

Guide to the
**Laws Governing the
Practice of Medicine**
by Physicians and Surgeons

Medical Board of California • Seventh Edition: 2013

Cover illustration: RNA polymerase II
David Bushnell, Ken Westover and Roger Kornberg, Stanford University

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Medical Board of California

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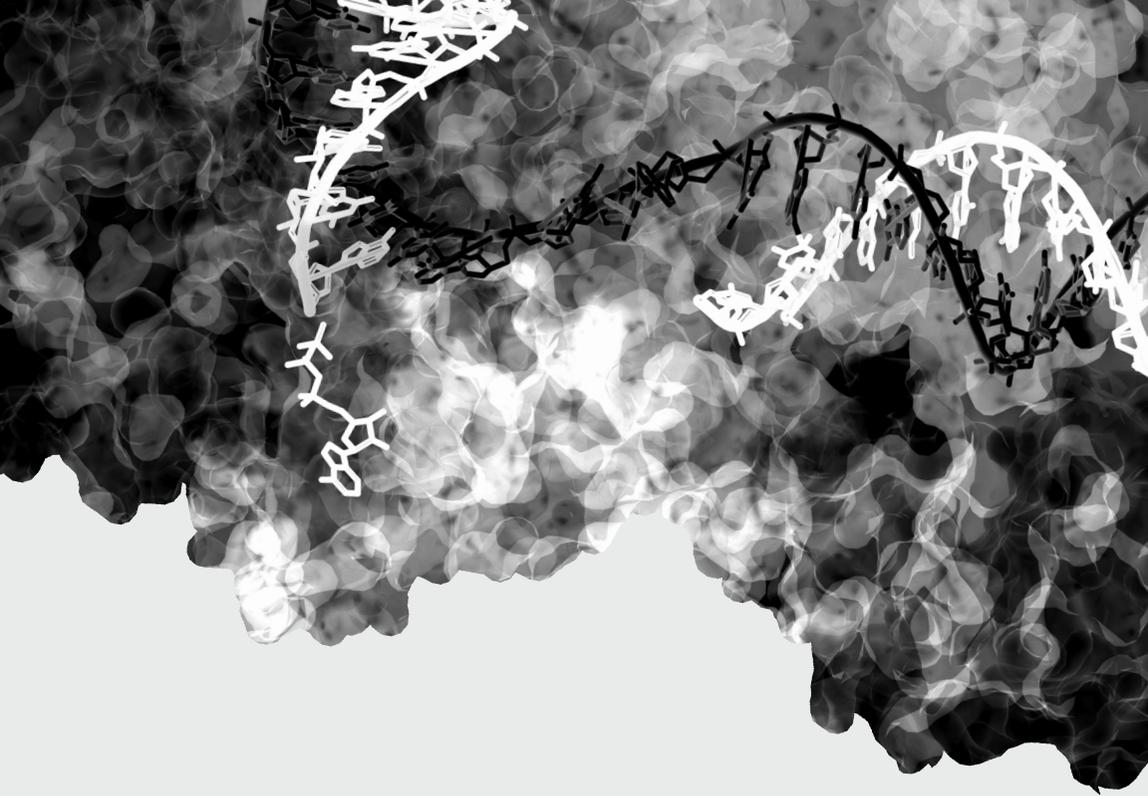
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The Medical Board of California

The Mission of the Medical Board of California

The mission of the Medical Board of California is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and, to promote access to quality medical care through the Board's licensing and regulatory functions.

Offices of the Medical Board of California

Executive Office

2005 Evergreen Street
Suite 1200
Sacramento, CA 95815

Standards & Training

2005 Evergreen Street
Suite 1200
Sacramento, CA 95815

Operation Safe Medicine

160 E. Via Verde
Suite 245
San Dimas, CA 91773

Probation North

2535 Capitol Oaks Drive
Suite 225
Sacramento, CA 95833

Probation South

160 E. Via Verde
Suite 230
San Dimas, CA 91773

Probation L.A. Metro

12750 Center Court Dr. South
Suite 750
Cerritos, CA 90703

Northern California Area

Sacramento District Office

2535 Capitol Oaks Drive
Suite 220
Sacramento, CA 95833

Department of Consumer Affairs

1625 North Market Boulevard
Sacramento, CA 95834

Pleasant Hill District Office

3478 Buskirk Avenue
Suite 217
Pleasant Hill, CA 94523-4326

Fresno District Office

1277 Alluvial Avenue
Suite 110
Fresno, CA 93720

San Jose District Office

1735 Technology Drive
Suite 800
San Jose, CA 95110-1313

Los Angeles Metropolitan Area

Cerritos District Office

12750 Center Court Dr. South
Suite 750
Cerritos, CA 90703

San Dimas District Office

1370 South Valley Vista Drive
Suite 240
Diamond Bar, CA 91765-3923

Glendale District Office

320 Arden Avenue
Suite 250
Glendale, CA 91203

Valencia District Office

27202 Turnberry Lane
Suite 280
Valencia, CA 91355

Southern California Area

San Bernardino District Office

464 West 4th Street
Suite 429
San Bernardino, CA 92401

San Diego District Office

4995 Murphy Canyon Road
Suite 203
San Diego, CA 92123

Rancho Cucamonga District Office

9166 Anaheim Place
Suite 110
Rancho Cucamonga, CA 91730

Tustin District Office

15641 Redhill Avenue
Suite 215
Tustin, CA 92780

The Medical Board of California

Foreword

This publication is a reference source on the federal and state laws and additional information which govern your medical practice. It is in summary form and should not be used in place of the laws themselves. For more information, the complete laws are in the California Business and Professions Code, Health and Safety Code, and other codes cited herein. Specific sections or articles of the law are cited in each chapter for your assistance and can be read online at www.leginfo.ca.gov/calaw.html.

This is the seventh edition of this Guide, and is current as of Winter 2012. Please retain this booklet for future reference. It has been designed to give you a summary of information that will assist you in your daily medical activities.

Introduction to the Medical Board of California

The Medical Board of California is the state agency responsible for regulating physicians and surgeons and a number of other allied health professions. The Board is composed of 15 members (eight physicians and seven public members). Members are appointed by the Governor and the Legislature for terms of four years.

The Medical Board of California is one of 40 regulatory entities within the Department of Consumer Affairs.

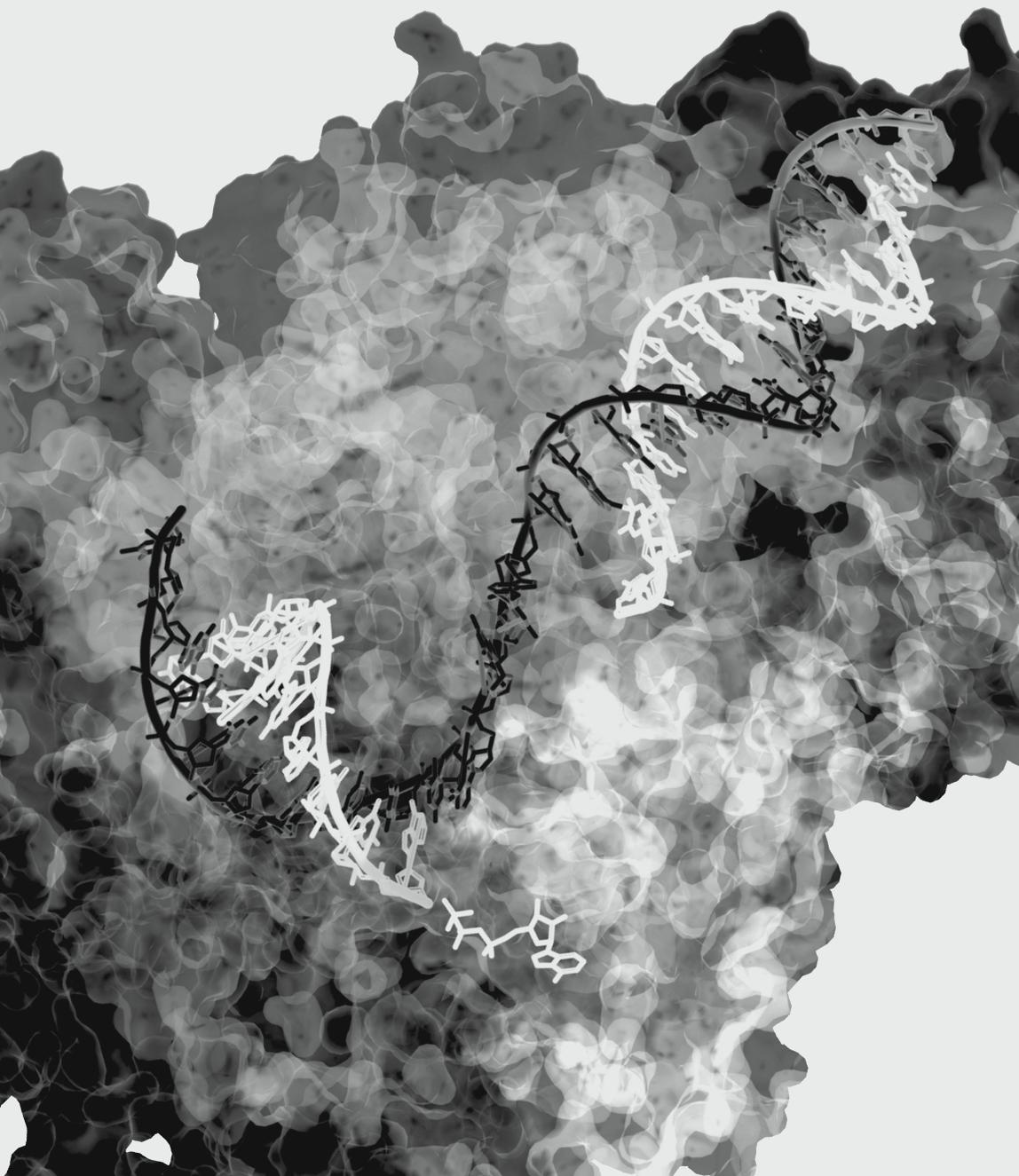
Members of the Board meet as one deliberative body, giving all members of the Board knowledge about policy and statutes for both licensing and enforcement functions.

The Board's responsibilities include issuing licenses and certificates under the Board's jurisdiction; the enforcement of the disciplinary and criminal provisions of the Medical Practice Act; the administration and hearing of disciplinary actions; carrying out disciplinary actions appropriate to findings made by a panel or administrative law judge; suspending, revoking, or otherwise limiting certificates after the conclusion of disciplinary actions; reviewing the quality of medical practice carried out by physicians under the jurisdiction of the Board; and more. (BUSINESS AND PROFESSIONS CODE §2004)

(Note: Osteopathic physicians and surgeons (DOs) are licensed by the Osteopathic Medical Board of California - www.ombc.ca.gov.)

SECTION I:

The Licensing Program



I. The Licensing Program

1.1 General Responsibilities

The Licensing Program of the Medical Board of California (Board) is primarily responsible for licensing physicians and surgeons and providing licensing verification services to the public and the medical community. In addition to licensing physicians, the program licenses midwives, registered dispensing opticians, contact lens and spectacle lens dispensers, research psychoanalysts, student research psychoanalysts and polysomnographic technologists, technicians, and trainees; approves accreditation agencies for accreditation of outpatient surgery settings, reviews and approves non-ABMS specialty boards, issues fictitious name permits for medical businesses, and approves licensing exemptions for medical school faculty appointments.

Each year, the licensing program staff performs more than one million license verifications and issues more than 5,000 new physician licenses.

The license expires at midnight on the last day of the month in which the physician was born.

Physicians must complete a survey when the license is renewed.

1.2 License Renewal

A license to practice medicine in California must be renewed every two years. It is illegal to practice medicine with an expired license. The license expires at midnight on the expiration date, which is the last day of the birth month of the physician.

To renew a license, the physician must apply within 90 days of the expiration date, allowing eight weeks for processing. The renewal must be on the Board's renewal form and must include the current renewal fee. The license must be renewed before the expiration date regardless of whether a renewal form has been received. At the time of initial licensure, and each time the licensure is renewed, physicians must complete a mandatory physician survey (BUSINESS AND PROFESSIONS CODE §§2425.1 and 2425.3). The purpose of the survey is to gain a better understanding of the physician workforce in California and assist consumers in making more informed decisions when choosing a physician.

Other renewal requirements include certifying under penalty of perjury that the applicants have completed an average of 50 hours of approved continuing medical education during the renewal cycle, and disclosing the names of all health-related facilities in which they or their family have a financial interest (Refer to sections 1.8 and 1.9 of this guidebook for additional information).

Forms, information about current renewal fees, and other renewal requirements may be obtained by contacting the Medical Board of California at

2005 Evergreen Street, Suite 1200
Sacramento, CA 95815
(800) 633-2322 (California only), (916) 263-2382
www.mbc.ca.gov

**A retired physician
may not practice
medicine.**

A physician may be exempt from paying a renewal fee if he or she meets one of the following requirements and notifies the Board accordingly:

A. Military Status

A licensee with military status requires full-time employment in active service or training in the U.S. Army, Navy, Air Force, Marines, or U.S. Public Health Service (BUSINESS AND PROFESSIONS CODE §2440).

B. Retired Status

A retired licensee is exempt from payment of renewal fee and continuing medical education, but cannot engage in the practice of medicine (BUSINESS AND PROFESSIONS CODE §2439).

C. Disabled Status

Any licensee who demonstrates to the satisfaction of the Board that he or she is unable to practice medicine due to a disability may request a waiver of the license renewal fee. A physician with disabled status may return to work once it has been established that the disability either no longer exists or no longer affects the physician's ability to safely practice medicine, or upon signing an agreement with the Board limiting practice in the manner prescribed by the reviewing physician (BUSINESS AND PROFESSIONS CODE §2441).

D. Volunteer Status

Voluntary license status is for the sole purpose of providing voluntary, unpaid service (BUSINESS AND PROFESSIONS CODE §2442).

1.3 Failure to Renew License

Practicing medicine without a valid license may lead to disciplinary action against a physician.

A physician who practices with an expired license may be subject to a citation and fine from the Board. There is no grace period. On the date a license expires, the status is changed to “delinquent” if a renewal application has not been processed nor fees paid. If a license has not been renewed within 30 days following the expiration date, the Licensing Program will notify the physician by certified mail.

If a license is renewed more than 90 days following the expiration date, the licensee is required to pay a penalty fee equal to 50 percent of the renewal plus a delinquency fee equal to 10 percent of the renewal fee, in addition to the renewal fee. The renewal of an expired license within six months from date of expiration is retroactive to the expiration date (BUSINESS AND PROFESSIONS CODE §§2424 and 2435).

After a license has been in “delinquent” status for five years, the license is automatically canceled. A canceled license may not be reactivated. The physician must apply for a new license and meet the current licensure requirements.

A physician who practices with an expired license may be cited and fined by the Medical Board.

1.4 Inactive Licenses

Physicians who want to retain a license while not actively engaged in their profession may apply for an inactive license. Applications are available from the Licensing Program (refer to §1.2 for address). An inactive license must be renewed at the same time and with the same fee as an active license.

A physician who holds an inactive license may not practice medicine in California. The holder of an inactive license need not comply with continuing medical education requirements (CME) until he or she wishes to restore the license to active status. At that time, the physician must have completed 50 CME units (the number of continuing medical education units required for a single license renewal period), including any specific types of required units (BUSINESS AND PROFESSIONS CODE §704). For additional information, visit the Board’s Web site at www.mbc.ca.gov/licensee/inactive_license.html

1.5 Reporting Address Changes

California law requires physicians to report to the Board, within 30 days, any change of address. If the new address is a post office box, the licensee is required by law to provide the Board with a separate street address which will be kept confidential. Reporting an address change can be completed online or in writing using a Change of Address Form, which can be obtained on the Board’s Web site: http://www.mbc.ca.gov/licensee/address_record.html. When filling out the form, include both old and new addresses, license number and signature to assure correct identification (BUSINESS AND PROFESSIONS CODE §2021), and send to the Board’s Sacramento headquarters at:

Physicians must report any change of address within 30 days of moving.

Medical Board of California
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

Note: Current address of record and complete physician profile can be checked at www.mbc.ca.gov under Check Your Doctor. Any address listed as the address of record is public record and will be displayed on the Board’s Web site.

1.6 Fictitious-Name Permits

Sole proprietors, partnerships, groups, and medical corporations intending to use a fictitious name for their practices must first register the name and obtain a fictitious-name permit from the Board prior to its use. The name may not be deceptive, misleading, or confusing. The initial permit fee is \$50. The biennial renewal fee is \$40 (BUSINESS AND PROFESSIONS CODE §§2415 and 2443). For additional information, visit the Board’s Web site at www.mbc.ca.gov/licensee/fictitious_name.html.

1.7 Medical Corporations

After the formation of a professional medical corporation, there is no requirement to obtain a “certificate of registration” from the Board, which is a common requirement for some other professions (CORPORATIONS CODE §13401). Refer to §1.6 for additional information on corporations.

You should contact the California Secretary of State if you are looking for information regarding:

The Secretary of State can be reached at:

California Secretary of State
1500 11th Street
Sacramento, CA 95814
(916) 653-6814

Visit the California Secretary of State’s Web site at <http://www.sos.ca.gov/business/business.htm>

1.8 Continuing Medical Education (CME) Requirements

California physicians must meet the Board's standards for continuing medical education to renew their licenses. The following is an overview of the Board's requirements, audits, and coursework.

For additional information on CME, visit the Board's Web site at www.mbc.ca.gov/licensee/continuing_education.html.

Briefly, the CME requirements are:

A. Required Hours

Physicians must complete an average of 50 hours of approved CME during the renewal cycle, i.e., the two-year period immediately preceding the expiration date of the license.

All physicians also must complete a mandatory, one-time requirement of 12 hours continuing education in pain management and the treatment of terminally ill and dying patients (BUSINESS AND PROFESSIONS CODE §2190.5). A list of courses meeting the pain management requirement is listed at the Web site address mentioned in §1.8 above.

Additionally, all general internists and family physicians who have a patient population of which over 25 percent are 65 years of age or older must complete at least 20 percent of all mandatory CME in a course in the field of geriatric medicine or the care of older patients (BUSINESS AND PROFESSIONS CODE §2190.3).

B. Reporting Requirements

Each time the license is renewed, the physician must certify completion of the CME requirements.

A physician who cannot certify compliance with the CME requirement must apply for and receive a waiver. Waivers must be based on either disability, military service, or undue hardship. Applications for a waiver are available from the Licensing Program, and on the Board's Web site: www.mbc.ca.gov/forms/cme-1w.pdf

Any physician who submits an application for a waiver which is denied by the Board must bring all CME requirements current before a license renewal can be issued (TITLE 16, CALIFORNIA CODE OF REGULATIONS §1338) (www.oal.ca.gov/ccr.htm).

It is unprofessional conduct, which may result in disciplinary action or a citation and fine, for any physician to misrepresent his or her compliance with the CME requirement.

A physician's license cannot be renewed until 50 hours of approved CME have been completed.

C. CME Audits

Each year the Board audits a random sample of physicians who have reported compliance with the CME requirement. Those physicians selected for audit must document their compliance with the CME requirement.

Any physician who has been certified as complying with the CME requirement by either the California Medical Association (CMA) or the American Academy of Family Physicians (AAFP) will not be required to submit documentation or records of CME coursework completed, but instead may request the records be directly submitted to the Board from those organizations.

The Medical Board annually audits a random sample of physicians to ensure compliance with the CME requirement..

D. Acceptable Continuing Medical Education

The following programs and courses are accepted by the Board for continuing medical education credit:

1. Programs or courses that qualify for Category I credit from the California Medical Association or the American Medical Association.
2. Programs or courses that qualify for prescribed credit from the American Academy of Family Physicians.
3. CME that meets Title 16, California Code of Regulations §1337 (d-f):
 - (d) Any physician who takes and passes a certifying or recertifying examination administered by a recognized specialty board shall be granted credit for four consecutive years (100 hours) of continuing education credit for relicensure purposes. Such credit may be applied retroactively or prospectively.
 - (e) A maximum of sixty hours of continuing education shall be granted to a physician for receiving the Board's Physician Humanitarian Award.
 - (f) A maximum of six hours of continuing education shall be granted for each month that a physician is engaged in an approved postgraduate residency training program or approved clinical fellowship program accredited by the Accreditation Council for Graduate Medical Education (ACGME) for relicensure purposes.

