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MEMORANDUM

DATE	October 18, 2010
TO	Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals
FROM	Kurt Heppler Senior Staff Counsel Legal Affairs
SUBJECT	**Questions and Answers**

ISSUE

This memorandum addresses issues surrounding the practice of medicine, the unlicensed practice of medicine, and the Medical Board of California's (Board) power to adopt regulations. The Board's Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals (Committee) met recently and some substantive questions arose regarding these issues.

BACKGROUND

The Board is the state agency charged with the responsibility of issuing physician's and surgeon's certificates (medical licenses) to qualified applicants as well as disciplining those physicians who engage in unprofessional conduct.[1]

At the last meeting of this Committee, questions arose regarding the Board's power or authority to promulgate regulations. It is critical to understand the difference between statutes and regulations. Statutes are passed by the California Legislature and signed by the Governor; they are the framework or skeleton from which a state agency operates. Regulations are rules that are adopted to add flesh to the statutory skeleton. In fact, the purpose of a regulation is to implement, interpret or make specific a statute. However, a regulation cannot expand or alter the scope of statute. If it does, it is void. The test for determining if a regulation is valid consists of two parts: 1) The regulation is consistent and not in conflict with existing statute, and 2) it is reasonably necessary to effect the purpose of the statute. Of course, there must be sufficient statutory authority for the agency to promulgate the regulation.

[1] For the purposes of this memorandum, a license also includes a registration, certificate, or other means to engage in a business or profession regulated by the Business and Professions Code.

Another way to look at the relationship between statutes and regulations is that a statute would be the roof and structure of a building and the regulations would be the contents of the building. To be valid, the agency's regulations must fall under the statute's roof. The most recent example of a Board regulation that implemented a statute is the Notice to Consumers rule adopted by the Board. That regulation made specific the requirements of section 138 of the Business and Professions Code (Code)[2], which obligated agencies with the Department of Consumer Affairs to adopt a mechanism by which the public would be made aware that a practitioner was licensed by a health care board.

SPECIFIC QUESTIONS RAISED BY THE COMMITTEE

1. What is the definition of the practice of medicine?

Section 2051 of the Code provides:

"The physician's and surgeon's certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions."

Similarly, section 2052 of the Code provides:

"(a) Notwithstanding Section 146, any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended certificate as provided in this chapter or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense, punishable by a fine not exceeding ten thousand dollars ($10,000), by imprisonment in the state prison, by imprisonment in a county jail not exceeding one year, or by both the fine and either imprisonment.
(b) Any person who conspires with or aids or abets another to commit any act described in subdivision (a) is guilty of a public offense, subject to the punishment described in that subdivision.
(c) The remedy provided in this section shall not preclude any other remedy provided by law."

Section 2053.5 provides:

a) Notwithstanding any other provision of law, a person who complies with the requirements of Section 2053.6 shall not be in

[2] All further statutory references are to the Business and Professions Code unless otherwise indicated.

violation of Section 2051 or 2052 unless that person does any of the following:
(1) Conducts surgery or any other procedure on another person that punctures the skin or harmfully invades the body.
(2) Administers or prescribes X-ray radiation to another person.
(3) Prescribes or administers legend drugs or controlled substances to another person.
(4) Recommends the discontinuance of legend drugs or controlled substances prescribed by an appropriately licensed practitioner.
(5) Willfully diagnoses and treats a physical or mental condition of any person under circumstances or conditions that cause or create a risk of great bodily harm, serious physical or mental illness, or death.
(6) Sets fractures.
(7) Treats lacerations or abrasions through electrotherapy.
(8) Holds out, states, indicates, advertises, or implies to a client or prospective client that he or she is a physician, a surgeon, or a physician and surgeon.
(b) A person who advertises any services that are not unlawful under Section 2051 or 2052 pursuant to subdivision (a) shall disclose in the advertisement that he or she is not licensed by the state as a healing arts practitioner."

