# CALIFORNIA

## ENFORCEMENT MONITOR'S WARNING: UNDUE DELAYS PUT PUBLIC AT RISK

One of the more important pieces of Senate Bill 1950 (passed in 2002) was the creation of Business and Professions Code section 2220.1, which allowed for the appointment of an Enforcement Program Monitor, who "shall monitor and evaluate the disciplinary system and procedures of the board ..." The monitor was appointed for a two-year period, and in November 2004, her initial report was published. The monitor's report can be viewed in its entirety at http://www.cpil.org/pubs.htm, and includes 65 recommendations affecting various parts of the Enforcement Program and the board's Diversion Program. Although all recommendations have been reviewed by board staff for potential program changes, two are being implemented immediately.

The monitor expressed concerns about delays during the investigation of complaints and observed that B&P Code section 2319 set as a goal, "that no more than six months will elapse from the receipt of a complaint to the completion of an investigation." Board data currently reflects, on average, it takes 66 days to obtain medical records and another 60 days to schedule an interview with a physician. These two activities alone comprise over two-thirds of the 180 days. Board staff must take some responsibility in allowing this to occur, by its past practice of sending two or more letters to physician offices and/or clinics with follow-up telephone calls to encourage them to send the needed medical records.

B&P Code section 2225.5 is clear on this issue: When the board sends a request to a physician or a hospital, which is accompanied by a patient's written authorization for release of the records, the physician must respond within 15 days, while hospitals must respond within 30 days. Unless there is "good cause," a civil penalty of $1,000 per day for each day the documents have not been produced, shall accrue. Although board staff have been reluctant to pursue civil remedies, except in the most egregious circumstances, civil penalties will now be pursued as dictated by this section of the law, beginning in January 2005. It is important to understand that 75 percent of incoming complaints to the board's Central Complaint Unit do not result in a formal investigation in a district office. However, most of the complaints require medical records before this determination can be made. Similarly, 75 percent of the complaints investigated in the district offices result in case closures with no action against the physician. However, most of these conclusions also necessitate the review of the applicable medical record. Board correspondence is being changed to emphasize an advisory notice about the civil penalties, and board investigative staff will point out the potential penalties as the correspondence is served to the records custodians at hospitals and physician offices.

The other area of undue delay has occurred when physicians are requested to come to one of the board's district offices for an interview. Scheduling conflicts do occur, however the prevailing "average" time of 60 days is not acceptable. Effective Jan. 1, 2005, board staff will make contact with the physician over the telephone requesting an interview appointment. The physician will be given 72 hours to respond with a date, which must occur in the next 15 days. If the physician fails to respond within 72 hours of the investigator's call or fails to keep the scheduled appointment, a subpoena will be served to compel the physician to attend an interview at a time and date of the board's choosing.

The board hopes these new procedures will assist in its mission of public protection by promoting the timely resolution of all complaints, which will best serve the interests of patients and physicians.

## INVESTIGATING PHYSICIANS WHO ARE SUSPECTED OF SUFFERING FROM DISABLING MENTAL AND PHYSICAL CONDITIONS THAT POSE A THREAT TO PATIENT CARE

In the October 2004 *Action Report*, the board published an article regarding Business and Professions Code (B&P Code) section 821.5, addressing medical staff initiating a "formal investigation" of a physician when there are concerns the physician may be suffering from a disabling mental or physical condition that poses a threat to patient care.

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B&P Code section 821.5 requires completing the steps of the "formal investigations" within specified timelines. This follow-up article summarizes 13 reports submitted to the board per B&P Code section 821.5 and addresses the more frequently asked questions relating to the filing of an 821.5 report. The board developed forms for the initial report and for the final report that are available on request.

### Do cases under 821.5 get reported to the board?

Under 821.5, all cases under "formal investigation" must be reported to the Diversion Program Administrator. Under the law, the Program Administrator must report cases to the Chief of Enforcement if the Program Administrator determines that there is a danger to the public. Cases that are not completed in a timely manner are automatically reported to the Chief of Enforcement.

### Which committee within the medical staff should initiate the referral?

In accordance with JCAHO standards, medical staffs should separate disciplinary functions from physician's assistance functions. Well-being committees should act in the role of helping bodies and not be a part of the discipline system. In light of JCAHO standards, "formal investigations" and referrals under 821.5 are best made by medical staff executive committees, not well-being committees. According to 821.5, "For purposes of this section 'formal investigation' means an investigation ordered by the peer review body's medical executive committee or its equivalent ... 'Formal investigation' does not include the usual activities of the well-being or assistance committee … For purposes of this section, 'usual activities' of the well-being or assistance committee are activities to assist medical staff members who may be impaired by chemical dependency or mental illness to obtain necessary evaluation and rehabilitation or monitoring services that do not result in referral to the medical executive committee …"

It may not be necessary to refer physicians who voluntarily accept the recommendations and conditions set forth by the well-being committee and practice in a manner that does not endanger patients. Concerns about physicians who have already entered the Diversion Program should be communicated from the well-being committee to the Diversion Program, which is part of the participant Diversion agreement.