E. Note for Physicians on CME Coursework

The California Legislature has directed the Board to consider the inclusion of courses in the following subjects in the continuing medical education requirement for physicians. The Board does not require specific continuing medical education coursework in these subjects at present. However, physicians are encouraged to voluntarily seek continuing education in these areas:

- Human sexuality
- Child abuse detection and treatment
- Acupuncture
- Nutrition
- Elder abuse detection and treatment
- Early detection and treatment of substance abusing pregnant women
- Special care needs of drug addicted infants
- Spousal or partner abuse detection or treatment
- End-of-life care
- Geriatric pharmacology
- Pain management

(BUSINESS AND PROFESSIONS CODE §2191)

All CME courses must include cultural and linguistic competency related to medicine.

F. Cultural and Linguistic Competency

Commencing July 1, 2006, all continuing medical education courses must contain curriculum that includes cultural and linguistic competency in the practice of medicine (BUSINESS AND PROFESSIONS CODE §2190.1 (b)(1)). Cultural competency is defined in law as a set of integrated attitudes, knowledge, and skills that enables a healthcare professional or organization to care effectively for patients from diverse cultures, groups, and communities. At a minimum, cultural competency is recommended to include the following:

- Applying linguistic skills to communicate effectively with the target population
- Using cultural information to establish therapeutic relationships.
- Eliciting and incorporating pertinent cultural data in diagnosis and treatment
- Understanding and applying cultural and ethnic data to the process of clinical care

Linguistic competency is defined in law as the ability of a physician to provide patients who do not speak English or who have limited ability to speak English, direct communication in the patient's primary language (BUSINESS AND PROFESSIONS CODE §2190.1(c)(2))

A review and explanation of relevant federal and state laws and regulations regarding linguistic access include, but are not limited to, the federal Civil Rights Act (42 U.S.C. SEC. 1981, ET SEQ.), Executive Order 13166 of August 11, 2000 of the President of the United States, and the Dymally-Alatorre Bilingual Services Act (CHAPTER 17.5 (COMMENCING WITH §7290) OF DIVISION 7 OF TITLE 1 OF THE GOVERNMENT CODE).

1.9 Disclosure of Financial Interests in Health-Related Facilities

Existing law requires physicians to report any financial interest in specified health-related facilities held by them or by members of their immediate families.

At the time of license renewal, physicians must report this information on the renewal application form. Failure to complete the reporting sections will result in a delay of the renewal.

“Health-related facilities” are defined in this law as those which provide any of the following eight services:

1. Clinical laboratory services
2. Radiation oncology
3. Physical therapy
4. Physical rehabilitation
5. Psychometric testing
6. Home infusion therapy
7. Diagnostic imaging
8. Outpatient surgery centers

(BUSINESS AND PROFESSIONS CODE §2426)

Physicians are required to report any financial interest in health-related facilities.

1.10 Prohibited Referrals

Another law relating to financial interests in health-related facilities makes it unlawful for a physician to refer a patient to a facility which provides any of the services listed in 1–8 above, if the physician or his or her immediate family has a financial interest in the facility which receives the referral. Patient referrals to facilities in which there is a financial interest, and which provide services other than the services described above, are permitted if the physician first discloses the financial interest in writing to the patient at the time of referral, and advises the patient that he or she is free to go elsewhere for the services (BUSINESS AND PROFESSIONS CODE §654.2).

Violation of the no-referrals law by a licensee is unprofessional conduct, and a cause for disciplinary action. Exceptions to the statute relating to patient referrals are included in Business and Professions Code §650.02 (BUSINESS AND PROFESSIONS CODE §652).

It may be difficult for a physician to determine whether or not he or she is required to disclose a particular financial interest. In some cases, exceptions in the law may further blur disclosure requirements. Physicians who need additional guidance should seek independent legal counsel for assistance.

1.11 Outpatient Surgery

Surgery performed in outpatient settings under anesthesia that places patients at risk of losing their life-preserving protective reflexes can only be performed in a licensed, certified or accredited setting.

The setting must be one of the following:

- An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII of the federal Social Security Act.
- Tribal clinic located on land recognized as tribal land by the federal government.
- Directly operated by the federal government
- Primary care clinic licensed by the California Department of Health Care Services
- Facility licensed as a general acute care hospital
- Facility used by dentists or physicians as prescribed in Health and Safety Code §1248.1
- Accredited by an accreditation agency approved by the Board

Failure to comply with the law is unprofessional conduct and could result in disciplinary action (BUSINESS AND PROFESSIONS CODE §2216).

The law also requires outpatient settings to:

- Post a plan of correction to violations for public view.
- Remove certificates of accreditation if suspended, revoked, or if accreditation is denied.
- Disclose a full report of denial if applying for accreditation with a different agency.
- Add in vitro fertilization facilities to the definition of outpatient setting.
- Submit for approval a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications.
- Comply with corrective action within a time frame specified by agency (BUSINESS AND PROFESSIONS CODE §2023.5).
- Filing report after peer review final decision/recommendation. Grounds for disciplinary action (BUSINESS AND PROFESSIONS CODE §805.01).

Outpatient settings do not apply to the Board for accreditation, but to an approved accreditation agency. The agencies listed on the Board's Web site at www.mbc.ca.gov/outpatient_surgery.html have been approved.

Violation of the no-referrals law is a misdemeanor and may result in disciplinary action.

Accreditation is granted by an accreditation agency, not by the Medical Board.

Pursuant to SB 100, effective January 1, 2012, Health and Safety Code Section 1248.2(b)(c) and (d) provides that the Board shall obtain and maintain a list of accredited outpatient settings from the information provided by the accreditation agencies approved by the Board. The Board shall notify the public, by placing the information on its Internet Web site, whether an outpatient setting is accredited or the setting's accreditation has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency.

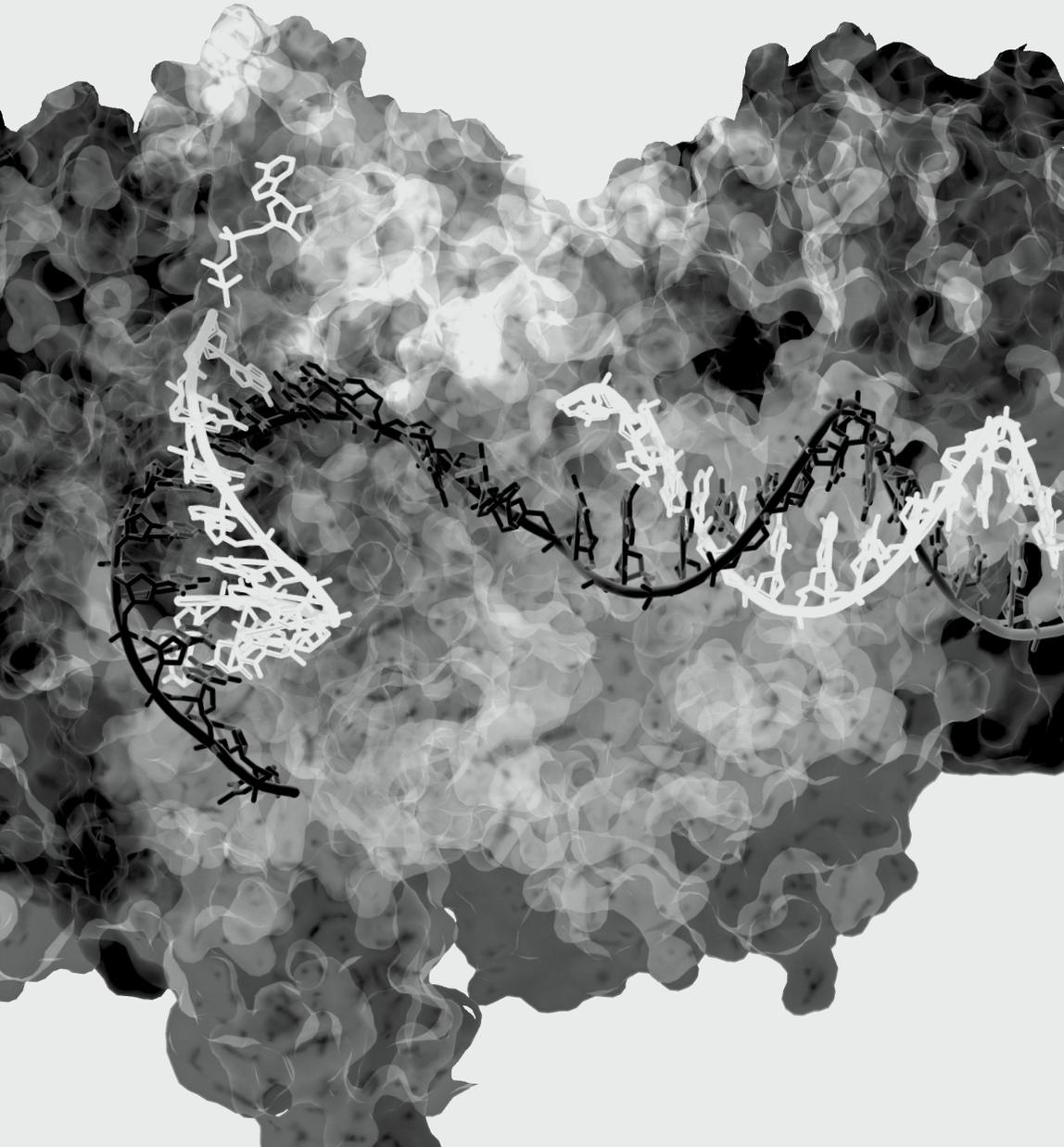
The list of outpatient settings shall include all of the following:

1. The name, address, and telephone number of any owners, and their medical license numbers.
2. The name and address of the facility.
3. The name and telephone number of the accreditation agency.
4. The effective and expiration dates of the accreditation.

Accrediting agencies approved by the Board shall notify the Board and update the Board on all outpatient settings that are accredited.

SECTION II:

The Enforcement Program



II. The Enforcement Program

2.1 General Responsibilities

The responsibilities of the Enforcement Program include:

- Receive, review, and evaluate complaints and other information relating to the practice of licensees
- Investigate the circumstances relating to complaints to determine whether the laws relating to physician practice have been violated
- Review proposed stipulated decisions and decisions following administrative hearings, and other disciplinary matters
- Carry out disciplinary action pursuant to final decisions
- Administer a program to oversee physicians on probation

For disciplinary matters, the Board has the authority to make final decisions on cases (BUSINESS AND PROFESSIONS CODE §2227).

The Board makes final decisions on disciplinary matters.

2.2 Mandatory Reporting

Required reporting to the Medical Board:

- 1. Death In Outpatient Surgery Setting**
(BUSINESS AND PROFESSIONS CODE §2240(A))
- 2. Peer Review/Health Facility Reporting**
(BUSINESS AND PROFESSIONS CODE §805)
- 3. Insurers' Report of Settlement, Judgment, or Arbitration Award**
(BUSINESS AND PROFESSIONS CODE §801.01)
- 4. Reporting Requirements for Coroners**
(BUSINESS AND PROFESSIONS CODE §802.5)
- 5. Reporting Requirements for Prosecutors' Court Clerks**
(BUSINESS AND PROFESSIONS CODE §§801.01, 803.5 AND 803.6)
- 6. Report of Charge of Felony, or Conviction of Felony or Misdemeanor** (BUSINESS AND PROFESSIONS CODE §802.1)
- 7. Reports of Liability Insurers**
- 8. Other Mandatory Reporting** (see Section VI of this book)

Medical malpractice reports against licensees come from several sources, each mandated to report to the Board by separate sections of the Business and Professions Code.

Some sources and code sections are:

Professional Liability Insurers (§801.01): Insurers are required to report to the Board every settlement over \$30,000 or arbitration/judgment of

any amount in a claim or action for damages for death or personal injury caused by a physician's negligence, error or omission in practice, or rendering of unauthorized professional services. Such reports must be sent within 30 days of the settlement, award or judgment.

Self-Insured Employers of Physicians (§801.01(c)):

This requires all agencies, private, state or local government, that self-insure physicians to report all settlements over \$30,000 for damages for death or personal injury caused by a physician's negligence, error, or omission in practice, or rendering unauthorized professional services, and a party to the settlement is an entity in which the licensee is employed, contracted, or has ownership interest.

State or Local Government Agencies that Self-Insure Physicians (§801.01(b)):

This requires state or local government agencies that self-insure physicians to report all settlements over \$30,000 for damages for death or personal injury caused by negligence, error, or omission in practice, or rendering unauthorized professional services, and a party to the settlement is an entity in which the licensee is employed, contracted, or has an ownership interest.

Uninsured Licensee or their Counsel (§801.01(b)(2)): This requires an uninsured physician or his/her attorney to report settlements or awards of the type described above.

Clerks of the Court (§803): Clerks of the court are required to report a medical malpractice judgment against a physician of any amount, or any criminal conviction.

Penalties for non-reporting (§801.01): Failure by either the physician or their counsel to report malpractice actions is a public offense punishable by a fine which could range from \$50 to \$500. An intentional failure to comply with the reporting requirement could result in a fine of \$5,000 to \$50,000.

Other entities required by the Business and Professions Code to make reports about physicians are:

Physicians (§802.1): Physicians and surgeons must report any indictment or information charging a felony, or any felony or misdemeanor conviction, to the Board, in writing, within 30 days. Failure to make a report is a public offense, punishable by a fine not to exceed \$5,000.

Coroners (§802.5): A coroner must report a death that may be the result of a physician's gross negligence or incompetence.

Prosecuting Attorney Agencies (§803.5): The district attorney, city attorney, or other prosecuting agency must notify the Board of any filing charging a felony against a licensee. If the charges end in a conviction, the court clerk is obligated to report that conviction to the relevant board.

Court Clerks (§803.6): Additionally, the clerk of the court must transmit any felony preliminary hearing transcript concerning a defendant licensee to the Board.

Health Facility/Peer Review (§805.01): Requires the chief of staff of a medical or professional staff or other chief executive officer, medical director or administrator of any peer review body & the CEO or administrator of any licensed healthcare facility or clinic to files a report with the Board after a peer review makes a final decision or recommendation regarding the disciplinary action, resulting in a final proposed action to be taken against a licentiate based on the peer review body’s determination.

Required reporting to the Office of Statewide Health Planning and Development (OSHPD):

Physicians must report both a patient death that occurred as a result of a procedure performed in an outpatient setting and a procedure performed in an outpatient surgery setting that requires transfer to an acute care hospital for emergency medical treatment (BUSINESS AND PROFESSIONS CODE §2240).

These forms can be downloaded from the Board’s Web site at www.mbc.ca.gov, click on *Forms*, and click on the appropriate form.

2.3 Reporting Requirements for Peer Review Bodies

Section 805 of the Business and Professions Code requires hospitals and specified peer review bodies to report certain adverse actions to the Board, and also specifies what information can be released by the Board. The law requires the chief executive officer or the chief of the medical staff of a hospital or similar institution to report to the Board all actions taken against physicians, which deny, restrict for 30 days or more in a 12-month period, or terminate staff privileges for medical disciplinary cause or reason. If the termination or restriction occurred due to a resignation or other voluntary action following notice of an impending investigation, that also must be reported. Failure to make the required report is punishable by a fine of not more than \$50,000, or, if the failure was intentional, a fine of not more than \$100,000.

Patient deaths as a result of outpatient procedures must be reported, even if the patient was transferred to an emergency room for further treatment.

California law specifies which unprofessional actions must be reported to the Board by hospitals and peer review bodies.

A report must be made to the Board within 15 days of the action. The report must contain:

- The name and license number of the licensee involved.
- A description of the facts and circumstances of the medical disciplinary cause or reason.
- Any other relevant information deemed appropriate by the person making the report.

Reporting this information does not constitute a waiver of confidentiality of medical records and committee reports. Persons making a report under this section are exempted by law from civil or criminal liability as a result of making the report.

Hospitals and other health facilities must ask the Board if a health facilities report (805 report) has been filed against each licensee under consideration, prior to granting or renewing staff privileges to physicians, or specified healthcare providers (BUSINESS AND PROFESSIONS CODE §805.5).

If an 805 report exists, the Board is required to provide a copy to the health facility within 30 working days. If the Board does not respond within 30 working days, the facility may process the application without regard to any 805 report. All decisions regarding staff privileges remain entirely at the discretion of the health facility. The law requires only that information be obtained from the Board regarding reports from other facilities before a facility makes a final decision. Failure by the health facility to request such information is a misdemeanor.

The reporting requirements are intended to facilitate information sharing among health facilities regarding the qualifications and performance of health professionals. The goal is to enhance the quality of health care by assisting facilities in making informed decisions about providers of care.

Most forms for filing reports under the above sections, with the exception of §802.1, can be downloaded from the Board's Web site at www.mbc.ca.gov, click on *Forms*, and click on the appropriate form.

The reporting requirements allow health facilities to share information about the qualifications and performance of health professionals.

2.4 Complaint and Investigative Process

Anyone may file a complaint, preferably in writing, to:

Central Complaint Unit: Medical Board of California

2005 Evergreen Street, Suite 1200, Sacramento, CA 95815

Or by calling toll-free: 800-MED BDCA (1-800-633-2322) (CA only) or (916) 263-2382.

Additionally, a Consumer Complaint form may be obtained from the Board's Web site at www.mbc.ca.gov

A. Complaints

The Board provides forms on which members of the public, physicians or other healthcare professionals, may file written complaints (BUSINESS AND PROFESSIONS CODE §800(b)). The complaint and all accompanying documentation are reviewed by a consumer services analyst and a medical consultant, if applicable, to determine if possible violations of the Medical Practice Act exist that warrant further action.

If a physician is considering filing a complaint against another physician, the complaint can be filed anonymously—although anonymous complaints are more difficult to investigate.

Medi-Cal providers must give patient records to Department of Health Care Services investigators, if requested.

B. Complaints Outside the Board’s Jurisdiction

Not all complaints filed against physicians are within the jurisdiction of the Medical Board. If it is determined that a complaint is not within its jurisdiction, the Board will refer the complaint information to the appropriate agency.

For example:

- **Ethical matters that do not violate the law:** referred to county medical societies.
- **Fee disputes where fraud or other illegal activity is not involved:** referred to county medical societies.
- **Health facility complaints:** referred to the California Department of Public Health
- **Managed care complaints (involving HMOs, PPOs, etc.):** referred to the Department of Managed Health Care.

C. Medi-Cal Violations

The Board does not generally have jurisdiction in Medi-Cal disputes except insofar as a physician may be involved in a violation of the Medical Practice Act. Investigation of Medi-Cal fraud or other misuse of the Medi-Cal program is the responsibility of the Department of Justice.

For information, contact:

The Bureau of Medi-Cal Fraud and Elder Abuse
 P.O. Box 94425
 Sacramento, CA 94244-2550
 (800) 722-0432 or visit the Web site: oag.ca.gov/bmfea

Medi-Cal providers are required to furnish patient records to the Department of Health Care Services’ investigators on demand (WELFARE AND INSTITUTIONS CODE §14124.2). Failure to comply may result in the physician’s suspension from the Medi-Cal program. Furthermore, such failure or refusal to comply may constitute

unprofessional conduct as defined in the Medical Practice Act and, therefore, may result in disciplinary action by the Board. Likewise, Medi-Cal fraud is a violation of the Medical Practice Act.

D. The Investigative Process

The Board investigates complaints or reports which may involve a violation of the Medical Practice Act. Investigations are conducted by investigators, in consultation with deputy attorneys general, medical consultants, and medical experts. The initiation of an investigation is not evidence of wrongdoing.

An investigation is not a conviction; a person is presumed innocent unless proven otherwise.

It is unprofessional conduct for the repeated failure by a physician, in the absence of good cause, to attend and participate in an interview scheduled by the mutual agreement of the physician and the Board. This subdivision only applies to physicians who are the subject of an investigation by the Board (BUSINESS AND PROFESSIONS CODE §2234(h)).

E. Medical Records

Business and Professions Code §2266 requires physicians to maintain adequate and accurate medical records. This documentation may prove critical in the event a complaint is filed against a physician. For more information on medical records, refer to section 6.1 of this Guide.

California law requires that physicians keep complete and accurate records.

