fluids" by adding a new "Category II" that would bring in "medications including, but not limited to, anticoagulants or antibiotics."

The primary question at issue here is whether the Legislature envisioned the definition of "intravenous fluids," as emphasized above, to include "medications" such as antibiotics and anticoagulants. The Board of Registered Nursing, and the associations representing registered nurses argue that the answer is "no," even though LVNs are authorized to administer medications by hypodermic injection. They explain that because medicine administered intravenously may quickly affect a patient's condition, such treatment should only be done by a registered nurse or physician, either of whom would be better qualified to assess changes in a patient's condition occurring during the treatment. The Board disagreed with this contention, and included within its proposed amendments several precautionary measures intended to assure adequate training of the LVNs and the availability of a registered nurse or physician during LVN administration of medicine by intravenous methods.

The Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health (5th Ed., 1992) Miller-Keane, page 790, defines "intravenous" as meaning:

> "within a vein. 1. infusion, administration of fluids into a vein through the use of a steel needle or plastic catheter. This method of fluid replacement is used most often to maintain fluid and electrolyte balance, or to correct fluid volume deficits after excessive loss of body fluids, in patients unable to take sufficient volumes orally. Besides these uses, many medications are administered by intravenous infusion; . . . .
> PATIENT CARE. . . . The label of each container of fluid or medication is very carefully checked against the physician's prescription before it is connected to the infusion apparatus. . . ." [Emphasis added.]

In researching other medical dictionaries and reference sources, the combined words "intravenous fluids" were not found as a discrete term. Where "intravenous" was defined, "intravenous fluids" did not include "medication" as an integral component or ingredient, but the two terms were invariably separated by "and," "or" or a comma, or other distinguishing words, as shown by the emphasized words above. For example, one manufacturer of intravenous products (Bard Access Systems) states in its medical literature: "Peripherally Inserted Central Catheters (PICC) are designed for the administration of I.V. fluids, blood products, medications and parenteral nutrition solutions, as well as blood withdrawal."

The Board argues in its response to comments (Final Statement of Reasons, Attachment A, page 10), that "[i]f the Legislature had intended to prevent 'medicated' IV fluids from

being started or superimposed by LVNs pursuant to B&P Code section 2860(c), it could easily have so stated by simply inserting the adjective 'non-medicated' before 'intravenous fluids.' It did not." The Board thus assumes that authorization to administer intravenous fluids includes authority to administer medicine in such fluids. Under the Board's analysis, the lack of an exception excluding medicine from intravenous fluids indicates that the Legislature understood "intravenous fluids" intrinsically include "medications." Unfortunately, the Board did not collect any other evidence tending to show that the Legislature and/or the medical community understand intravenous fluids to contain medication, as a general rule. Our own analysis of the available information indicates that, while intravenous fluid may serve as the vehicle for administration of a medicine in liquid form, the intravenous fluid itself, without modifiers, is not necessarily medicinal.

Although the matter is not free from doubt, it appears to us that in ordinary medical terminology, use of the term "intravenous fluids" does not include medication, and the Legislature would have expressly stated in subdivision (c), "intravenous fluids and medications," if that indeed was its intent. In subdivision (a), for example, they provided for the administration of medications by hypodermic injection. They know how to use language, to broaden or to narrow the scope of practice.

It is helpful to contrast the authority of an LVN with that of a registered nurse. Business and Professions Code section 2725 describes the practice of nursing (by registered nurses). Concerning medicines, in subdivision (b)(2), it provides that nursing includes:

> "Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code."

No limitations on the method of administration of medicine are included here. On the other hand, for an LVN, the only method listed in section 2860.5 is hypodermic injection. This suggests the intent to more narrowly circumscribe practice of the LVN. With regard to changes in the scope of practice of nursing by a registered nurse, section 2725 provides:

> "[T]he Legislature recognizes that nursing is a dynamic field, the practice of which is continually evolving to include more sophisticated patient care activities. It is the intent of the Legislature in amending this section at the 1973-74 session to provide clear legal authority for functions and procedures that have common acceptance and usage."

The Vocational Nursing Act has no similar language and, thus, does not afford the same kind of flexibility for interpretation of the scope of practice.

The primary task of statutory construction is to ascertain the intent of the Legislature so as to effectuate the purpose of the law (People v. Snook (1997) 13 Cal.4th 1210, 1215). The legislative history of section 2860.5 offers a little assistance in resolving this question. The statute was added in 1968 (Senate Bill 584; ch. 891, sec. 1). Prior to its enactment, an Attorney General Opinion, No. 67/175, dated December 5, 1967, in concluding that an LVN may not draw blood by venipuncture, opined that "[i]t is foreseeable that although judicial construction may allow the vocational nurse, where acting under the immediate direction and supervision of a licensed physician, to perform some acts which would otherwise constitute the illegal practice of medicine, the scope of her allowable activities will not be as broad as those activities allowed registered nurses." (Emphasis in original.) The statutory amendment of 1969 (ch. 112, sec. 1) is not relevant. The 1974 amendment (Assembly Bill 3618; ch. 1084, sec. 1), added subdivision (c), which has remained unchanged to this date. Staff analyses of the bill before various committees basically indicate that the purpose of subdivision (c) was to expand the authority of LVNs with respect to the withdrawal of blood and intravenous therapy, and that the bill provided that LVNs could start and superimpose intravenous fluids if they met certain specified conditions.