Section 2053.6 of the Code provides:

"(a) A person who provides services pursuant to Section 2053.5 that are not unlawful under Section 2051 or 2052 shall, prior to providing those services, do the following:
(1) Disclose to the client in a written statement using plain language the following information:
(A) That he or she is not a licensed physician.
(B) That the treatment is alternative or complementary to healing arts services licensed by the state.
(C) That the services to be provided are not licensed by the state.
(D) The nature of the services to be provided.
(E) The theory of treatment upon which the services are based.
(F) His or her educational, training, experience, and other qualifications regarding the services to be provided.
(2) Obtain a written acknowledgment from the client stating that he or she has been provided with the information described in paragraph (1). The client shall be provided with a copy of the written acknowledgement, which shall be maintained by the person providing the service for three years."

> (b) The information required by subdivision (a) shall be provided in a language that the client understands.
> (c) Nothing in this section or in Section 2053.5 shall be construed to do the following:
> (1) Affect the scope of practice of licensed physicians and surgeons.
> (2) Limit the right of any person to seek relief for negligence or any other civil remedy against a person providing services subject to the requirements of this section."

The Board has addressed the unlicensed practice of medicine in the elective cosmetic arena with the adoption of the *Basile* case as a precedental decision. In *Basile*, the physician was associated with a medical office that utilized an intense pulse light device to treat various conditions. The device also contained a laser to treat other conditions. The device penetrated human tissue to treat blemishes and other conditions. "In short, the use of IPL (intense pulse light) and laser clearly involves penetration of human tissue and therefore falls within the scope of medical practice." (*Basile*, page 5.)

Respondent permitted his wife, who was an unlicensed person, to use the device to treat patients. Respondent, by allowing such actions, was found to have committed unprofessional conduct and to have aided and abetted the unlicensed practice of medicine. Regarding the practice of medicine, it is important to note the Board does not issue specialty or limited licenses except in the case of a disabled physician who seeks a limited license.

2. Is there a statutory or regulatory definition of a 'medical spa' or 'medi-spa' within the Medical Practice Act or its attendant regulations?

No. Remember, the terms above contemplate a place or a physical location for the practice of medicine, which generally speaking the Board does not license. However, Committee members should be aware that there is some interplay between a physical location, fictitious name permits, and the statutory bar on the corporate practice of medicine. With certain exceptions, if a physician wants to practice under a name other than his or her licensed name, a fictitious name permit is required. (See §§ 2285, 2415.) This permit needs to be placed at the location where the services are to be provided so that the public is informed of the physicians 'behind' the permit.

The corporate practice of medicine bar essentially means that general corporations cannot engage in the practice of medicine. A professional medical corporation, however, may do so. Courts have identified sound public policy reasons for the bar: 1) Avoidance of divided loyalty to the patient and a profit motive, and 2) Avoidance of a lay person directing the actions of medical professional. From a real world perspective, the bar means that a general corporation cannot employ physicians, so if a medical spa or medi-spa is owned and operated by a general corporation and that corporation employs one or more physicians, then the law has been violated. The same analysis would hold if a physician is somehow supervised by an allied health provider,

as such a person is still an unlicensed person for the purpose of the corporate practice prohibition.

3. Does the Board have the power to adopt regulations regarding the specialty of physicians who supervise other licensed health care personnel? For example, could the Board require a physician to be Board certified in a certain field as a condition of supervising a licensed health care provider? Can there be a regulatory supervision ratio?

A. Yes and No.

At the most recent Committee meeting, there was considerable discussion regarding the applicable statutes and regulations regarding physician supervision of other licensed healthcare practitioners and the delegation of certain medical procedures and functions to those practitioners. The discussion also touched upon the Board's power to potentially restrict or limit a physician's authority to delegate or supervise in certain areas.

In keeping with the legal concept that any regulatory attempt to limit delegation or supervision must fit within existing statute, it is necessary to examine the scope of existing law. Section 2018 does provide the Board with general regulatory authority, as follows:

> "The board may adopt, amend, or repeal, in accordance with the provisions of the Administrative Procedure Act, those regulations as may be necessary to enable it to carry into effect the provisions of law relating to the practice of medicine."

a. Physician Assistants

Section 3516 of the Code prohibits a physician and surgeon from supervising more than four physician assistants at any one time. This same section of law provides that the Board may restrict a physician and surgeon's ability to supervise specific types of physician assistants, including those physician assistants outside of the field of specialty of the physician and surgeon.