F. Corporate Practice of Medicine

“Corporations and other artificial entities shall have no professional rights, privileges, or powers” (BUSINESS AND PROFESSIONS CODE §2400). BUSINESS AND PROFESSIONS CODE §2052 defines the practice of medicine as “Any person who practices...advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted...or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder...” The policy expressed in these sections against the corporate practice of medicine is to prevent unlicensed persons from interfering with or influencing the physician’s professional judgment.

Ownership of a medical practice is largely limited to physicians. Partial or full ownership of a physician’s practice by lay persons is prohibited. Business and Professions Code §2400 and similar laws apply to privately held, partnership, and incorporated practices, except that the law (CORPORATIONS CODE §§13400-13410; THE MOSCONE-KNOX PROFESSIONAL CORPORATION ACT) allows some non-physician licensed health professionals to own up to 49 percent of the shares in a professional medical corporation.

The following types of medical practice ownership and operating structures are also prohibited:

- Non-physicians operating a business for which physician ownership and operation are required: any business advertising, offering, and/or providing patient evaluation, diagnosis, care, and/or treatment—services that can only be offered or provided by physicians.
- Physician(s) operating a medical practice as a limited liability company.
- Management Service Organizations arranging for, advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice (non-physicians exercising controls over physician medical practices, even where physicians own and operate the business).
- A physician acting as “medical director” when physicians do not own the practice. For example, a business offering spa treatments that include medical procedures such as Botox injections and laser hair removal that contracts with a physician to be its “medical director.”

In the above examples, non-physicians would be involved in the unlicensed practice of medicine, and the physician may be aiding and abetting the unlicensed practice of medicine.

The following are examples of some of the types of behaviors and subtle controls that the corporate practice doctrine is intended to prevent. From the Board's perspective, the following health care decisions should be made by a physician licensed in the State of California and would constitute the unlicensed practice of medicine if performed by an unlicensed person:

- Determining what diagnostic tests are appropriate for a particular condition.
- Determining the need for referrals to or consultation with another physician or specialist.
- Responsibility for the ultimate overall care of the patient, including treatment options available to the patient.
- Determining how many patients a physician must see in a given period of time or how many hours a physician must work.

G. Review of Records by the Investigator

Patients are entitled to confidentiality of their medical records and doctor-patient communications. There are statutory exceptions, including requirements of physician reports regarding child and elder abuse, communicable diseases, pesticide poisonings, and so forth, and Board investigations (BUSINESS AND PROFESSIONS CODE §2225) (refer to section 6.6 of this guidebook).

A non-physician may not own any part of a physician's practice.

The Board's policies regarding the corporate practice of medicine exist to prevent unlicensed people from interfering or influencing a physician's professional judgment.

Board investigators have peace officer authority (Penal Code §830.3). The Board may secure patient medical records in any of three ways: 1) through securing a properly executed patient release of records; 2) with a search warrant; or, 3) with a subpoena duces tecum. BUSINESS AND PROFESSIONS CODE §§2225 and 2225.5 require the production of records within 15 days, and provide for a civil penalty of \$1,000 per day for a physician’s failure to comply.

The Board is a state regulatory and oversight agency and therefore exempt from the usual requirements of HIPAA.

H. Citation and Fine

Under regulations adopted in 1994, the Board may issue administrative citations for technical violations of the law or regulations. Along with the citation, the Board may impose a fine of not more than \$5,000 per violation. A citation is not considered discipline, but is publicly disclosed on the Board’s Web site.

Technical violations of the law may result in administrative citations.

I. Formal Accusation

If an investigation produces evidence that a physician appears to have violated the Medical Practice Act, the Board transmits the case file to the Health Quality Enforcement Section (HQES) of the Office of the Attorney General. An attorney in the HQES drafts a formal accusation (the name of the charging document), and represents the Board in any subsequent disciplinary process. The information contained in a formal accusation is public record.

Medical records and doctor-patient communications are confidential.

Not all alleged violations result in an accusation. Some offenses may be resolved through a public letter of reprimand (BUSINESS AND PROFESSIONS CODE §2233), citation and fine, or other actions.

Citations issued by the Medical Board are not disciplinary actions but will be disclosed on the public Web site.

By law, a physician has a right to a hearing when formal charges are filed. There are legal protections available to the physician that can best be pursued with the assistance of an attorney experienced in medical-legal matters.

If the physician chooses to contest the charges in an accusation (i.e., defend against them), he or she may request an administrative hearing conducted by an administrative law judge. The hearing will result in a proposed decision that is submitted to the Board for a final decision.

The Board must act on the proposed decision within 100 days, and may adopt it, modify it, or substitute an alternate decision. If the Board wishes to impose a more stringent order, each member participating in the decision must read the transcript of the hearing and deliberate on the decision. Final decisions are public record.

Prior to the hearing, the physician may be offered an opportunity to negotiate a resolution to an accusation—in effect, to plea bargain. If this is done, a proposed stipulated decision is prepared by the parties and submitted to the Board. As with a decision after hearing, the Board may adopt the stipulated decision or make changes. The proposed changes then will be offered to the physician. If an outcome satisfactory to both sides cannot be negotiated, the case will proceed to hearing.

Information in formal accusations is public record.

By law, a physician has a right to a hearing when formal charges are filed.

2.5 Disciplinary Actions

A. Discipline of a Physician’s License by the Board

(BUSINESS AND PROFESSIONS CODE §2227)

Disciplinary action taken against a physician’s license may take any of the following forms:

- Revoking a license.
- Suspending a license for a period not to exceed one year.
- Placing a physician’s license on probation and restricting or limiting the scope or type of practice.
- Imposing as part of probation additional requirements such as undergoing psychiatric treatment, obtaining additional clinical training or education, or practicing under supervision.
- Issuing a public reprimand.

B. Disciplinary Guidelines

The Medical Practice Act mandates, among other things, that the Board “shall promulgate recommended uniform disciplinary measures for particular situations.” The Board’s *Manual of Model Disciplinary Orders and Disciplinary Guidelines* are codified in Title 16, California Code of Regulations §1361, and available on the Board’s Web site.

The guidelines are for the intended use of those involved in the physician disciplinary process:

- Administrative law judges.
- Defense attorneys.
- Physician respondents.
- Trial attorneys from the Office of the Attorney General.
- Board’s disciplinary panel members who review proposed decisions and stipulations, and make final decisions.

These guidelines set forth the discipline the Board finds appropriate and necessary for the identified violations.

The Model Disciplinary Orders contain three sections:

1. Disciplinary Orders.
2. Standard conditions that generally appear in all probation cases.
3. Optional Conditions - whose use depends on the nature and circumstances of the particular case.

The guidelines are designed to assure reasonable consistency in the decisions of the Board. The guidelines are revised periodically to reflect changes in policy and in law and court rulings, and to keep current with medical and legal practices.

The Board recognizes that these orders and conditions of probation are merely guidelines. Variations can and are made to accommodate the unique circumstances of individual cases.

For copies of the disciplinary guidelines, write:

Medical Board of California
Discipline Coordination Unit
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

Or download at: http://www.mbc.ca.gov/publications/disciplinary_guide.pdf

The rules of professional conduct for healthcare providers are available on the Board's Web site.

C. Public Letter of Reprimand

The Board may by stipulation or settlement with the affected physician, after it has conducted an investigation, issue a public letter of reprimand, which may include a requirement for specified training or education, in lieu of filing a formal accusation. The physician must indicate agreement or non-agreement in writing within 30 days of formal notification. Use of public letters of reprimand is limited to minor violations and the physician has the right to reject the proposed letter. If this occurs, the Board will pursue an accusation. A public letter of reprimand is discipline and is subject to public disclosure (BUSINESS AND PROFESSIONS CODE §2233).

The Medical Board may issue a public letter of reprimand instead of filing a formal accusation.

2.6 Competency Examinations

The Board has the legal authority to compel a physician, who is suspected of not being able to practice medicine with reasonable skill, and safety to patients, to take an oral competency examination (BUSINESS AND PROFESSIONS CODE §2292). The law states that the Board can order an examination if it finds there is reasonable cause to doubt the physician's competence to practice.

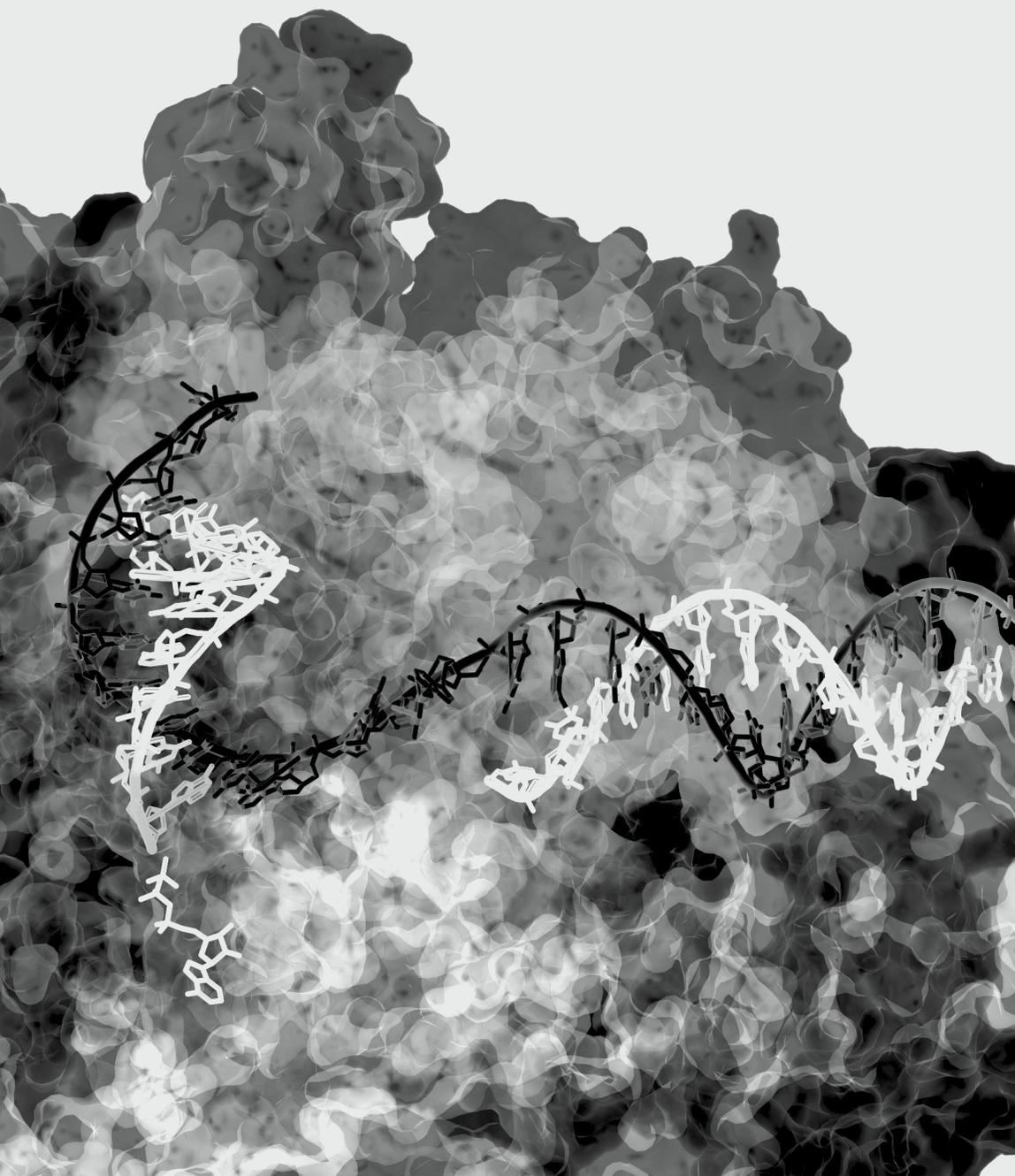
“Reasonable cause” is defined in the law as:

- A single incident of gross negligence.
- A pattern of inappropriate prescribing.
- An act of incompetence or negligence causing death or serious bodily injury.
- A pattern of substandard care.

The physician has the opportunity to review and rebut the petition for the examination. A competency examination is administered by a panel, usually consisting of three physicians, selected by the Board or its designee. The examination focuses on the physician’s specialty, or on the areas of medicine relating to specific suspected deficiencies. The exam is tape-recorded. A failing grade from two examiners constitutes failure of the examination. A passing grade constitutes prima facie evidence of present competence in the area covered by the examination. The physician has the right to a hearing to appeal a failing grade or to request re-examination. However, if there is no appeal, or the re-examination is denied, the Board has the authority to proceed to disciplinary action for incompetence and any other appropriate charges (BUSINESS AND PROFESSIONS CODE §2234).

SECTION III:

Allied Health Care Professions



III. Allied Health Care Professions

3.1 General Responsibilities

The Board is charged with the following responsibilities with respect to allied health care professions:

- Supervision over the activities of the professions and non-physician license holders within the purview of the Board.
- Discipline non-physician license holders to the extent that such discipline is not currently within the jurisdiction of the appropriate committee or Board.
- Act as liaison with other allied health care healing arts boards concerning the activities of their licensees.

The following occupations are regulated directly by the Board.

- Licensed Midwife.
- Research Psychoanalyst and Student Research Psychoanalyst.
- Registered Dispensing Optician Program.
- Contact Lens Dispenser.
- Spectacle Lens Dispenser.
- Non-resident Contact Lens Seller.
- Medical Assistant (unlicensed).
- Registered Polysomnographic Trainee, Technician and Technologist.

All complaints relating to the allied health care professions may be submitted by any consumer, individual, or group, (preferably in writing) to the following address:

Medical Board of California
Central Complaint Unit
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815
(800) 633-2322 (CA only), (916) 263-2382

The following are descriptions of each of the affiliated health care professions with information of special interest to physicians regarding each profession.

A. Licensed Midwife

A licensed midwife is an individual licensed by the Board to practice midwifery. A licensed midwife is required to work under the supervision of a physician who has current training or practice in obstetrics. The license authorizes the midwife to attend cases of normal childbirth and to provide prenatal, intrapartum and postpartum care, which includes family-planning care for the mother, and immediate care for the newborn. (Licensed midwives should not be confused with certified nurse midwives, who are under the jurisdiction of the Board of Registered Nursing).

Of note to physicians

The supervising physician is not required to be physically present when care is given, but must be located in reasonable proximity, in geography or time, to the client. Specific required disclosure to a client regarding the practice of midwifery is described in Business and Professions Code §2508. A physician may supervise no more than four midwives at any time (BUSINESS AND PROFESSIONS CODE §2507 and TITLE 16, CALIFORNIA CODE OF REGULATIONS §§1379.1-1379.22).

Licensed midwives are under the jurisdiction of the Medical Board. Certified nurse midwives are under the jurisdiction of the Board of Registered Nursing.

B. Research Psychoanalyst and Student Research Psychoanalyst

A graduate or student research psychoanalyst is a person clinically trained in psychoanalysis in a program approved by the Board, who is not licensed as a physician or in another mental health profession. As defined in law and regulations, research psychoanalysts must have a primary profession in teaching, training, or research, and may not perform psychoanalysis more than one-third of their total professional time (including time spent in practice, teaching, training and or research).

A psychoanalyst registered by the Medical Board can perform psychoanalysis without a referral from other health professionals.

Of note to physicians

A graduate research psychoanalyst registered by the Board is fully trained and presumed competent to perform psychoanalysis, and may do so with or without referral from other health professionals. A student research psychoanalyst may engage in psychoanalysis only under supervision by a graduate research psychoanalyst (BUSINESS AND PROFESSIONS CODE §2529 and TITLE 16, CALIFORNIA CODE OF REGULATIONS, §1373).

C. Registered Dispensing Optician

A registered dispensing optician (RDO) actually is a business entity licensed to engage in the business of optical dispensing. Optical dispensing means filling the prescriptions of physicians or optometrists, fitting, adjusting, and dispensing spectacles and contact lenses (BUSINESS AND PROFESSIONS CODE §2550).

See contact lens dispensers (CLD) and spectacle lens dispensers (SLD) below. Whenever an RDO is engaged in dispensing, fitting, or adjusting spectacle lenses, an SLD must be physically present. A CLD must be present when contact lenses are dispensed, fitted, or adjusted.

Registered dispensing optician firms can dispense, fit or adjust glasses or contact lenses only when a properly certified dispenser is present.

Of note to physicians

A registered dispensing optician must have a valid prescription to fit, adjust, or dispense any prescription lens. Contact lenses may be dispensed only if the prescription specifies or authorizes CLs. If any prescription is given orally, the optician must document it in writing and send a copy of the prescription to the prescriber prior to dispensing the lenses. An RDO firm may not duplicate a lens, dispense lenses of a different type, brand, or mode of wear than what is specified on a prescription, if such is specified, or change a prescription.

If an optician business dispenses contact lenses, it must have a registered contact lens dispenser on staff.

D. Contact Lens Dispenser

If a registered dispensing optician business wishes to dispense contact lenses, at least one individual in the business must be registered as a CLD. A CLD is a person who successfully passed the contact lens registry examination of the National Committee of Contact Lens Examiners, and is registered with the Board. All contact lens dispensing must be performed by, or under the direct responsibility and supervision of, a CLD.

Of note to physicians

A registered CLD may not dispense contact lenses without a current prescription which specifically refers to or approves contact lenses, or dispense plano contact lenses without a prescription. If a CLD takes an oral prescription or prescription change by phone, he or she must document the prescription in writing and send a copy of the written prescription to the prescriber before the lenses are dispensed to the patient.

E. Spectacle Lens Dispenser

A SLD is a person who has satisfactorily passed the registry examination of the American Board of Opticianry, and has registered with the

Medical Board. A registered dispensing optician firm that fits, adjusts, or dispenses spectacle lenses and similar products must have a registered SLD on the premises whenever fitting and adjusting is done. Unregistered individuals can fit and adjust lenses and frames under the direct responsibility and supervision of an SLD or a physician.

Of note to physicians

An SLD must have a current, valid prescription prior to fitting, adjusting, or dispensing spectacle lenses. He or she may not duplicate an existing lens or change a prescription without the authorization of the prescriber. If an oral prescription is given, or a prescription change is authorized orally, the prescription or change must be documented in writing, and a copy sent to the prescriber before the lenses are dispensed.

The law relating to relationships between physicians and optical dispensers is unique. A physician can employ a technician to fit, adjust, and dispense optical lenses including contact lenses under the following conditions:

- The technician must be physically located in the physician's office.
- The technician may fill only prescriptions of his or her employing physician(s).
- The technician may not perform a refraction or other test to determine the accommodative or refractive state of the eye or the range of vision.
- The technician may not be referred to as an optician, RDO, spectacle or contact lens dispenser or any other term suggesting that he or she is an optician.

Spectacle lenses can be fitted, adjusted and dispensed only if the patient has a current, valid written prescription.

A physician may hire a technician to fit, adjust, and dispense optical lenses, including contact lenses.

F. Medical Assistant

A medical assistant (MA) is an unlicensed individual who may administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and provide technical supportive services with the specific authorization and supervision of a physician.

The following is a summary of the laws and regulations affecting the scope of practice of MAs in physician and podiatrist offices. The full text of the law and regulations is available by writing:

Medical Board of California

ATTN: Licensing Program

2005 Evergreen Street, Suite 1200, Sacramento, CA 95815

or on the Board's Web site: www.mbc.ca.gov/allied/medical_assistants.html

Medical assistants are allowed to give intramuscular, intradermal or subcutaneous injections; perform skin tests; and draw blood by venipuncture or skin puncture.

1. What is a medical assistant? An MA is an unlicensed person who may perform non-invasive, routine, technical supportive services in the office of a physician or podiatrist. By law, MAs may not be employed in an acute care hospital. Under the supervision of a physician or podiatrist, an MA can perform the above patient-related tasks, with appropriate training.

2. Who can train an MA? A licensed physician or podiatrist can personally train an MA, or can direct a registered nurse, licensed vocational nurse, physician assistant, or qualified MA under the direction of a licensed physician or podiatrist to train the MA in specified tasks, but must personally observe and document that the MA is competent to perform each task. Or, the MA can be trained and certified in a formal training program at a college or vocational school (TITLE 16, CALIFORNIA CODE OF REGULATIONS, §1366.3).