### Can the reporting/evaluating entity request extensions regarding the timetables for completion?

Yes, the Diversion Program Administrator has some discretion in granting extensions. For example, if there is a need for additional time to arrange for outside evaluations or complete the evaluations, the Program Administrator can grant additional time.

### Under what circumstances do 821.5 cases get referred to Enforcement?

If the Diversion Program Administrator determines the progress of the investigation is "not adequate to protect the public," the Program Administrator must notify the Chief of Enforcement, who must promptly open an investigation. At the same time, the Diversion Program Administrator must notify the Peer Review Body and the chief executive officer of the hospital of this decision.

### Do all cases reported under 821.5 require physician enrollment in the Diversion Program?

No, although cases are reported to the Diversion Program Administrator, physicians reported under 821.5 are not automatically enrolled as participants in the Diversion Program. The role of the Diversion Program Administrator is to ensure the medical staff complies with timely completion of the formal investigation. In the course of investigation, medical staffs may or may not conclude that referring the physician for participation in the Diversion Program is an appropriate disposition.

### Can non-physician licensed professionals be reported to the board's Diversion Program under 821.5?

No. According to the law, section 821.5 is a reporting mechanism for physicians and surgeons. The board interprets this to mean it is a reporting mechanism only for physicians and surgeons and no other allied health professionals.

From July 2003 to July 2004, there have been 13 821.5 reports to the Diversion Program Administrator. The following is a list of types of problems prompting referrals:

- Disruptive behavior toward coworkers
- Suspected or confirmed substance use involving drugs or alcohol
- Physical condition causing practice impairment
- Mental condition causing practice impairment
- Cognitive disorder causing practice impairment

Outcomes vary depending on the details of the case. One case concluded the physician could return to duties and posed no significant risk to patients. Some investigations resulted in referrals to treatment and referrals to the Diversion Program. Some cases involved 805 reports by the



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referring party, for example, when the physician failed to complete the steps of the 821.5 investigation. In another case, the Diversion Program Administrator made a referral to the Enforcement Unit because of danger to the public.

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# COLORADO

## SUPERVISION OF DELEGATED MEDICAL FUNCTIONS

In November 2002, the Colorado Board of Medical Examiners adopted Rule 800, intended to provide guidance and clarity regarding the statutory authority of physicians to delegate medical functions to nonphysicians. In the past year, the board has taken a number of disciplinary actions for violations of Rule 800, so the board thought another discussion might be useful to Colorado physicians.

Specifically, the board has received and acted on a number of complaints where a physician was serving as the supervisor for non-physicians providing cosmetic services such as Botox injections and laser therapy. In these situations, the service was provided at a separate office site, often operated solely by the delegatee, with little if any real supervision by the physician. These relationships appeared to be supervision in name only, in direct violation of Rule 800. Other than violating the intent of the rule in terms of supervision, where the physician "must make the decisions as to the necessity, type, effectiveness and method of treatment and must devote sufficient time to on-the-spot inspection directions are regularly being followed," these relationships are also not consistent with the part of the Rule stating services must be provided in the context of an appropriate physician/ patient relationship. In the cases of concern to the board, the only relationship with the patient was with the delegatee. Finally, the delegating physician must be available to attend the patient in person within 30 minutes in those settings where the physician is not on site, and in these settings, the delegatee must be using detailed written protocols for care delivery and have adequate written protocols for emergencies. Rule 800 is not intended to provide a legal umbrella under which nonphysicians can independently practice medicine. It is intended to extend the physician's ability to provide care where the physician delegates his or her authority to practice to an individual with appropriate training and supervision. Delegated services are intended to be provided within the context of ongoing care for the patient, and in settings where the physician can personally respond to any problems quickly. Physicians must only delegate services they themselves are trained and competent to perform, and the service will be held to the same standard of care as if a competent physician performed it personally. Remember, the delegating physician alone is responsible for the delivery and outcome of the service. You can view the complete rule on the Internet at www.dora.state.co.us/medical/Rule800.htm.