Pursuant to section 3516, the Physician Assistant Committee (PAC) promulgated Section 1399.545 of title 16 of the California Code of Regulations, which provides as follows:

> "Bb) A supervising physician shall delegate to a physician assistant only those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition."

With regard to the adequacy of physician supervision, Section 1399.545 also provides:

> "(e) A physician assistant and his or her supervising physician shall establish in writing guidelines for the adequate supervision of the physician assistant which shall include one or more of the following mechanisms:

> (1) *Examination of the patient by a supervising physician the same day as care is given by the physician assistant*;
> (2) Countersignature and dating of all medical records written by the physician assistant within thirty (30) days that the care was given by the physician assistant;
> (3) The supervising physician may adopt protocols to govern the performance of a physician assistant for some or all tasks. The minimum content for a protocol governing diagnosis and management as referred to in this section shall include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be given the patient. For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the follow-up care. Protocols shall be developed by the physician, adopted from, or referenced to, texts or other sources. Protocols shall be signed and dated by the supervising physician and the physician assistant. The supervising physician shall review, countersign, and date a minimum of 10% sample of medical records of patients treated by the physician assistant functioning under these protocols within thirty (30) days. The physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient;
> (4) Other mechanisms approved in advance by the committee." (Emphasis added.)

The above regulations make specific the provisions of law regarding the supervision of physician assistants. Subdivision (e) of section 1399.545 does make it clear that a physician is not required to examine a patient prior to the patient receiving properly delegated medical services from the physician assistant since it provides other alternatives for compliance.

b. Licensed Midwives

Another example of a statutory scheme that limits a physician's ability to supervise allied health personnel is the Licensed Midwifery Practice Act. Section 2507 of the Code provides in pertinent part:

> "(a) The license to practice midwifery authorizes the holder, under the supervision of a licensed physician and surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother, and immediate care for the newborn.
> (b) As used in this article, the practice of midwifery constitutes the furthering or undertaking by any licensed midwife, *under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics*, to assist a woman in childbirth so long as progress meets criteria accepted as normal. All complications shall be referred to a physician and surgeon immediately. The practice of midwifery does not include the assisting of childbirth by any artificial, forcible, or mechanical means, nor the performance of any version.

> (c) As used in this article, "supervision" shall not be construed to require the physical presence of the supervising physician and surgeon.
> (d) *The ratio of licensed midwives to supervising physicians and surgeons shall not be greater than four individual licensed midwives to one individual supervising physician and surgeon.*
> (e) A midwife is not authorized to practice medicine and surgery by this article.
> (f) *The board shall, not later than July 1, 2003, adopt in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), regulations defining the appropriate standard of care and level of supervision required for the practice of midwifery.* (Emphasis added.)
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> * * *

Section 2507 sets a *statutory* limitation on which physicians can supervise a licensed midwife. The Committee should recognize that despite the statutory obligation in subdivision (f), the Board has been unable to adopt regulations that specify the appropriate level of supervision despite several attempts over a number of years. Of course, any regulation relating to the physician supervision of a midwife would be adopted pursuant to the specific authority granted above.

c. Nurse Practitioners

The Committee also inquired about the issue of nurse practitioners and physician supervision. With regard to nurse practitioners and the ordering or furnishing of drugs and devices, Section 2836.1 of the Code provides[3]:

> "Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:
> (a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the *supervising physician and surgeon* when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.
> (b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by *the supervising physician and surgeon*, the nurse practitioner, and the facility administrator or the designee.
> (c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what

[3] Section 2836.1 is outside of the Medical Practice Act.

circumstances, the extent of *physician and surgeon supervision*, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.
(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.
(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under *physician and surgeon supervision.* Physician and surgeon supervision shall not be construed to require the physical presence of the *physician,* but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.
(e) *For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.*
(f) (1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and *physician and surgeon* and specified in the standardized procedure.
(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or *supervising physician.* A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order."(Emphasis added.)