3. What kinds of tasks can an MA do? MAs are allowed to give injections by intramuscular, intradermal, or subcutaneous routes, to perform skin tests, and to draw blood by venipuncture or skin puncture. The Board has adopted regulations spelling out additional “technical supportive services” the MA can do (TITLE 16, CALIFORNIA CODE OF REGULATIONS, §1366). For a complete scope of work: www.mbc.ca.gov/allied/medical_assistants_questions.html

4. What kinds of tasks are beyond the MA scope of practice?

- Placing the needle or starting and disconnecting the infusion tube of an administering medications or injections into the IV line.
- Charting the pupillary responses.
- Inserting a urine catheter.
- Independently performing telephone triage.
- Injecting collagen.
- Using lasers to remove hair, wrinkles, scars, moles, or other blemishes.
- Administering chemotherapy.
- Practicing optometry including but not limited to performing refractions, eye examinations, tonometry, biomicroscopy, etc.
- Interpret the results of skin tests, although they may measure and describe the test reaction and make a record in a patient’s chart.

An MA **cannot** perform any physical examination, make a diagnosis, initiate a treatment, prescribe or order drugs, do any surgical procedure or penetrate the tissues except to administer injections, perform skin tests, venipuncture, or skin puncture.

5. What supervision is required? The law says an MA must be supervised by a physician or podiatrist. A registered nurse or physician assistant may supervise an MA only in a clinic licensed pursuant to Health and Safety Code §1204(a). The supervising healthcare provider must be physically present in the facility when any services are performed by the MA. Every task must be authorized or ordered through a standing order which is documented in the individual patient medical record, with the MA's initials, date, time description of the service and the supervising healthcare provider who ordered the service.

6. What about training? In general, the physician or podiatrist is obligated to make sure the MA knows what he or she is doing. In-office training should be of the duration and extent necessary to assure competence. The law specifies that for venipuncture and injections the MA should have a minimum of 10 hours of training in each, and should demonstrate proper technique 10 times for each procedure under supervision and be certified and a certification placed in the employee file.

Once a training process is completed for a given task, the trainer must document the training in writing, provide a copy to the MA and retain a copy in the personnel record. More than one task can be documented on a single record, or individual records of training can be documented as competence is attained. An MA trained in a formal program should have a certificate documenting the content and extent of the training. In either case, the training must be documented in writing and retained by the employer.

The questions and answers above are only a summary and are not exhaustive. If a provider is unclear whether an MA can do a particular task, he or she should contact the Board.

G. Registered Polysomnographic Personnel

A registered polysomnographic trainee, technician or technologist is defined as an individual who treats, manages, diagnostic tests, controls, educates and cares for patients with sleep and wake disorders (BUSINESS AND PROFESSIONS CODE §3575).

- **Trainee** - The registration is required for individuals under the direct supervision of a supervising physician and surgeon, polysomnographic technologist or other licensed health care professional who may provide basic supportive services as part of their educational program, including but not limited to gathering

A medical assistant must be supervised by a physician or podiatrist, NOT by a registered nurse or physician assistant unless in a clinical setting.

and verifying patient information, testing preparation and monitoring, documenting routine observations, data acquisition and scoring, and assisting with appropriate interventions for patient safety in California.

- **Technician** - The registration is required for individuals who may perform the services that of a polysomnographic trainee under general supervision and may implement appropriate interventions necessary for patient safety in California.
- **Technologist** - The registration is required for individuals who are responsible for the treatment, management, diagnostic testing, control, education, and care of patients with sleep and wake disorders in California.

Of Note to Physicians

A registered polysomnographic trainee, technician or technologist is required to work under the supervision of a physician and surgeon who shall remain available, either in person or through telephonic or electronic means, at the time that services are provided. The polysomnographic shall pass a national certifying exam, credentials issued by a national accrediting agency approved by the Board and background check. Specific requirements are found in Business & Professional Codes §§3575 through 3579.

For additional information on Licensed Midwives, Research Psychoanalysts, Opticians, Contact and Spectacle Lens Dispensers, Medical Assistants, Research Psychoanalysts and Registered Polysomnographic Trainees, Technicians and Technologists, contact:

Medical Board of California
2005 Evergreen Street, Suite 1200, Sacramento, CA 95815
(916) 263-2382, Fax (916) 263-2567

Or visit our Web site: www.mbc.ca.gov using the *A-Z Index* link.

SECTION IV:

Laws Relating to Other Health Care Personnel



IV. Laws Relating to Other Healthcare Personnel

This section describes various laws pertaining to other related healthcare professionals who have a close working relationship with physicians, but who are not licensed by the Board. Whenever a physician establishes a working relationship with another healthcare professional, it is advisable to contact that professional's licensing agency to check that his or her license is valid and current. Visit the Department of Consumer Affairs' Web site at www.dca.ca.gov.

A. Dentists

Dentistry is the diagnosis or treatment of diseases and lesions and the correction of malposition of the human teeth, alveolar process, gums, jaws, or associated structures. Such diagnoses and treatment may include all necessary related procedures, including surgery, the use of drugs, anesthetic agents, and physical evaluation. A person is said to be engaged in the practice of dentistry if he or she does any one or more of the following:

- Performs, or offers to perform, an operation, diagnosis or treatment of the human teeth, alveolar process, gums, jaws, or associated structures.
- Indicates that he or she will perform the above, or construct, alter, repair, or sell any bridge, crown, denture, or other prosthetic or orthodontic appliance.
- Manages a place where dental operations are performed.
- Advertises or represents him or herself to be a dentist (BUSINESS AND PROFESSIONS CODE §1625).

For additional information, contact:

Dental Board of California
2005 Evergreen Street, Suite 1550,
Sacramento, CA 95815
(916) 263-2300, Fax (916) 263-2140
Web site: www.dbc.ca.gov

B. Licensed Vocational Nurses

The licensed vocational nurse (LVN) functions under the direction of a physician or registered professional nurse and performs services requiring those technical, manual skills acquired by a course in an accredited school of vocational nursing or its equivalent. Pursuant to a physician's order, an LVN may administer medications by oral, topical and hypodermic injection, and may perform tuberculin, coccidioidin, and histoplasmin skin tests in accordance with specified guidelines. The LVN may withdraw blood from a patient, or start

For additional
information, contact:

Dental Board
of California
2005 Evergreen
Street, Suite 1550
Sacramento, CA
95815
(916) 263-2300 or
fax (916) 263-2140.

and superimpose intravenous fluids, if prior thereto such nurse has attained certification from the Board by satisfactorily completing a prescribed course of instruction approved by the Board of Vocational Nursing and Psychiatric Technicians and the procedure is performed in an organized health care system. Intravenous fluids include electrolytes, nutrients, vitamins, blood, and blood products.

The LVN is not an independent practitioner. The licensee functions under the direction of a physician or registered nurse. However, he or she must adhere to the legal scope of vocational nursing practice. The LVN cannot perform tasks outside the legal scope based on direction to do so by a physician or registered nurse (BUSINESS AND PROFESSIONS CODE §§2859, 2860.5 and 2860.7, and TITLE 16, CALIFORNIA CODE OF REGULATIONS §§2542, 2544, and 2547).

A licensed vocational nurse cannot practice independently. He or she must work under the supervision of a physician or registered nurse.

C. Psychiatric Technician

“Psychiatric technician” means any person who...implements procedures and techniques...which are used in the care, treatment, and rehabilitation of mentally ill, emotionally disturbed or mentally retarded persons and who has...

- Direct responsibility for administering or implementing specific therapeutic procedures, techniques, treatments, or medications with the aim of enabling...patients to make optimal use of their therapeutic regime, their social and personal resources, and their residential care
- Direct responsibility for the application of interpersonal and technical skills in the observation and recognition of symptoms and reactions of...patients, for the accurate recording of such symptoms and reactions, and for the carrying out of treatments and medications as prescribed by a licensed physician and surgeon or a psychiatrist (BUSINESS AND PROFESSIONS CODE §4502)

**For additional information, contact:
Board of Vocational Nursing and Psychiatric Technicians
2535 Capitol Oaks Drive, Suite 205
Sacramento, CA 95815
(916) 263-7800
fax (916) 263-7859.**

The psychiatric technician, in the performance of such procedures and techniques, is responsible to the director of the service in which his duties are performed. The director may be a licensed physician (psychiatrist), psychologist, rehabilitation therapist, social worker, registered nurse, or other professional personnel...(BUSINESS AND PROFESSIONS CODE §4502).

For additional information, contact:

Board of Vocational Nursing and Psychiatric Technicians
2535 Capitol Oaks Drive, Suite 205
Sacramento, CA 95833
(916) 263-7800, Fax (916) 263-7859, Web site: www.bvnpt.ca.gov

D. Registered Nurses

The practice of registered nurses (RNs) means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill. It includes observing signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition; determining abnormal characteristics, and reporting or referring to the physician or implementing changes in treatment regimen in accordance with standardized procedures, or initiating emergency procedures (BUSINESS AND PROFESSIONS CODE §2725(b)).

Registered nurses in a free or community clinic may dispense drugs and devices under the supervision of a physician and surgeon.

Registered nursing includes direct and indirect patient care services that ensure safety, comfort, personal hygiene, protection, disease prevention; and restorative measures. RNs administer medications and therapeutic agents to implement a treatment for disease prevention, or rehabilitation regimen ordered by a physician, dentist, podiatrist, or clinical psychologist. RNs perform skin tests, immunizations, and withdrawal of blood from veins or arteries.

Registered nursing practice is recognized as having overlapping functions with physicians. The RN scope of practice permits additional sharing of functions in the organized health care system that provides for collaboration between physicians and registered nurses. Standardized procedures include policies and protocols developed in collaboration with physicians, nurses, and administrators of facilities.

RNs may dispense drugs and devices upon the order of a physician and surgeon when the nurse is dispensing within a free or community clinic. Dispensing of drugs by a registered nurse shall not include substances included in the California Uniform Controlled Substances Act (BUSINESS AND PROFESSIONS CODE §2725.1).

The Board of Registered Nursing (BRN) registers and has oversight of RNs. For additional information, contact:

Board of Registered Nursing (BRN)
1747 N. Market Blvd., STE 150
Sacramento, CA 95834
(916) 322-3350 or www.rn.ca.gov

E. Nurse Practitioners

The nurse practitioner (NP) is a registered nurse with additional educational preparation and skills in physical diagnosis, psychosocial assessment, and management of health/illness needs in primary health care. NPs who have been certified by the BRN may use the title “R.N., N.P.” The nurse practitioner relies on standardized procedures for

authorization to perform medical functions of diagnosing and treating patients. NPs who meet BRN requirements may obtain a furnishing number to make drugs and devices available to patients in strict accord with standardized procedures (BUSINESS AND PROFESSIONS CODE §2836.1, and TITLE 16, CALIFORNIA CODE OF REGULATIONS §1480).

F. Certified Nurse-Midwives

BRN certified nurse-midwives (CNM), under the supervision of a physician, are authorized to attend cases of normal childbirth and provide prenatal, intrapartum, and postpartum care, including family planning care for the mother, and immediate care of the newborn. The practice of nurse-midwifery constitutes the furthering or undertaking by a certified person, under supervision of a physician who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal. Physician supervision must not be construed to require the physical presence of the supervising physician. All complications must be referred to a physician immediately. The practice of nurse-midwifery does not include the assisting of childbirth by any artificial, forcible, or mechanical means, nor the performance of any version (BUSINESS AND PROFESSIONS CODE §2746.5 and TITLE 16, CALIFORNIA CODE OF REGULATIONS §1480).

Nurse practitioners follow standard procedures to obtain authorization to diagnose or treat patients.

A patient-specific protocol specifies which categories of patients may be given a particular class of drug.

G. Authorization to Furnish Drugs

Furnishing is defined as the ordering of a drug or device in accordance with the standardized procedure, and transmitting an order of a supervising physician and surgeon. Nurse practitioners or nurse-midwives who have received a furnishing number from the BRN and have acquired a DEA number may furnish controlled substances, Schedule II, III, IV, and V. The act of furnishing a controlled substance is termed an “order,” and the order is considered the same as an order initiated by the physician. CNMs are authorized to furnish Schedules II controlled substances in acute care hospitals. NPs furnishing or ordering Schedule III controlled substances and CNMs furnishing or ordering Schedule II and III controlled substances are required to have a patient-specific protocol contained in the standardized procedure. A patient-specific protocol is a protocol within the standardized procedure that specifies which categories of patients may be furnished or ordered this class of drug. The protocol may state any other limitations as agreed upon by the NP or CNM and the supervising physician, such as the amount of the substance to be furnished and criteria for consultation. There are no practice site restrictions for NPs and CNMs when performing their furnishing function under approved standardized procedures (BUSINESS AND PROFESSIONS CODE §§2836.1 and 2746.5).

H. Certified Registered Nurse Anesthetists

The Nursing Practice Act authorizes the certified registered nurse anesthetist (CRNA) to provide anesthesia services ordered by a physician, dentist, or doctor of podiatric medicine, in accordance with community practice and policies of the organized health care system in which the service is provided. Anesthesia services include regional or local anesthesia by injection as well as general anesthesia (BUSINESS AND PROFESSIONS CODE §2826).

I. Clinical Nurse Specialist

A clinical nurse specialist is a registered nurse with advanced education who participates in expert clinical practice, education, research, consultation, and clinical leadership as the major component of his or her role. The clinical nurse specialist does not have an additional scope of practice beyond the usual RN scope and must use standardized procedures for authorization to perform medical or surgical functions. The clinical nurse specialist may possess a master’s degree in a clinical field of nursing, or a master’s degree in a clinical field related to nursing with academic coursework in the CNS components of expert clinical practice, education, research, consultation, and clinical leadership (BUSINESS AND PROFESSIONS CODE §2838.2). The BRN provides certification for the use of the title “clinical nurse specialist” and no person can refer to him/herself as a clinical nurse specialist unless certified by the BRN (BUSINESS AND PROFESSIONS CODE §2838).

J. Hospital privileges: Other Healthcare Providers

Acute care facilities may employ their own providers and grant staff privileges to other healthcare providers who are not employees of the facility. These healthcare providers include doctors of podiatric medicine, psychologists, nurse practitioners, physician assistants, physical therapists, respiratory care practitioners, acupuncturists, speech pathologists, audiologists, and polysomnographic trainees, technicians and technologists.

The hospital has the authority to assign these healthcare professionals to a department, to establish policies, set standards and limit their scope of practice on an individual basis, and to monitor and discipline them in accordance with the hospital rules for functions performed in the hospital. Regardless of hospital policies, none of the different health professionals may legally exceed their respective scopes of practice as set forth in the statutes and regulations of their licensing agency. Key features distinguishing each of these healthcare providers are given below.

A clinical nurse specialist has been certified by the Board of Registered Nursing. No one without this certification can use the title.

K. Clinical Psychologist

A psychologist receives his or her staff privileges from the hospital medical staff and does not need a referral from a physician to treat a patient. The clinical psychologist may bill directly.

L. Doctor of Podiatric Medicine (Podiatrist)

Doctors of podiatric medicine receive their staff privileges from the executive committee of the medical staff and they do not need a physician's referral to treat a patient. They may qualify as a Medi-Cal provider and may bill patients directly.

M. Physician Assistant (PA)

Physician assistants must apply to and must be approved for privileges by the executive committee of the medical staff of the facility.

The staff privileges granted to the PA may never exceed those granted to the supervising physician responsible for the patient being treated by the PA.

Nothing in the PA Practice Act prohibits a PA from billing directly for his or her services, although third-party payers may have special terms and conditions for their reimbursement process.

A physician assistant's privileges may not exceed the privileges granted to the physician supervising the patient that the physician assistant is treating.

Representation on the medical staff

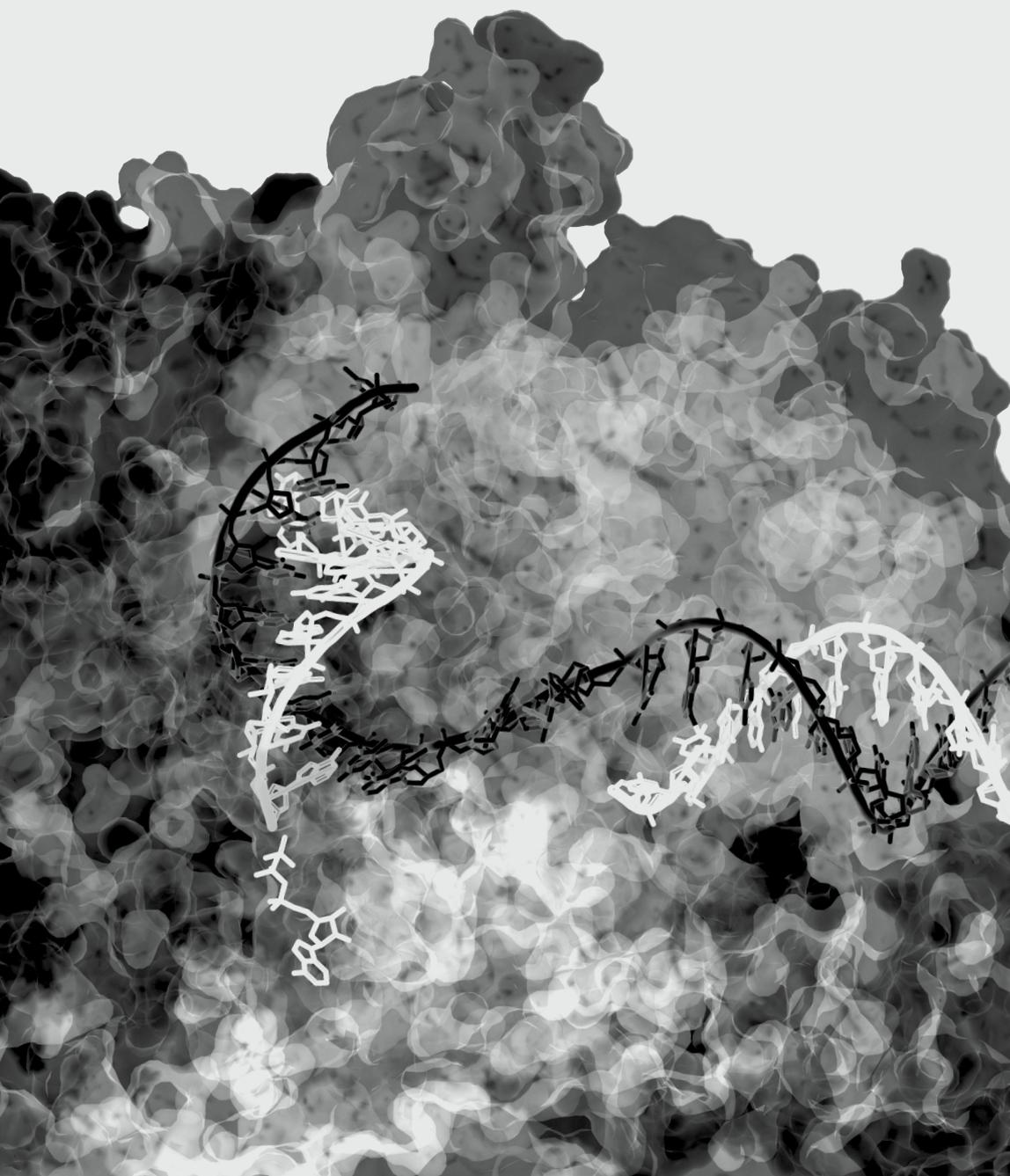
Hospitals have permissive authority to grant staff privileges to psychologists and doctors of podiatric medicine. However, if the hospital elects to grant them staff privileges, they must also be allowed representation on the medical staff.

The health care team

The health care team continues to evolve as new health occupations emerge, and as laws are changed to augment and revise the relationships among physicians, physician extenders, and other health care personnel. The preceding two chapters have enumerated the extent of currently acceptable practice, but because of rapid modifications to existing laws in this area, physicians are strongly advised to read the current laws and regulations before delegating certain tasks to the health care team, and to remain informed of any new laws or regulations. The health care team must practice under the supervision of a physician or a podiatrist and within approved standard protocols set by the supervisor.