## TITLE OF 'NURSE' NOW DEFINED AND PROTECTED BY A REVISED COLORADO STATUTE

The Colorado Nurses Association was recently heavily involved in a revision of the Colorado Nurse Practice Act. The revised statute, C.R.S.12-38-123 now reads:

1. It is unlawful for any person:
   a. To practice as a practical or professional nurse unless licensed therefore;
   b. (I) To represent himself or herself to an individual or to the general public by use of any word or abbreviation to indicate or induce others to believe that he or she is a licensed practical or professional nurse unless the person is actually licensed as a practical nurse or professional nurse, respectively;
      (II) To use the title "nurse", "registered nurse", "R.N.", "practical nurse", "trained practical nurse", "licensed vocational nurse", "licensed practical nurse", or "L.P.N." unless the person is licensed by the board.
      (III) Notwithstanding any provision of this paragraph (b) to the contrary, a person who provides nonmedical support services may use the title "Christian Science nurse" when offering or providing services to a member of his or her own religious organization.
   c. To practice as a practical or professional nurse during a period when his license has been suspended or revoked;
   d. To sell or fraudulently obtain or furnish a license to practice as a nurse or to aid or abet therein.
2. Any person who violates the provisions of this section commits a class 3 misdemeanor and shall be punished as provided in section 18-1.3-501, C.R.S. Any person who subsequently violates any provision of this section within three years after the date of the first conviction commits a class 6 felony and shall be punished as provided in section 18-1.3-401, C.R.S.



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Practically speaking, the revisions mean office personnel, such as a medical assistant or nursing assistant, may no longer call themselves the doctor's "nurse." Certified nurse aides in nursing homes may not tell a patient or family that they are their "nurse" for the day. Only LPNs and RNs with an active license may use the title of nurse. Failure to comply with the above statute may result in a class three misdemeanor.

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## PENNSYLVANIA
### OFFICE-BASED METHADONE TREATMENT

For the first time in almost a century, physicians may treat opioid addiction with opioid medications in office-based settings. Until this recent change, physicians had been prohibited from prescribing and dispensing opioid medications in the treatment of opioid addiction, except within the confines of federally and state regulated opioid treatment programs. Because of the increasing number of opioid-addicted individuals and the associated public health problems, as well as the limited availability of addiction treatment programs, federal laws now [enable] permit qualified physicians to prescribe Schedule III-V medications approved by the Food and Drug Administration (FDA) for office-based treatment of opioid addiction. The only medication approved for office-based treatment of opioid addiction is buprenorphine that is available under the trade names of Suboxone® and Subutex®. Any other form of buprenorphine may not be used. Physicians who consider office-based treatment of opioid addiction must be able to recognize the condition of drug or opioid addiction and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications. Physicians must also demonstrate required qualifications as defined under and in accordance with the "Drug Addiction Treatment Act of 2000" (DATA 2000) (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), as authorized by the Secretary of Health and Human Services (HHS).

DATA 2000 expands the clinical context of medication assisted opioid addiction treatment by allowing qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional Opioid Treatment Program (OTP) (i.e., methadone clinic). In addition, DATA 2000 reduces the regulatory burden on physicians who choose to practice opioid addiction therapy by permitting qualified physicians to apply for and receive waivers of the special registration requirements defined in the Controlled Substances Act. This new treatment modality makes it possible for physicians to treat patients for opioid addiction with these Schedules III-V narcotic controlled substances specifically approved by the FDA for addiction treatment in their offices without the requirement that they be referred to specialized OTPs as previously required under federal law.

The DATA 2000 "Waiver Authority for Physicians who Dispense or Prescribe Certain Narcotic Drugs for Maintenance Treatment or Detoxification Treatment" sets forth conditions a physician must satisfy to be eligible for a separate DEA registration number permitting them to prescribe buprenorphine. The waiver presently limits physicians in solo or group practices to no more than 30 combined patients [legislation is pending to remove this restriction]. The Pennsylvania Department of Health, Division of Drug and Alcohol Program Licensure (Division) has the responsibility for the approval and monitoring of the narcotic treatment programs in the Commonwealth. If the physician prescribes or dispenses buprenorphine from his or her private practice [called office-based], this does not require Division approval. The waiver requires the physician have an "affiliation" to make counseling services available. In this context, the physician can simply refer a patient for counseling. However, when the physician is working for a licensed drug and alcohol treatment provider, then Division approval is required, i.e., patient seen by the physician at the drug and alcohol treatment program. Questions regarding the approval process for use of buprenorphine in a licensed drug and alcohol treatment program may be directed to the Division at (717) 783-8675.

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