We realize that Business and Professions Code section 2860.5 was last amended in 1974, and that modern medical technology has advanced considerably since then. Old definitions and understandings may need to be changed if medical and nursing practice have evolved to the point where professionals in the field would consider such medications as an integral component or ingredient of intravenous fluids. If the Board can supplement the record with facts, studies, expert opinion or other information that tends to show this evolution in nursing practice, these regulations could be resubmitted within 120 days of receipt of this decision for further OAL review and consideration. First, of course, the new information would have to be made available to the affected public as data relied upon, for a 15-day comment period. (See Gov. Code section 11347.1 and section 44, title 1, CCR; and enclosed resubmittal instructions.)

II. CLARITY.

Government Code section 11349.1(a)(3) requires that OAL review all regulations for compliance with the "clarity" standard. Government Code section 11349(c) defines "clarity" to mean "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

Section 16, title 1 of the CCR provides, in relevant part:

> "In examining a regulation for compliance with the 'clarity' requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
>
> "(a) A regulation shall be presumed not to comply with the 'clarity' standard if any of the following conditions exists:

(1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
(2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
(3) the regulation uses terms which do not have meanings generally familiar to those 'directly affected' by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
(4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
(5) the regulation presents information in a format that is not readily understandable by persons 'directly affected;' . . . .

"(b) Persons shall be presumed to be 'directly affected' if they:

(1) are legally required to comply with the regulation; or
(2) are legally required to enforce the regulation; or
(3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
(4) incur from the enforcement of the regulation a detriment that is not common to the public in general." [Emphasis added.]

A. Proposed sections 2542.1(b) and 2547.1(b) would provide that an LVN may start and superimpose Category II intravenous fluids in hemodialysis, pheresis or blood bank settings under specified conditions, including: "(5) A registered nurse or licensed physician is in the immediate vicinity." (Emphasis added.)

Ballentine's Law Dictionary (Lexis Law Publishing, 1969) defines "vicinity" as:

"1. A place near to a place designated, but not adjoining or abutting on it.

"2. The word is not an absolute but a relative one, and what is in the vicinity of a place under one set of circumstances may not be so under other circumstances. In a sparsely settled region a person residing fifteen miles from a road might be regarded as being in the vicinity of it."

Ballentine's further defines "immediate vicinity" as:

"A place adjoining or abutting. . . . An expression not capable of precise definition, its meaning depending upon the context in which it appears, sometimes indicating actual contact, while at other times and in other connections applicable even where there is an intervening space between the objects or tracts of real estate under consideration." [Citation omitted.]

Neither the Board's governing statutes nor its regulations define the term. It appears in Business and Professions Code, undefined, for the Structural Pest Control Board and the

Department of Alcoholic Beverage Control, with different meanings. It also appears and is defined in the Elections Code, section 18546:

> "As used in this article [Division 18, Chapter 6, Article 3], . . .
> (b) 'Immediate vicinity' means the area within a distance of 100 feet from the room or rooms in which the voters are signing the roster and casting ballots."

The Board states, in its response to comments, that it has a mandate of consumer protection. It further states that it is the Board's position that consumer protection is enhanced when the LVN performs defined tasks related to the IV administration of fluids in hemodialysis, pheresis and blood bank settings, in part because of the LVN's training, experience and supervised status. OAL concurs that consumer protection is an issue of the utmost importance when administering intravenous therapy. Hemodialysis medications are circulated rapidly through the patient's system and may cause potentially lethal reactions. The distance the supervising physician or registered nurse is from the patient and the time it may take to reach the bedside may literally spell the difference between a reversible and a non-reversible complication or reaction, when an LVN is administering Category II medications to prevent clot formations and support renal function.

The Board has not explained this provision or its effects in the initial or final statements of reasons, or elsewhere in the rulemaking file. It is not clear if "immediate vicinity" means the patient's room or ward, the same floor, or somewhere on the facility grounds; or if the Board is leaving that decision to the individual facility's "standardized procedures"; or possibly to the discretion of each individual supervising physician or registered nurse, who may be occupied with many other patients or temporarily unavailable.

B. Although OAL is not listing this as ground for disapproval, it is suggested that proposed sections 2542 and 2547 list the definitions in alphabetical order, as a more reader-friendly format.

III. MISSING OR DEFECTIVE DOCUMENTS.

Government Code section 11347.3(b)(8) provides that the rulemaking file shall include "[a] transcript, recording, or minutes of any public hearing connected with the adoption, amendment, or repeal of the regulation." Section 90, title 1 of the CCR further specifies that such information "shall fully and accurately reflect all proceedings applicable to the rulemaking action under review and shall be adequate:

> "(a)(1) to ensure effective review of the record by OAL, in light of the provisions of the APA providing for meaningful public participation; and
> "(2) to permit effective judicial review of the record.
>
> "(b) Material submitted as a 'transcript' or 'recording' in fulfillment of this requirement shall consist of a word-by-word, speaker-by-speaker record of all that

> is said on the record in any and all public hearings or public meetings held as part of the adoption, amendment or repeal of the regulation in question."

The rulemaking record contained a micro-cassette tape that purported to be a recording of the public hearing of April 17, 2001. There was no corresponding transcript or minutes. The tape was mostly inaudible, with the only clearly audible portion being a superimposed personal telephone call, unconnected to the hearing. The final statement of reasons contains summaries and responses to the oral hearing testimony but, without an audible recording or transcript, OAL has no opportunity to review them for accuracy and completeness.

CONCLUSION

For the reasons discussed above, OAL has disapproved the amendment of sections 2542, 2542.1, 2547 and 2547.1 of title 16, CCR. We also note that other minor issues of clarity, necessity and procedure were corrected during OAL's review, and for that reason are not listed in this Decision.

Date: April 19, 2002

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Encl.