* * *

Current law, not regulation, establishes a supervision ratio requirement for nurse practitioners.

d. Polysomnographic Registrants

The California Legislature has recently enacted legislation regarding the practice of polysomnography and the registration of polysomnographic technicians, technologists and trainees. Section 3575 of the Code provides in pertinent part:

"(e) Within one year after the effective date of this chapter, the board shall adopt regulations that establish the means and circumstances in which a *licensed physician and surgeon may employ polysomnographic technicians and polysomnographic trainees.* The board

> may also adopt regulations specifying the scope of services that may be provided by a polysomnographic technician or polysomnographic trainee. Any regulation adopted pursuant to this section may specify the level of supervision that polysomnographic technicians and trainees are required to have when working under the supervision of a certified polysomnographic technologist or licensed health care professional."(Emphasis added.)
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> * * *

Given this statutory framework, the Board is proposing regulations that will establish a physician-to-registrant supervision ratio as well as require a physician to meet certain training or experience standards as a condition of supervising polysomnographic registrants. These regulations will be analogous to the statutory supervision provisions regarding midwives.

e. Section 2023.5

The Legislature has directed the Board to study the issues and concerns surrounding the use of lasers and intense pulse light devices with the enactment of section 2023.5 of the Code. Specifically, section 2023.5 of the Code provides:

> "(a) The board, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:
> (1) The appropriate level of physician supervision needed.
> (2) The appropriate level of training to ensure competency.
> (3) Guidelines for standardized procedures and protocols that address, at a minimum, all of the following:
> (A) Patient selection.
> (B) Patient education, instruction, and informed consent.
> (C) Use of topical agents.
> (D) Procedures to be followed in the event of complications or side effects from the treatment.
> (E) Procedures governing emergency and urgent care situations.
> (b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.

This section gives the Board to authority adopt regulations in a narrow area: elective cosmetic procedures involving the use of laser or intense pulse light devices. The Board has not promulgated regulations in this area. However, it is important to note that the Board could not adopt regulations as to the scope of practice of registered nurses, as that is the responsibility of the Board of Registered Nursing. (See § 2725, subd. (e).)

4. Are the provisions of section 2242 of the Code applicable to this discussion as it pertains to elective cosmetic procedures?

Section 2242 of the Code provides:

> "(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.
> (b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:
> (1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of his or her practitioner, but in any case no longer than 72 hours.
> (2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:
> (A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.
> (B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be.
> (3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refill."

By its own terms, this section does not apply to the prescribing or use of devices by a physician. As set forth above, physician assistants and nurse practitioners may order drugs or devices for patients under certain circumstances.

As Committee members know, the Board is responsible for disciplining physicians. The Board may bring an accusation against a physician for incompetence, gross negligence, repeated negligent actions or generalized unprofessional conduct. To bring such an action, the Board must first establish the standard of care, and expert testimony is required to do that.

CONCLUSION

In those areas where the Legislature has spoken on the issues of physician delegation and supervision, the Board has a clearer path toward to the adoption of regulations that set parameters for physician supervision of allied health care providers. In areas where the Legislature has not so opined, the path is not so clear. Committee members should be aware that whenever the Board exercises its regulatory function, public protection is paramount. (See § 2001.1.)

As mentioned earlier, a regulation must meet several standards to be valid, and one of those standards is necessity. In other words, the Board would have to demonstrate by substantial evidence why the regulation is necessary, and from the Board's perspective, the objective would be to explain how the proposed regulation furthers public protection. The Board would have to explain what problem it is trying to solve and why it chose this particular method of solving it.

For example, if a proposed regulation were to state that only specialty board certified physicians could supervise licensed healthcare practitioners performing medical services in that specialty, the Board may encounter difficulty because 1) the Board does not issue specialty licenses and 2) it may be unreasonable to presume that a physician who has worked in a particular area of practice but for whatever reason is not board certified does not have necessary knowledge or expertise to supervise the safe provision of services. Other generalized attempts to limit physician supervision will be difficult as well in the absence of a specific statutory obligation to set standards for supervision.

If the Committee believes that additional regulations are necessary to protect the public, it may wish to explore utilizing the authority granted in section 2023.5 to propose regulations specific to the use of lasers and intense pulse light devices to the Board. However, the Committee may wish to consider the implementation of other mechanisms to protect the public, including but not limited to public awareness measures.