SECTION V:

Laws Relating to Controlled Substances



V. Laws Relating to Controlled Substances

The Federal Drug Laws

5.1 The Drug Enforcement Administration (DEA)

The Drug Enforcement Administration is the federal law enforcement agency charged with regulating controlled substances. The Controlled Substances Act of 1970 mandates the Drug Enforcement Administration to provide a “closed system” for legitimate manufacturers, distributors, and dispensers of these drugs. Such a closed system helps to reduce the diversion of these drugs from legitimate channels into the illicit market.

The drugs and drug products that come under the jurisdiction of the Controlled Substances Act are classified into five schedules. Definitions and examples of substances covered by each schedule are presented below. For a complete listing of all controlled drugs, write to one of the following addresses:

Drug Enforcement Administration:

San Francisco Division

450 Golden Gate Avenue
PO Box 36035
San Francisco, CA 94102
(415) 436-7900

Los Angeles Division

255 East Temple Street, 17th Floor
Los Angeles, CA 90012
(213) 621-670

San Diego Division

4560 Viewridge Avenue
San Diego, CA 92123-1672
(858) 616-4100

For a complete list of the DEA’s controlled substance drug scheduling, you can also check online at: www.justice.gov/dea

All licensed healthcare professionals who are authorized to obtain controlled substances security prescription forms are able to obtain a patient history or activity report from the Department of Justice to assist in identifying those patients who may be “doctor shopping.” The form can be downloaded from the Board’s Web site: click on *Licensee Information* and click on *Patient Activity Report* which is located under the heading of *Pain Management*. Any questions regarding this program can be directed to the Department of Justice, CURES Program at (916) 227-3843 or visit the Web site: oag.ca.gov/cures-pdmp

All licensed healthcare professionals authorized to use “controlled substances security prescription forms” are authorized to obtain a patient history to help them identify patients who may be doctor-shopping.

5.2 Schedules of Controlled Drugs

A. Schedule I Substances

Drugs in this schedule are those declared by law to have no accepted medical use in the United States and have a high potential for abuse.

Examples of drugs classified in Schedule I include:

- Heroin
- Marijuana
- LSD
- Peyote
- Mescaline
- Racemoramide
- Dihydromorphine
- Nicocodeine

Triplicate prescription forms are no longer required.

B. Schedule II Substances

Controlled Substance Utilization Review and Evaluation System (CURES)

Effective July 1, 2004, California law eliminated the triplicate prescription requirement for Schedule II controlled substances. After January 1, 2005, the new law required prescriptions for any controlled substance to be issued on controlled substance prescription forms obtained from a security printer pre-approved by the Board of Pharmacy and the Department of Justice (DOJ).

The new law permanently established the Controlled Substance Utilization Review and Evaluation System (CURES). DOJ has established guidelines for authorized prescribers. The law requires physicians who dispense prescriptions for Schedules II and III from their offices to keep a log and submit it to DOJ monthly in either a hard copy or electronic form. Schedule II controlled substances have a high abuse potential with severe psychic or physical dependence liability. Schedule II controlled substances consist of certain narcotic, stimulant, and depressant drugs.

Examples of drugs classified in Schedule II include:

- Morphine
- Hydromorphone (Dilaudid)
- Meperidine (Demerol)
- Cocaine
- Oxycodone (Percodan)

Physicians who dispense prescriptions for controlled substances on Schedules II and III from their offices must keep a log and submit it monthly to the Department of Justice.

- Methylphenidate (Ritalin)
- Oxycontin
- Fentanyl
- Methadone

C. Schedule III Substances

The drugs categorized into this schedule have an abuse potential less than those of Schedules I or II, and include compounds containing limited quantities of certain narcotic drugs in combination with non-narcotic substances.

Examples of drugs classified in Schedule III include:

- Vicodin
- Tylenol with Codeine
- Anabolic Steroids
- Ketamine
- Dronabinol

D. Schedule IV Substances

The drugs in this schedule have an abuse potential less than those listed in Schedule III.

Examples of drugs classified in Schedule IV include:

- Barbitol
- Penobarbital
- Diazepam (Valium)
- Propoxyphene (Darvon)
- Pentazocine (Talwin)
- Xanax
- Halcion
- Ambien
- Sonata

E. Schedule V Substances

The drugs in this schedule have an abuse potential less than those listed in Schedule IV but still sufficient to warrant control, and consist of preparations containing moderate, limited quantities of certain narcotics. These substances are generally used for antitussive and antidiarrheal purposes.

5.3 Federal Registration of Practitioners

Prior to administering, prescribing, or dispensing any scheduled drugs, a physician must be registered with the Drug Enforcement Administration, Office of Diversion Control. An application for registration (FORM DEA-224) may be obtained online at www.deadiversion.usdoj.gov/drugreg/index.html, by calling the toll-free number at (800) 882-9539, or by writing to the DEA addresses listed in section 5.1 of this guidebook. For registration help, contact DEA.Registration.Help@usdoj.gov.

No separate state drug license is needed or applicable in California.

The State of California does not issue its own state drug license.

Physicians applying for a DEA registration must indicate the schedule(s) of controlled substances they intend to administer, prescribe or dispense. The options include Schedule II narcotic, Schedule II non-narcotic, Schedule III narcotic, Schedule III non-narcotic, Schedule IV, and Schedule V. DEA issues a registration based upon the schedule(s) of controlled substances requested by the practitioner and any applicable state laws.

If a physician administers or dispenses any scheduled drugs through more than one office, he or she must register each office. However, if a physician administers or dispenses only at his or her principal office and only writes prescription orders at the other office or offices, that physician is only required to register the principal office, provided that each office is within the same state.

5.4 Federal Registration of Interns, Residents, and Foreign-Trained Physicians Who Are Fellows

Any intern, resident, or foreign-trained physician who is a fellow may dispense, administer, and prescribe controlled drugs under the registration of a hospital or other registered institution by whom he or she is employed, provided that the following conditions are satisfied:

- The dispensing, administering, or prescribing is performed in the usual course of his or her respective practices as an intern, resident, or fellow.
- Authority for dispensing, administering and prescribing controlled substances is given by the jurisdiction in which he or she is practicing.
- The hospital or other institution has verified that the intern, resident, or fellow is authorized in his or her jurisdiction.
- The intern, resident, or fellow acts only within the scope of his or her hospital employment.
- The hospital or institution authorizes the intern, resident, or fellow to dispense or prescribe under its registration and assigns a specific code number for each physician so authorized.

An example of a code number follows:

AB1234567 012
 DEA REGISTRATION HOSPITAL CODE
 NUMBER NUMBER

- A current list of these internal codes and the corresponding practitioners' names is kept by the hospital or other institution and is made available to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing practitioner.

Physicians who frequently dispense drugs are required by federal law to take an inventory every two years of all controlled substances on hand.

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5.5 Order Forms

A DEA registered physician who has a need for Schedule II controlled drugs for office or medical bag use must obtain these drugs by completing a federal order form. Order forms may be obtained by requesting Form DEA-222 from the DEA online at www.deadiversion.usdoj.gov/drugreg/index.html under *Registration Tools - Official Order Forms*, or at the address listed in section 5.1 of this guidebook.

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5.6 Inventory

When issued a DEA registration, a physician must take an initial inventory, which is an actual physical count of all controlled substances in his or her possession. If there are no stocks of controlled substances on hand, the physician should make a record showing a zero inventory.

Physicians who frequently dispense drugs are required by federal law to take an inventory every two years of all controlled substances on hand. A physician who plans to dispense drugs on a regular basis is advised to take the initial inventory when he or she first engages in dispensing. These records must be maintained on file for three years, since physicians are not required to submit copies to the Drug Enforcement Administration.

A current inventory of dangerous drugs and dangerous devices must be made and kept for at least three years by every physician who maintains a stock of dangerous drugs or dangerous devices according to Business and Professions Code §4081.

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5.7 Records

State and federal laws require physicians to maintain adequate and accurate medical records. For the Drug Enforcement Administration

to curtail the diversion of controlled substances, it is necessary for manufacturers, wholesalers, pharmacies, hospitals, and physicians to keep records of all drugs ordered, purchased, distributed, and dispensed. All stock of any dangerous drug or dangerous device is open to inspection at all times during business hours by authorized officers of the law. This includes investigative agents from the Medical Board, the Department of Justice and other local, state and federal law enforcement agencies. These records must be kept for a minimum of three years (BUSINESS AND PROFESSIONS CODE §§4080-4081 and HEALTH AND SAFETY CODE §11191).

Physicians must maintain adequate and accurate medical records.

Physicians who keep dangerous drugs or devices on hand must maintain an up-to-date inventory and keep it for at least 3 years.

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5.8 Security/Storage

A physician who stores controlled substances in an office or clinic is required to keep these drugs in a securely locked and substantially constructed cabinet or safe (BUSINESS AND PROFESSIONS CODE §4172, and TITLE 16, CALIFORNIA CODE OF REGULATIONS §1356.3). Syringes and partially used drugs should be disposed of in a manner which precludes them from being used again and complies with laws pertaining to the proper disposal of biohazardous waste (BUSINESS AND PROFESSIONS CODE §4119, and HEALTH AND SAFETY CODE §117600).

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5.9 Discontinuation of Practice by a Physician

A physician who discontinues his or her practice must return the Registration Certificate to the Drug Enforcement Administration office in San Francisco (refer to section 5.1 for address). A physician having controlled substances in his or her possession at the time of discontinuing practice should obtain information from the Drug Enforcement Administration on proper disposition of those drugs. Any remaining unused controlled substance prescription forms should be properly destroyed and a record system kept, accounting for their destruction.

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5.10 California Drug Laws

California laws relating to controlled substances are contained in the California Uniform Controlled Substances Act (HEALTH AND SAFETY CODE §§11000-11651). Physicians are urged to review this Act carefully for specific details and classifications of controlled substances. Generally, the state defines a controlled substance as a drug included in one of the five federal schedules.

5.11 Prescribing Controlled Substances

Only physicians, dentists, podiatrists, naturopaths, veterinarians, and under certain circumstances physician assistants and advanced practice nurses, are authorized to write prescriptions under California law. They may prescribe only in the regular practice of their profession, after an appropriate prior examination, and may not furnish any controlled substance to persons not under their care (HEALTH AND SAFETY CODE §§III50 AND III54).

5.12 Internet Prescribing

Computer-related violations of California state law regarding health care are occurring on the Internet. Business and Professions Code §2242.1 (Prescribing, dispensing, or furnishing dangerous drugs or devices on Internet), requires that a physician provide a patient with an appropriate prior examination and that there exist a medical indication before prescribing, dispensing or furnishing a dangerous drug. Violation of this law may result in a fine of up to \$25,000 for each occurrence. Essential components of proper prescribing include performing and documenting a physical examination that includes obtaining a legitimate medical history, engaging in sufficient dialogue to form a treatment opinion, determining the risks and benefits of the drug or treatment regimen, scheduling follow-up appointments to assess therapeutic outcome and maintaining an adequate and accurate medical record before prescribing any medication for the first time.

A prescription for a controlled substance is valid for six months.

Physicians can orally or electronically provide Schedule III and IV prescriptions to pharmacists. The pharmacist can then complete the required forms.

5.13 Written Prescriptions for Controlled Substances

As of January 1, 2005, written prescriptions for all controlled substances (II-V) must be issued on controlled substance prescription forms obtained from a security printer approved by the Board of Pharmacy and Department of Justice. After December 31, 2004, triplicate prescriptions were no longer valid in California. A prescription for a controlled substance is valid for six months (HEALTH AND SAFETY CODE §III66).

When prescribing Schedule III-V controlled substances, physicians can orally or electronically provide a prescription directly to the pharmacist who will complete the necessary forms as required by law. Pursuant to an authorization of the prescriber, any agent of the prescriber may, on behalf of the prescriber, orally or electronically transmit a prescription for a controlled substance in Schedule III-V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription (HEALTH AND SAFETY CODE §III64).

Physicians who prescribe Schedule II controlled substances for use by a patient who has a terminal illness may use a standard prescription pad. The physician must indicate that he or she certifies that the patient is terminally ill using the words “III59.2 exemption” (HEALTH AND SAFETY CODE §III59.2).

Those substances classified in Schedules II, III, IV, V are subject to the following requirements:

- The prescription must be signed and dated by the prescriber in ink and contain the prescriber’s address and telephone number, the name of the person for whom the controlled substance is prescribed, and the name, quantity, strength, and directions for use of the controlled substance prescribed.
- The prescription also must contain the address of the person for whom the controlled substance is prescribed.
- A physician may dispense directly to a patient a Schedule II controlled substance in an amount not to exceed a 72-hour supply. This is only permissible when the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours (HEALTH AND SAFETY CODE §III58).
- The prescription book containing the prescriber’s copies of prescriptions issued must be retained by the prescriber for three years (BUSINESS AND PROFESSIONS CODE §4081 and HEALTH AND SAFETY CODE §III91).
- A person who fills a prescription must keep it on file for at least three years from the date of filling it (HEALTH AND SAFETY CODE §III79).
- It is a violation of state law to issue a prescription that is false or fictitious in any respect (HEALTH AND SAFETY CODE §III57).
- A prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms to the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

A prescriber designated by a licensed healthcare facility may order controlled substance prescriptions for use by prescribers when treating patients in that facility without the prescriber’s preprinted name, category of licensure, license number and DEA number on the form. Forms ordered in this situation must have the name, category of licensure, license number, and DEA number of the

designated prescriber and the name, address, category of licensure, and license number of the licensed healthcare facility preprinted on the form. Each prescriber must fill in his name, category of licensure, license number and DEA number on each prescription he or she writes at said facility. The designated prescriber must maintain a record of the prescription information which is kept on file at the facility for three years (HEALTH AND SAFETY CODE §III62.1).

Guidelines for Prescribing Controlled Substances for Intractable Pain

Preamble

In 1994, the Medical Board of California formally adopted a policy statement titled, “Prescribing Controlled Substances for Pain.” The statement outlined the Board’s proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings, and discussions. California physicians and surgeons are encouraged to consult the policy statement and these guidelines, which can be found at www.mbc.ca.gov/pain_guidelines.html or obtained from the Medical Board of California.

In May 2002, as a result of AB 487 (Statutes of 2001), a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to “develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient’s pain.” The task force expanded the scope of the Guidelines, from intractable pain patients to all patients with pain.

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognizes that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the Medical Board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient’s pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

Effective pain management does not under-treat or over-treat a patient’s pain.

A High Priority

The Board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of medical organizations have developed guidelines for acute and chronic pain management. Links to these references may be found on the Medical Board of California's Web site at www.mbc.ca.gov/pain_guidelines.html.

The prescribing of opioid analgesics for patients with pain may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section. (§2241.5(A)(B) BUSINESS AND PROFESSIONS CODE).

Physicians and surgeons who prescribe opioids either for acute or persistent pain should not fear disciplinary or other action from California law enforcement or regulatory agencies for the mere fact of having prescribed opioids. The appropriate use of opioids in the treatment of intractable pain has long been recognized in California's Intractable Pain Treatment Act, which provides that "No physician and surgeon shall be subject to disciplinary action by the Medical Board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." (§2241.5(C) BUSINESS AND PROFESSIONS CODE).

Medical organizations have developed guidelines for acute and chronic pain management. Links to these sites may be found at www.mbc.ca.gov.

Physicians and surgeons will not be disciplined for prescribing or administering controlled substances to treat a person for intractable pain.

The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

Guidelines

1. History/Physical Examination

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

Annotation One: The prescribing of controlled substances for pain may require referral to one or more consulting physicians.

Annotation Two: The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests, and physical exam.

2. Treatment Plan, Objectives

The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

Annotation One: Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.

Annotation Two: When the patient is requesting opioid medications for his or her pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

Before treating a person for pain, a medical history and physical examination must be done.

If a patient's request for opioid medication for pain is inconsistent with the patient's history, presentation, or physical findings, the physician may withhold the medication but must document the reason for the decisions.

3. Informed Consent

The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver, or guardian.

Annotation: A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient’s use of medications for relief from pain.

Patients who are prescribed controlled substances should be seen frequently and regularly.

4. Periodic Review

The physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient’s state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician’s evaluation of progress toward treatment objectives. If the patient’s progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Managing pain in patients with a history of substance abuse requires extra monitoring, documentation, and consultation with a specialist in addiction medicine.

Annotation One: Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.

Annotation Two: Satisfactory response to treatment may be indicated by the patient’s decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient’s response to treatment.

5. Consultation

The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation, and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

Annotation One: Coordination of care in prescribing chronic analgesics is of paramount importance.

Annotation Two: In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code §2241.5.

6. Records

The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

Annotation One: Documentation of the periodic reviews should be done at least annually or more frequently as warranted.

Annotation Two: Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

In order to prescribe controlled substances, a physician must be licensed, have a valid controlled substances registration, and comply with all laws restricting such prescriptions.

Compliance with Controlled Substances Laws and Regulations

To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guide to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

Annotation One: There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.

Annotation Two: Physicians and surgeons who supervise Physician Assistants (PAs) or Nurse Practitioners (NPs) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at www.pac.ca.gov.

NP supervision requirements are available at www.rn.ca.gov.

PAs are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for Schedule II through Schedule V controlled substances with the advanced approval by a supervising physician for a specific patient, unless a PA completes an approved education course in controlled substances and is delegated by the supervising physician.

To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days (CALIFORNIA CODE OF REGULATIONS §1399.545(f)).

NPs are allowed to furnish Schedule III-V controlled substances underwritten protocols.

Physicians who know that a patient is using controlled substances for nontherapeutic purposes must not prescribe such substances. The Intractable Pain Treatment Act does not apply in such cases.

Patients who are both addicted to drugs and have severe pain require special care.

.....
Postscript

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain, there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (CALIFORNIA HEALTH AND SAFETY CODE §§11215-11222). The California Intractable Pain Treatment Act (CIPTA) does not apply to those persons being treated by the physician and surgeon only for chemical dependency because of use of drugs or controlled substances (§2241.5(d)). The CIPTA does not authorize a physician and surgeon to prescribe, dispense, or administer controlled substances to a person the practitioner knows to be using the prescribed drugs or controlled substances for non-therapeutic purposes (§2241.5(e)). At the same time, California law permits the prescribing, furnishing, or administering of controlled substances to or for a patient who is suffering from disease, ailments, injury, or infirmities attendant on old age, other than addiction (CALIFORNIA HEALTH AND SAFETY CODE §11210) and the CIPTA does apply to “a practitioner who is prescribing controlled substances for intractable pain, and as long as that

practitioner is not also treating the patient for chemical dependency.”

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient’s current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.

California Physicians and Medicinal Marijuana

The following statement was adopted by the full Medical Board on May 7, 2004 and revised November 5, 2004.

On November 5, 1996, the people of California passed Proposition 215. Through this Initiative Measure, section 11362.5 was added to the Health and Safety Code, and is also known as the Compassionate Use Act of 1996. The purposes of the Act include, in part:

- “(A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where the medical use is deemed appropriate and has been recommended by a physician who has determined that the person’s health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief; and
- (B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.”

Furthermore, Health and Safety Code §11362.5(c) provides strong protection for physicians who choose to participate in the implementation of the Act. “Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.”

The Medical Board of California developed this statement since medical marijuana is an emerging treatment modality. The Medical Board wants to assure physicians who choose to recommend medical marijuana to their patients, as part of their regular practice of medicine, that they **WILL NOT** be subject to investigation or disciplinary action by the MBC if they arrive at the decision to

The use of marijuana for medical purposes is legal in the State of California. No physician shall be punished or denied any right for recommending such use if done for medical purposes.

make this recommendation in accordance with accepted standards of medical responsibility. The mere receipt of a complaint that the physician is recommending medical marijuana will not generate an investigation, absent additional information indicating that the physician is not adhering to accepted medical standards.

These accepted standards are the same as any reasonable and prudent physician would follow when recommending or approving any other medication, and include the following:

Physicians should be as careful when recommending medical marijuana to patients as they are when recommending any medication.

- History and appropriate prior examination of the patient.
- Development of a treatment plan with objectives.
- Provision of informed consent including discussion of side effects.
- Periodic review of the treatment’s efficacy.
- Consultation, as necessary.
- Proper recordkeeping that supports the decision to recommend the use of medical marijuana.

In other words, if physicians use the same care in recommending medical marijuana to patients as they would recommending or approving any other medication, they have nothing to fear from the Medical Board.

Here are some important points to consider when recommending medical marijuana:

- Although it could trigger federal action, making a recommendation in writing to the patient will not trigger action by the Medical Board of California.
- A patient need not have failed on all standard medications in order for a physician to recommend or approve the use of medical marijuana.
- The physician should determine that medical marijuana use is not masking an acute or treatable progressive condition, or that such use will lead to a worsening of the patient’s condition.
- The Act names certain medical conditions for which medical marijuana may be useful, although physicians are not limited in their recommendations to those specific conditions. In all cases, the physician should base his/her determination on the results of clinical trials, if available, medical literature and reports, or on experience of that physician or other physicians, or on credible patient reports. In all cases, the physician must determine that the risk/benefits ratio of medical marijuana is as good, or better, than other medications that could be used for that individual patient.

- A physician who is not the primary treating physician may still recommend medical marijuana for a patient's symptoms. However, it is incumbent upon that physician to consult with the patient's primary treating physician or obtain the appropriate patient records to confirm the patient's underlying diagnosis and prior treatment history.
- Recommendations should be limited to the time necessary to appropriately monitor the patient. Periodic reviews should occur and be documented at least annually or more frequently as warranted.
- If a physician recommends or approves the use of medical marijuana for a minor, the parents or legal guardians must be fully informed of the risks and benefits of such use and must consent to that use.

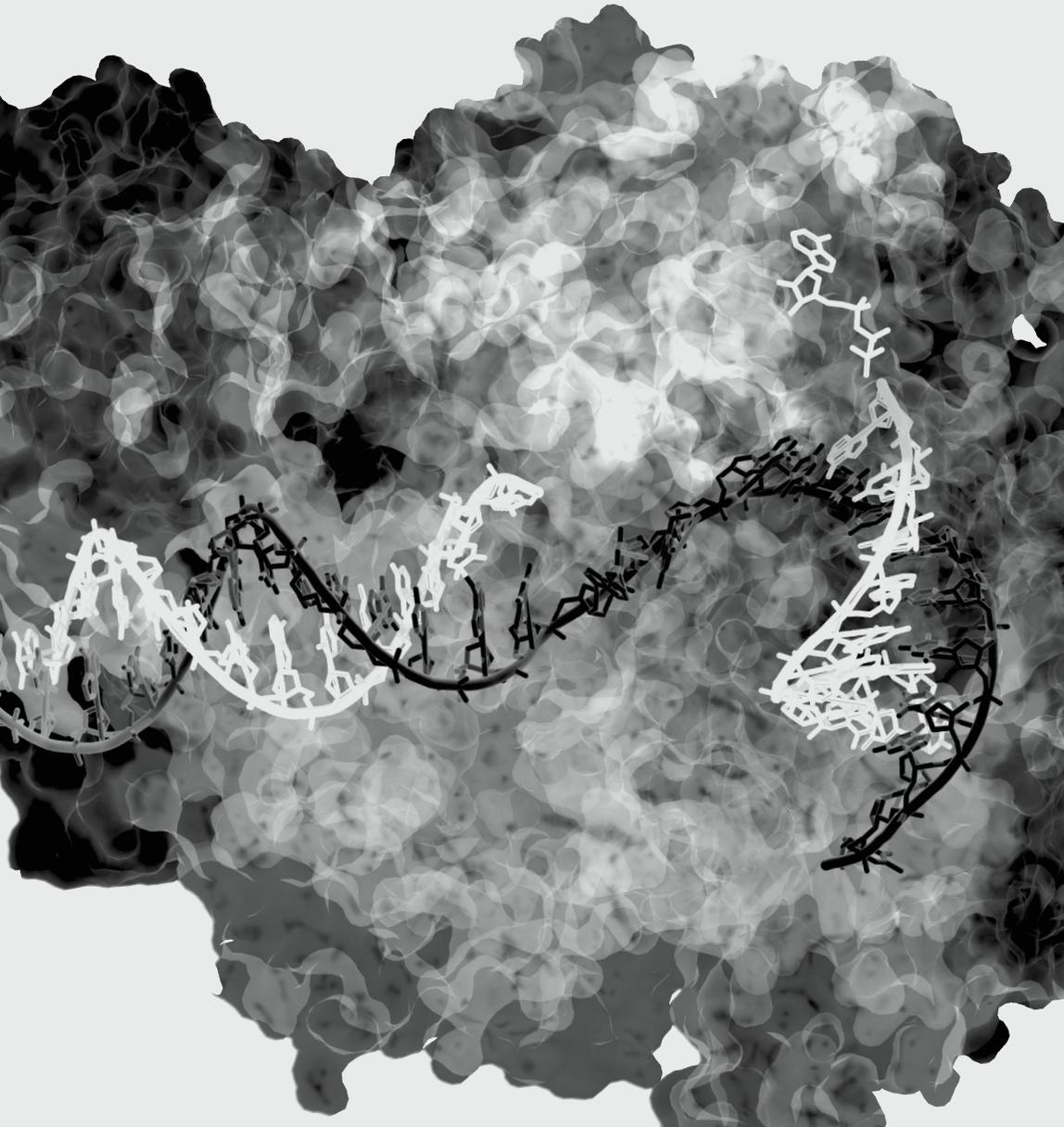
Physicians may wish to refer to CMA's ON-CALL Document #1315 titled, "The Compassionate Use Act of 1996," updated annually for additional information and guidance: www.cmanet.org. Click on professional resources then resource library and store.

Although the Compassionate Use Act allows the use of medical marijuana by a patient upon the recommendation or approval of a physician, California physicians should bear in mind that marijuana is listed in Schedule I of the federal Controlled Substances Act, which means that it has no accepted medical use under federal law. However, in *Conant v. Walters* (9th Cir.2002) 309 F.3d 629 the United States Court of Appeals recognized that physicians have a constitutionally-protected right to discuss medical marijuana as a treatment option with their patients and make oral or written recommendation for medical marijuana. However, the court cautioned that physicians could exceed the scope of this constitutional protection if they conspire with, or aid and abet, their patients in obtaining medical marijuana.

Before marijuana can be recommended for medical use, the physician must make an appropriate prior examination.

SECTION VI:

**Other Laws and Information
Pertaining to the
Practice of Medicine**



VI. Other Laws and Information Pertaining to the Practice of Medicine

This chapter explains various other laws and general information pertaining to the practice of medicine in California.

6.1 Medical Records

A. Accuracy and Consistency

Complete medical records are necessary not only to document the quality of patient care, but also to contribute to quality by facilitating the continuity of care. A physician has a personal responsibility to maintain accurate and consistent patient records, including hospital, nursing home, and office records. A physician's refusal to maintain adequate and accurate hospital records may be subject to discipline under Business and Professions Code §2266 and considered unprofessional conduct. It would also be reportable to the Board under Business and Professions Code §805.

Physicians must maintain accurate and consistent patient records for patients seen in the hospital, in a nursing home or in an office.

Physicians who comply with the following recommendations are likely to minimize any problems that might develop in the event that records are subpoenaed and reviewed.

B. A Comprehensive Patient Record

In addition to the patient's condition, treatment, and explanations, the following information is important and should be included in the medical record:

- Any consultation informing the patient of his or her condition and the intended procedures, risks, hazards, and alternative therapy.
- Any instructions given to a patient by telephone. Extreme caution should be exercised when giving or receiving information by telephone.
- Any cautions regarding prescription drugs that may interfere with a patient's occupation or driving safely. Special note should be made of any allergies or sensitivities.
- Surgical records which are comprehensive and promptly dictated or written. The anesthetist should record both pre- and post-operative information.
- Instructions to patients on follow-up care.
- Pathology and X-ray reports.
- The justification for treatment.

Any technical errors that the physician may have made should be

recorded objectively together with measures taken to correct the situation. Fraudulent alteration of medical records is a violation of the law and may subject the physician to civil penalties and disciplinary action. To make corrections, the physician should draw a horizontal line through the relevant comments and write the correction in the margin with signature and date. Errors should not be erased.

C. Obtaining Patient Records from a Previous Physician

When a physician who is presently treating a patient requests records from the patient's former physician, the former physician should make those records available promptly. However, proper authorization to transfer these records must be granted by the patient. A physician may be sued for breach of confidence or an invasion of privacy for divulging information without a patient's written authorization.

Alteration of medical records is an act of fraud and may bring legal penalties and disciplinary action.

D. Subpoena of Records

In the event that medical records are subpoenaed for a deposition or court hearing, the physician need not surrender the original documents, but may provide certified copies of medical records. The physician may be asked to produce originals for inspection. The original medical records themselves are the property of the physician.

Physicians may be sued for disclosing patient information without the patient's permission.

E. Retention of Medical Records

California laws relating to the retention of medical records are limited to a few specific areas. Medi-Cal patient records must be kept for at least three years after the last date of service. Records for patients whose care was paid out of the Emergency Medical Services Fund also must be retained for three years following the date of the last service reimbursed by the Fund. And, there is a three-year retention requirement for records of prescribing, dispensing, or administering Schedule II controlled substances (BUSINESS AND PROFESSIONS CODE §4080-4081, and HEALTH AND SAFETY CODE §11191). There also are specific laws relating to records under the Knox-Keene Act, and under OSHA. Physicians with patients in those programs should consult with the regulatory agency on the specific requirements.

Medical records should be kept indefinitely for current patients. If possible, all patient records should be retained for at least 7 years.

In general, medical records should be retained indefinitely for those patients under active treatment. If space and storage facilities are limited, physicians should retain all records for at least seven years. For those patients who might be considered inactive, a 10-year retention period is advised. It is recommended that records of minors be kept at least until the patient reaches the age of majority (18) plus one year.

The California Evidence Code permits the use of microfilmed records under any conditions, as well as photocopied records

if the originals have been lost or destroyed. Therefore, records need not be retained in their original form.

F. Patients' Rights to Access their Medical Records

Patients have the right to inspect and obtain copies of their healthcare records (HEALTH AND SAFETY CODE §§123100-123149.5).

Within five working days after receiving a patient's written request for medical records, a healthcare provider, including health facilities, clinics, home health agencies, physicians, podiatrists, dentists, optometrists, and chiropractors, must permit their patients or authorized representatives to inspect their records relating to health history, diagnosis, and condition. "Patient representative" is narrowly defined as a parent or guardian of a minor, or guardian or conservator of an adult.

Patients also are entitled to copies of their records, including those from a previous physician. Within 15 days after receiving a written request, a provider must supply a patient, or representative, with copies of any records they have a right to inspect. The healthcare provider is entitled to charge a fee to defray costs (up to 25¢ per page, or 50¢ per page for records copied from microfilm plus reasonable clerical costs).

In lieu of making copies, the provider has the option of drafting a comprehensive summary for the patient. The summary must contain specified information and must be available to the patient within 10 working days from the date of the request (up to 30 days if the record is of extraordinary length or if the patient has been discharged from a health facility within the last 10 days). The summary must contain information for each injury, illness, or episode and any information included in the record relative to: chief complaint(s), findings from consultations and referrals, diagnosis (where determined), treatment plan and regimen including medications prescribed, progress of the treatment, prognosis including significant continuing problems or conditions, pertinent reports of diagnostic procedures and tests and all discharge summaries, and objective findings from the most recent physician examination, such as blood pressure, weight, and actual values from routine laboratory tests. The summary must contain a list of all current medications prescribed, including dosage, and any sensitivities or allergies to medications recorded by the physician. Again, the provider may charge a reasonable fee based on actual time and cost for preparation (CRITERIA PER HEALTH AND SAFETY CODE §123130).

Copies of X-rays and tracings derived from electrocardiography, electroencephalography, or electromyography need not be

A healthcare provider must allow a patient or the patient's representative to inspect patient records within 5 working days of receiving a written request to do so.

The provider must either make copies of the patient's record or provide a comprehensive summary for the patient within 10 working days from the date the request for records was made.

provided to the patient or representative if the originals are transmitted to another healthcare provider within 15 days after receipt of a written request, at the option of the provider.

There are special provisions defining the right of minor patients' parents or representatives to obtain records that include safeguards to protect physician relationships with minor patients (HEALTH AND SAFETY CODE §123115).

Also, if a provider determines that there is a substantial risk of significant adverse or detrimental consequence to a patient having access to psychiatric or mental health records, the request may be denied, subject to specified conditions (HEALTH AND SAFETY CODE §123115).

Willful violation of the "Patient Access to Health Records Act" by a healthcare provider constitutes unprofessional conduct.

Any adult patient who inspects his or her patient records has the right to provide to the healthcare provider a written addendum with respect to any item or statement in his or her records that the patient believes to be incomplete or incorrect. The healthcare provider must attach the addendum to the patient's records and must include the addendum whenever the records are provided to any third party (HEALTH AND SAFETY CODE §123111).

Willful violation of the "Patient Access to Health Records Act" by a healthcare provider constitutes unprofessional conduct and the respective licensing agency shall consider the violation as grounds for disciplinary action, including license suspension or revocation (HEALTH AND SAFETY CODE §123110(i)).

6.2 Closing Your Medical Practice

Due care should be exercised when closing your practice or otherwise leaving the profession. Not only does this ensure a smooth transition from the current physician to the new treating physician, but it also reduces the liability of "patient abandonment." The physician terminating the physician-patient relationship should notify patients sufficiently in advance.

It is the patient's decision from whom to receive medical care. Therefore, it is the responsibility of all physicians and other parties who may be involved to ensure that:

- Patients are notified of changes in the medical practice. This is best done by letter to patients by the physician explaining the change, including the final date of practice.

- Patients be advised as to where their medical records will be stored including how they may access them. To facilitate the transfer of medical records to the new treating physician, an authorization form should be included in the letter
- Patients secure another healthcare provider. If the practice is being taken over by another physician or another can be recommended, the patients can be referred to that physician.

6.3 HIPAA Privacy Rule

The first-ever federal privacy standards to protect patients' medical records and other health information provided to health plans, physicians and surgeons, hospitals and other healthcare providers took effect on April 14, 2003. Developed by the Department of Health and Human Services, these standards provide patients with access to their medical records and more control over how their personal health information (PHI) is used and disclosed. Physicians who do electronic billing or any other electronic transmission regulated by the HIPAA Transaction Rule are covered by the HIPAA Privacy Rules regarding all medical information whether transmitted electronically, on paper, or orally (HEALTH AND SAFETY CODE §130300).

HIPAA Transaction Privacy Rules cover all medical information, including billing, whether transmitted electronically, on paper, or orally.

Effective April 20, 2005, physicians covered by HIPAA also must comply with the HIPAA Security Rule which allows HIPAA-covered entities to permit business associates to create, receive, maintain, or transmit ePHI only if the business associate agreement contains appropriate assurances that the ePHI will be secure. The HIPAA Security Rule applies only to medical information maintained in electronic forms but adds requirements pertaining to the ongoing integrity and availability of the information. (Refer to www.hhs.gov/ocr/privacy for additional information and guidance.)

NOTE: Public health reporting requirements (e.g., STD reporting, tuberculosis reporting, etc.), are exempt from the HIPAA Privacy Rule.

6.4 Physician-Patient Communication

A. The Physician-Patient Relationship

An important concern for patients has been the deterioration of the physician-patient relationship. It is important for physicians to maintain good rapport and open communication with patients.

Physicians should make conscientious efforts to assure that the patient fully understands the nature of his or her illness or injury.

All of the patient's concerns relating to diagnosis, hospital stay, drug prescriptions, and any other aspects of care should be fully explained and discussed. If an intern or resident physician becomes involved in the treatment of a private patient, the intern or resident should explain to the patient the scope or limitations of his or her practice.

B. Informed Consent

The landmark California Supreme Court decision of *Cobbs v. Grant* set a legal standard for the disclosure of risks when a doctor advises his patient to undergo some treatment or diagnostic procedure (COBBS V. GRANT, 8 CAL.3D 229 [1972], 104 CAL.RPTR. 505). Since then, physicians have had a duty to obtain the informed consent of patients before performing certain medical procedures.

There are three exceptions to the informed consent requirements:

- Emergency situations
- Patient asks not to be informed
- Therapeutic privilege

Physicians who rely on any of these exceptions are advised to document in the patient's chart the reasons for the exception.

C. Publications that Physicians Must Distribute to Patients

A Patient's Guide to Blood Transfusion: Health and Safety Code §1645 (the Paul Gann Blood Safety Act) requires physicians to provide a standardized summary of the positive and negative aspects of receiving blood from volunteers whenever there is a reasonable possibility that a blood transfusion may be necessary as a result of a medical or surgical procedure. Available in English and Spanish in bundles of 50 up to 250 copies per order at no charge. Available online at www.mbc.ca.gov/publications or fax request to (916) 263-2479.

A Woman's Guide to Breast Cancer Diagnosis & Treatment: Health and Safety Code §109275 requires primary care physicians to provide a standardized summary discussing alternative breast cancer treatments and their risks and benefits to women who are being biopsied or treated for breast cancer. Available in English and Spanish in bundles of 25 up to one case (250 per case) per order at no charge. Available online in Chinese, Russian, Vietnamese, Korean, Japanese and Tagalog at www.mbc.ca.gov/publications.htm or fax request to (916) 263-2479.

Gynecologic Cancers...What Women Need to Know: Health and Safety Code §109278 requires healthcare providers, primarily responsible for providing patients with an annual gynecologic exam, to provide a

standardized summary containing a description of the symptoms and appropriate methods of diagnoses for gynecological cancers. Available in English in bundles of 25 at no charge. Fax request to (916) 263-2478. Available online in Armenian, Chinese, Cambodian, English, Farsi, Hmong, Korean, Russian, Spanish, and Vietnamese at www.mbc.ca.gov/publications or fax request to (916) 263-2479.

Professional Therapy Never Includes Sex: Business and Professions Code §728 requires physicians specializing in psychiatry to provide written information on the rights and remedies for patients who have been involved sexually with their psychotherapist when the physician becomes aware that the patient had alleged sexual intercourse or sexual contact with a previous psychotherapist during the course of a prior treatment. Available in English & Spanish in bundles of 5 per order at no charge. Available online in English and Spanish at www.mbc.ca.gov/publications or fax request to (916) 263-2479.

**Live births must
be registered with
the local registrar
within 10 days.**

Things to Consider Before Your Silicone Implant Surgery: Business and Professions Code §2259 (COSMETIC IMPLANT ACT OF 1992) requires physicians to provide written information to patients considering silicone implant surgery. Physicians may substitute written information authorized for use by the federal Food and Drug Administration (FDA) prepared by the manufacturer based upon the physician package insert. Available through the FDA Web site www.fda.gov/medicaldevices. Use the *A-Z Index* and click on *Breast Implants*.

What You Need to Know About Prostate Cancer: Business and Professions Code §2248 and Health and Safety Code §109280 (the Grant H. Kenyon Prostate Cancer Detection Act) requires physicians to provide a standardized summary about the availability of appropriate diagnostic procedures when examining a patient's prostate gland during a physical examination. Available in English and Spanish in bundles of 25 up to one case (300 per case) per order at no charge. Available online at www.mbc.ca.gov/publications or fax request to (916) 263-2479. (Pursuant to Business and Professions Code §2248, physicians and surgeons who are working on trauma cases are exempt from the requirement to distribute this publication).

NOTE: The Board is unable to fill out-of-state orders due to limited resources and the mandate is limited to California physicians, practicing in California.

6.5 Births and Deaths

A. Birth Certificates

Live births must be registered with the local registrar within 10 days following the events of births and deaths for the district in which the birth or death occurred (HEALTH AND SAFETY CODE §102400).

The physician or other healthcare practitioner in attendance at the birth, whether in a hospital or elsewhere, is responsible for registering live births. In the absence of a physician, either one of the parents, or any other individual who was actually present at the birth can enter the information on the certificate, secure the required signatures, and register the certificate with the local registrar (HEALTH AND SAFETY CODE §102405). For additional information, contact:

California Department of Public Health, Office of Vital Records
P.O. Box 997377, Sacramento, CA 95899-7377

The Health Care Decisions Law allows individuals to state their advance care directive preferences both in writing and orally.

B. Health care Decisions Law

Effective July 1, 2000, the Health care Decisions Law (PROBATE CODE §§4600-4806) consolidated California's previous advance directive laws to make it easier for individuals to make their preferences known through written and oral communications. A more generic advance directive, the Advance Health Care Directive (AHCD), replaced previous advance directive forms, such as the Natural Death Act Declaration, the Directive to Physicians, and the Durable Power of Attorney for Health Care (DPAHC). If a completed advance directive was previously valid, it remains so unless rescinded by the person. Forms that were legal before July 1, 2000 can continue to be used.

The AHCD allows a person who is at least 18 years of age and of sound mind to appoint a Power of Attorney for Health Care and state instructions for future health care decisions. The AHCD can be used to indicate preferences for health care treatment, such as management of the dying process and specifying personal values about quality of life. The law allows, but does not require, other preferences to be documented, such as appointment of a conservator or guardian, autopsy and funeral arrangements, and organ and tissue donation. The only statutory language required in the document is related to witnesses.

Immunity is explicitly granted to physicians and other healthcare professionals who make good faith health care decisions in accord with the patient's written or oral preferences. Physicians and other professionals acting under a physician's direction also are immune from any criminal prosecution or charges of unprofessional conduct, provided that the conditions of the law are satisfied.

Additional information on the Health care Decisions Law and the Advance Health care Directive may be obtained from either of the following two organizations:

California Hospital Association

1215 K Street, Suite 800, Sacramento, CA 95814
(916) 443-7401 or www.calhospital.org

California Medical Association

1201 J Street, Suite 200, Sacramento, CA 95814
(916) 444-5532 or www.cmanet.org

Additionally, POLST (Physician Orders for Life-Sustaining Treatment) is a form that states what kind of medical treatment patients want toward the end of their lives. Printed on bright pink paper, and signed by both a doctor and patient, POLST helps give seriously ill patients more control over their end of life care.

More information can be found at: www.capolst.org

C. Death Certificates

Death certificates are to be completed by the physician last in attendance of the deceased. The physician is required to complete and attest to the medical and health section data and the time of death, provided the physician is legally authorized to certify and attest to these facts. Otherwise, the coroner is required to fulfill these obligations (HEALTH AND SAFETY CODE §102825). Also, the physician or physician assistant must specifically indicate the existence of any cancer of which the physician or physician assistant has actual knowledge.

The medical and health section data and the physician's or coroner's certification must be completed by the attending physician within 15 hours after the death, or by the coroner within three days after examination of the body. Within 15 hours of the death, the physician must deposit the certificate at the place of death, or deliver it to the attending funeral director at his or her place of business or at the office of the physician (HEALTH AND SAFETY CODE §102800). Also, Health and Safety Code §§102795 and 102825 permit physician assistants (PAs), under the supervision of the physician last in attendance of the deceased, in a skilled nursing or intermediate care facility, to complete death certificates.

D. Certificates of Fetal Death

The physician in attendance at the delivery of a fetus must within 15 hours after the delivery state on the certificate of fetal death the following information:

The physician who last attended to a patient must complete the death certificate.

A physician assistant who works in a skilled nursing or intermediate care facility may complete death certificates if he or she is supervised by the physician who last saw the patient.

- Time of fetal death or delivery
- Direct causes of the fetal death
- Conditions, if any, that gave rise to these causes
- Other medical and health section data as required on the certificate
- Physician’s signature attesting to these facts

As in the case of death certificates generally, the physician must deposit the certificate of fetal death at the place of death, or deliver it to the attending funeral director at his or her place of business or at the office of the physician (HEALTH AND SAFETY CODE §102975).

Failure to report reportable diseases has resulted in charges of gross negligence and incompetence.

E. Determination of Death

The Uniform Determination of Death Act (HEALTH AND SAFETY CODE §§7180-7182) defines death in an individual if the individual has sustained either:

- Irreversible cessation of circulatory and respiratory functions, **OR**
- Irreversible cessation of all functions of the entire brain, including the brain stem.

When an individual is pronounced dead because of irreversible cessation of all functions of the brain, there must be independent confirmation by another physician (HEALTH AND SAFETY CODE §7181).

Neither physician confirming death shall participate in surgery to remove any bodily part for further transplantation (HEALTH AND SAFETY CODE §7182).

6.6 Reportable Conditions

A. General Comments

By law, California physicians must report certain diseases and conditions to their Local Health Officer. Specifically, the California Health and Safety Code §120250 sets forth the legal responsibility of physicians, and others, to notify local health authorities of persons ill of any infectious, contagious, or communicable diseases.

Reporting is necessary for proper surveillance of reportable diseases and conditions and to permit action by public health authorities wherever appropriate. Failure to report reportable diseases has resulted in charges of gross negligence and incompetence by the Board. For example, in a case of failure to report hepatitis in a patient known to be a food handler, the Board suspended a physician’s license.

Physicians may obtain reporting forms (Confidential Morbidity Report Cards) from their local health department. Addresses and

telephone numbers of local health departments are posted on the Board's Web site www.mbc.ca.gov (use the *A-Z Index* to locate Health Departments), and are also provided in local telephone directories. The list of reportable conditions is provided on the back cover of the Confidential Morbidity Report booklet.

A list of reportable diseases and conditions is provided in Title 17, California Code of Regulations, §2500. Check the list periodically as it changes. Available on the Board's Web site at www.mbc.ca.gov/laws/index.html

NOTE: Public health reporting requirements (e.g., STD reporting, tuberculosis reporting, etc.) are exempt from the HIPAA Privacy Rule.

B. Special Reporting Procedures for Syphilis

All cases of suspected or confirmed syphilis of any stage should be reported within one working day by phone, fax or electronically to the local health jurisdiction where the patient resides (CALIFORNIA CODE OF REGULATIONS, TITLE 17, §2500(j)). In addition, patients should be informed at the time of syphilis testing that, if their test result is positive, the provider is required by California law to confidentially report this information to the local health department, and that the health department may contact the patient to ensure adequate management.

When reporting cases of clinically suspicious syphilis, the physician should describe the stage of infection using the following classifications per the California Department of Public Health, STD Control Branch:

Primary: Chancre present, with or without laboratory evidence suggestive of syphilis;

Secondary: Localized or diffuse mucocutaneous lesions (e.g., rash, condyloma lata) and laboratory evidence suggestive of syphilis, if available; (chancre may still be present);

Early Latent: Asymptomatic infection, positive serologic test suggestive of syphilis, and

- Documentation of a negative serologic test or a fourfold or greater increase in titer during the prior 12 months, or
- Patient-reported history of symptoms consistent with primary or secondary syphilis within the prior 12 months, or
- Patient-reported history of sexual exposure to a partner who has been recently diagnosed with primary, secondary, or early latent syphilis;

All cases of suspected or confirmed syphilis of any stage should be reported within one working day by phone, fax or electronically to the health authority where the patient lives.

Late Latent: Asymptomatic infection, serologically confirmed syphilis, and no evidence that infection was acquired in the past 12 months;

Neurosyphilis: Any stage of syphilis, with positive CSF-VDRL or symptoms of CNS involvement (e.g., meningovascular involvement, tabes dorsalis, general paresis, etc.);

Late (Tertiary): Serologically confirmed syphilis with clinical or radiographic signs of cardiovascular, bone, or visceral involvement;

Congenital: Positive serologic test for syphilis or other clinical/ laboratory evidence of congenital syphilis in an infant or child less than 2 years of age or maternal serologic evidence of syphilis at time of delivery.

Any suspected case of syphilis in which the stage cannot be determined from the above criteria should be reported as “Syphilis—Stage Unknown”.

Healthcare providers must report suspected cases of tuberculosis to the Local Health Officer within one working day.

C. Special Reporting Procedures for Tuberculosis

Healthcare providers must report to the Local Health Officer* (LHO) within one working day when tuberculosis (TB) is suspected (CALIFORNIA CODE OF REGULATIONS, TITLE 17, §2500) and in turn the LHO has the duty to report TB cases to the California Department of Public Health. Note that both suspected and clinically or laboratory confirmed TB is reportable to the LHO.

- Sputa for acid-fast bacilli (AFB) smear and culture should be obtained in all patients in whom laryngeal, pleural, or pulmonary TB is suspected. The results of sputum analysis are important for diagnosis, treatment, and public health response.
 1. When TB is included in the differential diagnosis, the initial diagnostic test should be the examination of sputa for AFB smear and culture. Sputum smears are necessary to determine the patient’s infectiousness, and sputum cultures, when positive, should be used to monitor clinical response.
 2. Sputum induction should be performed for all patients unable to spontaneously expectorate sputum specimens adequate for smear and culture.
 3. Diagnostic bronchoscopy can be considered for persons who are unable to produce adequate induced sputum.
 4. In young children who are unable to produce adequate sputum, gastric aspirate should be done to confirm the diagnosis and guide treatment. More than 15 percent of

* 61 legally appointed physician health officers in California, one from each 58 counties and the three cities of Berkeley, Long Beach, and Pasadena. Provider reports should be made to the LHO for the county of residence of the patient with suspected TB.

all TB in California is resistant to at least one first line TB drug, so determining drug susceptibility is important for patient care. Diagnostic specimens for AFB culture should be obtained from all patients with suspected TB.

- Both AFB smear and culture should be ordered for all specimens collected during the diagnostic evaluation for TB (sputum, tissue, cerebrospinal fluid, urine, other body fluid, etc.)
- Providers should determine whether the laboratory they use automatically performs susceptibility testing on first-line drugs and, if not, susceptibilities should be ordered.
- Rapid molecular tests that identify Mycobacterium tuberculosis complex genetic material are available. These tests should be ordered for all AFB smear positive patients. The Mycobacterium Tuberculosis Direct Test (MTD, Gen-Probe®) can also be used for AFB smear negative patients at high risk for tuberculosis. This test has a high positive predictive value, but false negative results can occur with AFB smear negative patients.

Healthcare providers must also report to the Local Health Officer (LHO) when patients cease TB treatment and report all household contacts of the TB case (HEALTH & SAFETY CODE §§121362-121363).

Because each LHO has general legal authority to “take measures as may be necessary” to prevent and control the spread of TB, local requirements for TB screening, examination and testing may be in place and providers are encouraged to contact their local public health department.

D. Lapses of Consciousness

All physicians must report immediately in writing to the LHO the name, date of birth, and address of every patient at least 14 years of age or older whom the physician has diagnosed as having a case of a disorder characterized by lapses of consciousness. The report will be used as information to the California Department of Motor Vehicles in enforcing the provisions of the Vehicle Code and will be kept confidential and used solely for the purpose of determining a person’s eligibility to operate a motor vehicle on the highways of this state (HEALTH & SAFETY CODE §103900).

If a physician reasonably and in good faith believes that the reporting of a patient will serve the public interest, he or she may report a patient’s condition even if it may not be required under the department’s definition of disorders characterized by lapses of consciousness. “Disorders characterized by lapses of consciousness” means those medical conditions that involve:

A physician who diagnoses a disorder characterized by a lapse of consciousness in a patient who is at least 14 years old must immediately report the patient’s name, date of birth, and address in writing to the Local Health Officer.

1. A loss of consciousness or a marked reduction of alertness or responsiveness to external stimuli; and
2. The inability to perform one or more activities of daily living; and
3. The impairment of the sensory motor functions used to operate a motor vehicle. Examples of medical conditions that do not always, but may progress to the level of functional severity described in subsection (a) of this section include Alzheimer’s disease and related disorders, seizure disorders, brain tumors, narcolepsy, sleep apnea, and abnormal metabolic states, including hypo- and hyperglycemia associated with diabetes (CALIFORNIA CODE OF REGULATIONS, TITLE 17, §2806).

Physicians who dispense drugs in the office should let their patient know about a drug’s side effects and warnings.

This definition includes, but is not limited to, persons subject to lapses of consciousness or episodes of marked confusion resulting from neurological disorders, senility, diabetes mellitus, cardiovascular disease, alcoholism or excessive use of alcohol sufficient to bring about blackouts (retrograde amnesia for their activities while drinking).

Health practitioners must report known or suspected injuries caused by firearms or from assault or abuse.

E. Drugs—Duty to Warn

Pharmacists are required under state law to give warnings to patients of the harmful effects of a prescribed drug when combined with alcohol, or if the drug impairs the ability to drive. At times, physicians are guilty of the common practice of giving out sample pills of these drugs to patients in the office without giving the required warning about its harmful combination with alcohol or its impairment to driving. When dispensing in the office, physicians are reminded of their duty to keep informed of the drugs requiring warning and to properly warn their patients (BUSINESS AND PROFESSIONS CODE §4074).

A physician who knows, or has reasonable cause to believe that a patient has a pesticide-related illness, must report the case to the Local Health Officer by telephone within 24 hours and send a written copy of the report.

F. Injuries by Deadly Weapon or Criminal Act

Health practitioners, including physicians, have a broad obligation under law to report known or suspected wounds or injuries by means of a firearm, and any injury that they know or reasonably suspect resulted from assaultive or abusive conduct. The law defines what is meant by health practitioners, health facilities, injuries, wounds and assaultive or abusive conduct.

Practitioners are required to make an oral report by telephone immediately or as soon as practically possible and a written report to a local law enforcement agency within two working days of receiving information.

A summary of these laws are available on the Board’s Web site at www.mbc.ca.gov/laws/laws.html under California Law, Penal Code §11160.

G. Pesticide Poisoning

A physician who knows, or has reasonable cause to believe that a patient has a pesticide-related illness, must report the case to the Local Health Officer by telephone within 24 hours and by a copy of the report required per Labor Code §6409(a) within five days. If the treatment is for pesticide poisoning or a condition suspected to be pesticide poisoning, the physician must also file a complete report with the Division of Labor Statistics and Research, and within 24 hours of the initial examination must file a complete report with the Local Health Officer.

A brief manual, “Recognition and Management of Pesticide Poisonings, Fifth Edition” is available in both English and Spanish, for your information, from:

U.S. Environmental Protection Agency
Office of Pesticide Programs
401 M Street, SW (7506C), Washington, D.C. 20460 or,
www.epa.gov/oppfead1/safety/healthcare/handbook/handbook.htm.

H. Child Abuse

1. General Provisions

A physician or other medical practitioner who knows or suspects that a child is the victim of child abuse is required to report the information to a child protective agency as soon as possible by telephone, and in writing within 36 hours of receiving the information.

2. Penalties for Failure to Report Child Abuse

Failure to report known or suspected child abuse is punishable by imprisonment for up to six months and a fine of up to \$1,000 (PENAL CODE §11166(c)), and is considered unprofessional conduct and may result in disciplinary action by the Board. Failure to report also may be grounds for suit for civil damages for any subsequent injury to the child. The failure to report child abuse also can result in an administrative citation issued by the Board.

3. Reporting Consensual Sex Involving a Minor

In 2002, the California Attorney General issued a letter interpreting the Child Abuse and Neglect Reporting Act. The letter states that cases involving minors 14 years or older must be reported if there is a reasonable suspicion that the sexual contact was the result of child abuse; that is, that the girl or boy has been the victim of non-consensual, abusive sexual assault, or molestation. However, a girl or boy under 14 years of age is presumed to be unable

Any medical practitioner who knows or suspects that a child is being abused must report the information to a child protective agency by telephone as soon as possible and in writing within 36 hours.

Any sexual contact with a person younger than 14 is a violation of the law and must be reported.

to consent to sexual activity. Therefore, all sexual contact involving a person less than 14 years of age violates the law. The Child Abuse and Neglect Reporting Act requires the reporting of all instances in which there is reasonable suspicion that a girl or boy under 14 has been involved in sexual conduct, or has a sexually transmitted disease. Moreover, there is a reporting requirement when the female minor is under 16 years old and is impregnated by a man who is 21 years old or older. Requests for birth control pills or devices do not necessarily indicate sexual activity and need not be reported (PENAL CODE §261.5(d) and §288).

Healthcare practitioners, including physicians and podiatrists, are required to report actual or suspected abuse of dependent adults, including the elderly.

4. Adult/Elder Abuse Reporting Requirements

Physicians, podiatrists, and most other healthcare practitioners are required to report actual or suspected abuse of dependent adults, including elderly dependent adults. Reports must be made whenever there is reasonable cause to suspect abuse is present including physical or mental abuse, sexual abuse, exploitation or neglect, including self-neglect, intimidation, deprivation of nutrition or medical care, financial abuse or other forms of mistreatment. Reports must be made by telephone immediately or as soon as practically possible, and by written report sent within two working days to an adult protective service agency or a law enforcement agency, and are confidential (CALIFORNIA WELFARE AND INSTITUTIONS CODE §15630).

5. Injuries Resulting from Neglect or Abuse

Every physician, hospital administrator, or allied medical practitioner who receives a patient transferred from a health or community care facility who exhibits physical injuries or conditions which appear to be the result of neglect, abuse or battery, is required to report the case to both the local police authority and the county health department. The report must be made both in writing and by telephone within 36 hours, and must state the character and extent of the physical injury or condition. Anyone who makes such a report is immune from liability or civil or criminal action for enforcing this law. Failure to comply with these requirements is a misdemeanor punishable by up to six months in the county jail and/or a fine of up to \$1,000 (PENAL CODE §§11161.8-11162), and is considered unprofessional conduct and may result in disciplinary action by the Board.

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6.7 Cases Reportable to the County Coroner

All cases in which a person dies before an attending physician has had an opportunity to make a diagnosis are automatically the jurisdiction of the county coroner. Even though relatives may be willing to employ a private surgeon to perform an autopsy to determine the

.....

cause of death, such autopsy surgeon is not qualified to sign a death certificate because he or she was not in attendance prior to death. Therefore, the death certificate is the domain of the coroner. (Refer to Death Certificates, section 6.5(c) of this guidebook.)

It is the physician's duty to report to the coroner the following types of cases involving a person's death when the death occurred:

- Without medical attendance
- During the continued absence of an attending physician
- Indeterminate cause of death
- Suspected suicide
- Death following injury or accident
- Under circumstances affording a reasonable ground to suspect that death was caused by the criminal act of another person (HEALTH AND SAFETY CODE §102850)

The coroner must inquire into and determine the circumstances, manner, and cause of the following cases per Government Code §27491 and Health and Safety Code §102850:

- All violent, sudden, or unusual deaths.
- Unattended deaths.
- Deaths where the deceased has not been attended by a physician in the 20 days before death.
- Deaths related to or following known or suspected self-induced or criminal abortion.
- Known or suspected homicide, suicide, or accidental poisoning.
- Deaths known or suspected as resulting in whole or in part from or related to accident or injury, either old or recent.
- Deaths due to drowning, fire, hanging, gunshot, stabbing, cutting, exposure, starvation, alcoholism, drug addiction, strangulation, aspiration or suspected sudden infant death syndrome.
- Deaths in whole or in part occasioned by criminal means
- Deaths associated with a known or alleged rape or crime against nature.
- Deaths in prison or while under sentence.
- Deaths known or suspected as due to contagious disease and constituting a public hazard.
- Deaths from occupational diseases or occupational hazards.
- Deaths of patients in state mental hospitals serving the mentally disabled.
- Deaths of patients in state hospitals serving the developmentally disabled.

If a person dies before an attending physician has made a diagnosis, the death is automatically within the jurisdiction of the county coroner.

- Deaths under such circumstances giving reasonable ground to suspect that death was caused by the criminal act of another.
- Deaths reported by physicians or other persons with knowledge of death for inquiry by coroner.

If the reported case does not fall within the coroner’s jurisdiction, the coroner will advise the person reporting the case or the physician last in attendance. For further details, refer to the county coroner’s office in your county.

6.8 The Physician’s Responsibility to Give a Written Record of Immunization Administered

The California Health and Safety Code requires any person or organization administering immunizations which are legally required for school entry in California to furnish each child immunized, or his or her parent or guardian, with a written record of immunization given in a form prescribed by the California Department of Public Health (HEALTH AND SAFETY CODE §120355).

Immunizations required for school entry are those against Diphtheria, Hepatitis B, Haemophilus influenzae type b, Measles, Mumps, Pertussis, Poliomyelitis, Rubella, Tetanus, Varicella (chickenpox), and, any other disease deemed appropriate by the California Department of Public Health taking into consideration the most current recommendations of the U.S. Public Health Services’ Centers for Disease Control Immunization Practices Advisory Committee and the American Academy of Pediatrics Committee of Infectious Diseases.

The California Code of Regulations requires documentary proof by written record given to the child immunized or his or her parent or guardian, by the physician or agency performing the immunization, which must contain:

- Name of the person
- Birthdate
- Type of vaccine administered
- Date of each immunization
- Name of physician or agency administering the vaccine
(TITLE 17, CALIFORNIA CODE OF REGULATIONS §6065)

Supplies of the California Immunization Record are available free from county health departments or from:

California Department of Public Health, Immunization Branch
PO BOX 997377, MS 500
Sacramento, CA 95899-7377

Or you can download a copy (you must use yellow paper)

at: <http://www.eziz.org/assets/docs/IMM-75LK.pdf>

Also see section 8.1 of this guide for the requirement to provide patients with a “Vaccination Information Statement.”

6.9 Identifying Potential Organ Donors

Each general acute care hospital must have a protocol for identifying potential organ and tissue donors which requires that the deceased individual’s next of kin be asked whether the deceased was an organ donor. If not, the family will be given the option to donate organs and tissues, and will be asked to consent to the procurement of any organs. The protocol must encourage reasonable discretion and sensitivity to the family circumstances in all discussions regarding donations of tissue or organs (HEALTH AND SAFETY CODE §7184).

All general acute-care hospitals must have a protocol for identifying potential organ and tissue donors. The protocol must include asking the deceased individual’s next-of-kin if the deceased was an organ donor.

6.10 Smallpox Vaccination

The World Health Organization declared smallpox eradicated from the earth in 1980 and the need for routine vaccination of the population ceased. No changes to the legal requirements have been made, and a certificate of vaccination against smallpox is not required for travelers as a condition of entry into any country, including the United States.

In December 2002, mandatory vaccination of military personnel and voluntary vaccination of public health and healthcare workers was recommended in the U.S. as part of bioterrorism preparedness efforts. Emergency and first responders such as police officers and firefighters were proposed as the next recipients in an expanded vaccination program. The public may be offered voluntary vaccination in the future when new cell-culture vaccines are available and issues such as liability and health care costs are resolved. If any case of smallpox were to appear in the U.S., or anywhere in the world, it would be considered a terrorist act. Should an actual case of smallpox be detected, mass vaccination of the public may be initiated at the discretion of public health officials.

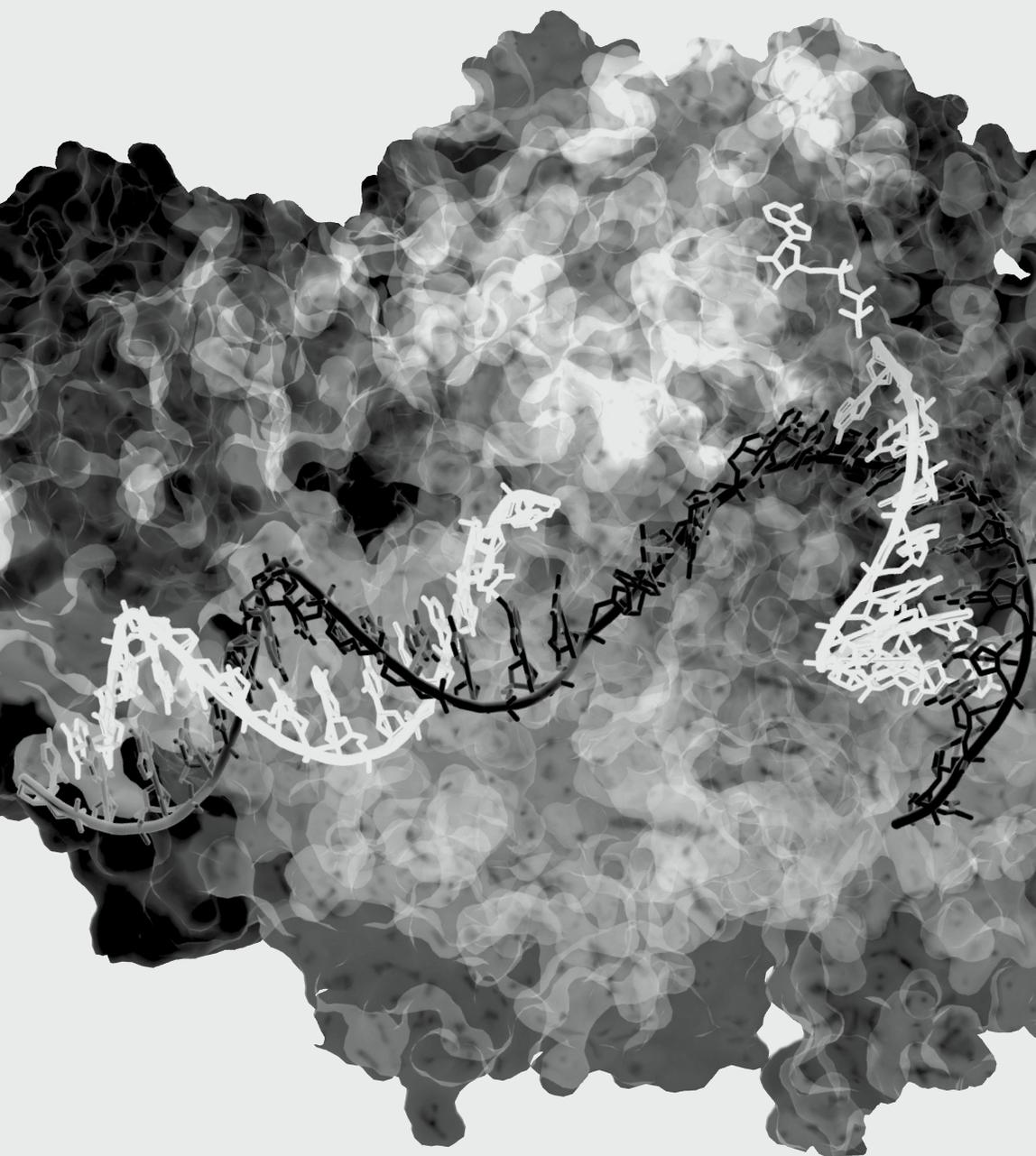
Misuse of Smallpox Vaccine: There is no evidence that smallpox vaccination has therapeutic value in the treatment of recurrent herpes simplex infection, warts, or any other condition. Many serious complications and deaths have resulted from such misuse of smallpox vaccine. Smallpox vaccine should never be used therapeutically.

If you would like more information about smallpox vaccination contact:

Centers for Disease Control and Prevention
800-232-4636 or cdcinfo@cdc.gov

SECTION VII:

Other Information



VII. Other Information

7.1 Proficiency Testing Requirement for Laboratory Tests Performed in Physician's Offices

Both the California Department of Public Health, Laboratory Field Services (LFS) and the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) require that all clinical laboratories, including physician office laboratories, performing moderate or high complexity testing on regulated analytes demonstrate satisfactory performance in a proficiency testing program.

A physician office clinical laboratory is defined under the California Business and Professions Code, Division 2, Chapter 3, §1265 and must be either licensed or registered.

Physicians who are performing moderate or high complexity testing and are enrolled in proficiency testing must certify to the following:

- The proficiency testing is performed in their own laboratory using their own instruments, reagents, etc.
- Is handled in the same manner as a patient sample.
- Must indicate to the testing organization that all results and scores are to be released to both the Centers of Medicare and Medicaid Services (CMS) and the state agency.

A physician's laboratory performing tests that are classified as moderate or high complexity and are not classified as regulated, must meet CLIA and state regulations requiring a lab to have a system for verifying the accuracy of its test results at least twice a year.

The only laboratory tests that are exempt from the above criteria are those classified as waived.

In addition, any facility in California performing clinical laboratory testing must register as a clinical laboratory with the federal Centers of Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), (42 USC 9201, §353(b)).

For further information contact:

California Department of Public Health
Laboratory Field Services Section
850 Marina Bay Pkwy., Bldg P1
Richmond, CA 94804-6403
(510) 620-3800
<http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx>

A clinical laboratory in a physician's office must be licensed or registered.

If a facility in California performs clinical laboratory testing, it must register as a clinical laboratory with the federal Centers of Medicare and Medicaid Services.

7.2 Use of X-ray Equipment by Physicians

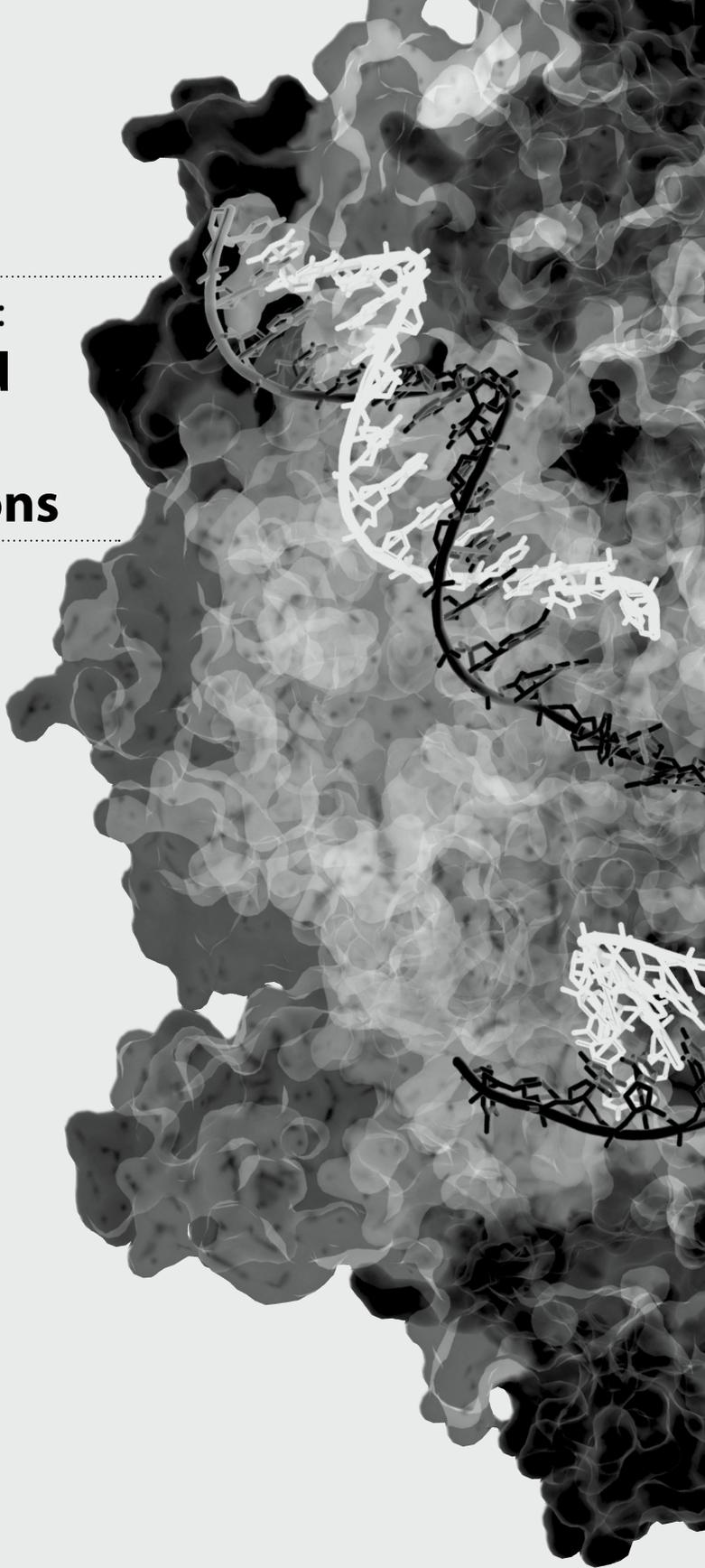
Physicians must submit an application to the California Department of Public Health (CDPH), Radiologic Health Branch and pay the application fee(s) in order to obtain a certificate or permit to use radiographic or fluoroscopic X-ray equipment. All physicians except diplomates of the American Board of Radiology or the American Osteopathic Board of Radiology, are required to pass appropriate examination(s) before authorization to use X-ray equipment can be issued (HEALTH AND SAFETY CODE §114850).

All physicians except diplomates of the American Board of Radiology or the American Osteopathic Board of Radiology are required to pass appropriate examinations before they can be authorized to use X-ray equipment.

Examinations can be scheduled to coincide with physicians work schedules. All physicians who are interested in taking the examination to use X-ray equipment on patients should contact:

California Department of Public Health
Radiologic Health Branch, Certification
P.O. Box 997414, MS 7610
Sacramento, CA 95899-7414
(916) 327-5106
www.cdph.ca.gov/programs/pages/RadiologicHealthBranch.aspx

SECTION VIII:
**Published
Laws and
Regulations**



VIII. Published Laws and Regulations

8.1 Required Use of Federal Vaccine Information Statements

Vaccine Information Statements (VIS) are informational sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VIS be handed out whenever (before each dose) certain vaccinations are given.

Federal law requires that Vaccine Information Statements be handed out whenever a dose of certain vaccinations are given.

When a healthcare provider gives a patient the Vaccine Information Statement, a notation must be made in the patient's permanent medical record.

A. The requirements

1. **Provide VIS when vaccination is given:** as required under the National Childhood Vaccine Injury Act, all healthcare providers in the U.S. who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, Haemophilus influenza type be (Hib), varicella (chickenpox), or pneumococcal conjugate vaccine must prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- To the parent or legal representative of any child to whom the provider intends to administer such vaccine, or
- To any adult to whom the provider intends to administer such vaccine.
- The materials must be supplemented with visual presentations or oral explanations, as appropriate.
- If there is not a single VIS for a combination vaccine (e.g., hepatitis A/hepatitis B), use the VIS for both component vaccines.

2. **Record Information for each VIS provided:** healthcare providers shall make a notation in each patient's permanent medical record at the time VIS are provided indicating:

- The edition date of the materials, and
- The date these materials were provided.
- This record keeping requirement supplements the requirement of 42 U.S.C. (UNITED STATES CODE, §300aa-25) that all healthcare providers administering these vaccines must record in the patient's permanent medical record or in a permanent office log:
- The name, address and title of the individual who administers the vaccine,
- The date of administration, and
- The vaccine manufacturer and lot number of the vaccine used.

The following vaccines are currently covered by this requirement, regardless of whether purchased with private or public funds-and one VIS is required for each:

Anthrax, Diphtheria/Tetanus/Pertussis (DTaP), Hepatitis A, Hepatitis B, Haemophilus Influenzae tpe b (Hib), Inactivated Influenza Vaccine, Live-Intranasal Influenza Vaccine, Japanese Encephalitis, Measles/Mumps/Rubella (MMR), Meningococcal, Pneumococcal Polysaccharide (PPV23), Pneumococcal Conjugate (PC27), Polio, Rabies, Smallpox (Vaccinia), Tetanus/Diphtheria (Td), Typhoid, Varicella (Chickenpox), and Yellow Fever.

VIS forms in English, Spanish, and many other languages, can be downloaded from the California Department of Public Health's Web site at: www.cdph.ca.gov/programs/immunize/Pages/VaccineInformationStatements.aspx.

Forms also can be downloaded from the Centers for Disease Control and Prevention at www.cdc.gov/vaccines/pubs/vis/default.htm.

8.2 Ordering Government Publications

You are encouraged to read the actual laws in the California and federal codes cited in this publication.

The following publications may be downloaded from the internet or in some cases purchased.

Laws Relating to the Medical Board of California, 2012 Edition:

Laws Relating to Physicians and Surgeons, Doctors of Podiatric Medicine, Registered Dispensing Opticians, Research Psychoanalysts, Medical Assistants, Perfusionists, Dieticians, and Licensed Midwives. (One book)

These laws and more are available online at: www.leginfo.ca.gov

Hard copy is available for a fee by writing:

Lexisnexis, Matthew Bender & Company, Inc.

1275 Broadway

Albany, NY 12204

Order by phone at (800) 223-1940 or online at: www.lexisnexis.com/store

ISBN #: 9780769846804.

California Code of Regulations, Title 16: Regulations Relating to the Practice of: Physicians and Surgeons, Podiatrists, Registered Dispensing Opticians, Speech-Language Pathologists and Audiologists, Physical Therapists, Psychologists, Hearing Aid Dispensers, Physician Assistants, Acupuncturists, Respiratory Care Practitioners, Research Psychoanalysts, Medical Assistants and Licensed Midwives

Available online at www.oal.ca.gov/Publications.htm

Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons (this publication):

Available online at www.mbc.ca.gov/publications/Index.html

Hard copy is available for a fee by writing to:

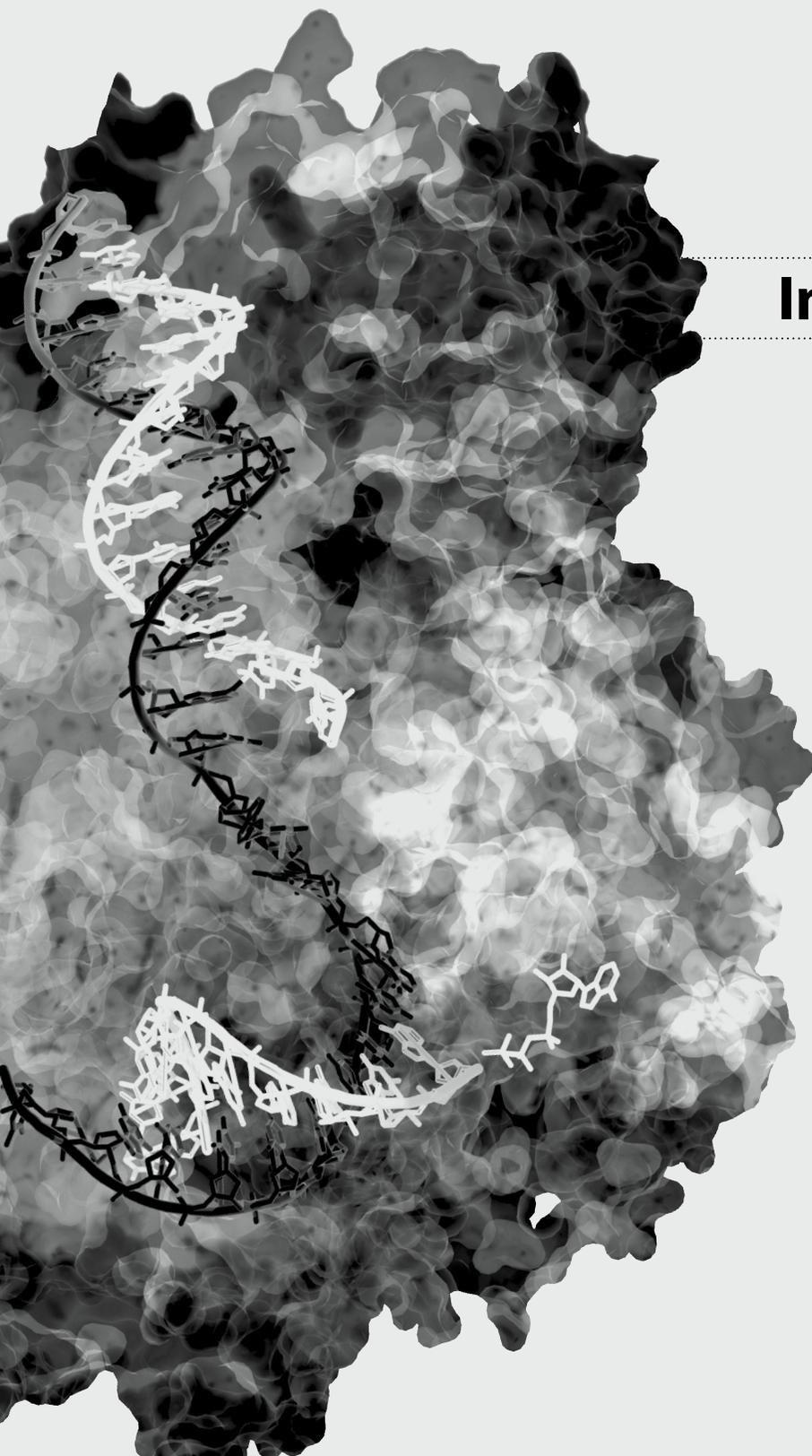
Medical Board of California
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

Drug Laws 2012: This publication contains the statutes that comprise the Uniform Controlled Substances Act from the Health and Safety Code.

Available for a fee from LawTech Publishing.

Order by phone at (800) 498-0911, ext. 5

Order online at www.lawtechpublishing.com, ISBN # 978-1-56325-188-7



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