

TITLE 16. MEDICAL BOARD OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Medical Board of California (Board) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held on October 28, 2016, at 9:00 a.m., at the Sheraton Mission Valley San Diego located at 1433 Camino Del Rio South, San Diego, California.

Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board at its office no later than 5:00 p.m. on October 25, 2016, or must be received at the hearing. The Board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 125.9, 148, and 2018 of the Business and Professions Code, and to implement, interpret or make specific section(s) 125.9, 148, 2027, 2227, 2228, 2229, and 2234 of said Code, the Board is considering amendments to Sections 1364.10, 1364.11, 1364.13 and 1364.15 of Division 13 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST

A. Informative Digest

This rulemaking action seeks to amend Division 13 of Title 16 of the California Code of Regulations (CCR) sections 1364.10, 1364.11, 1364.13 and 1364.15.

Proposed Amendments to 16 CCR 1364.10(b)

Under existing law, CCR section 1364.10, states that a Board official is authorized to determine when and against whom a citation will be issued and to issue citations containing orders of abatement and fines for violations by a licensed physician or surgeon of the statutes referred to in section 1364.11.

Licensed midwives and polysomnographic technologists, technicians, and trainees are licensed/registered and regulated by the Board, but are not currently covered by the Board's citation and fine regulations. This proposed rulemaking will add licensed midwives and polysomnographic technologists, technicians, and trainees under CCR section 1364.10(b) as licensees/registrants to whom the Board may issue citations with orders of abatement and fines when these allied health care professionals violate statutes or regulations referenced in CCR

section 1364.11.

These amendments are necessary to provide the Board with an administrative tool to bring licensed midwives, and polysomnographic technologists, technicians, and trainees into compliance if they commit a violation of the specified statutes. This supports the Board's mission of public protection.

Further, CCR section 1364.10(b) currently states that citations containing orders of abatement and fines may be issued for violations of the statutes referred to in Section 1364.11. Because CCR section 1364.11 also lists regulations as citable offenses, an amendment to 1364.10(b) is necessary to clarify that citations containing orders of abatement and fines may be issued for violations of regulations, as well as statutes, referred to in Section 1364.11.

Proposed Amendments to 16 CCR 1364.11

Under existing law, CCR section 1364.11(a) states that a Board official may issue a citation under section 1364.10 for a violation of the provisions listed in this section. This proposed rulemaking will add additional provisions of the Business and Professions (B&P) and Health and Safety (H&S) Codes and the CCR to the list of citable offenses to authorize the Board to issue citations with orders of abatement and fines to licensees found in violation of those statutes or regulations, furthering consumer protection.

The proposed additions to 16 CCR section 1364.11(a) include the following statutes and regulation:

- B&P Code section 2234(h), relating to the repeated failure of a certificate holder, in the absence of good cause, to attend and participate in an interview by the board;
- B&P Code section 2507, relating to the practice of midwifery, the midwifery scope of practice, and the requirement for physician referral under certain circumstances;
- B&P Code section 2508, relating to required disclosures by licensed midwives to their clients;
- B&P Code section 2510, relating to requirements for a licensed midwife upon transfer of a client to a hospital;
- B&P Code section 2514, relating to requirements for midwifery students practicing midwifery as part of his or her course of study;
- B&P Code section 2519, relating to grounds for suspension or revocation of a midwifery license;
- B&P Code section 3575, relating to requirements for engaging in polysomnography as a polysomnographic technologist, technician, or trainee;
- B&P Code section 3576, relating to grounds for denial, suspension, or revocation of a registration as a polysomnographic technologist,

- technician, or trainee;
- B&P Code section 4172, relating to any prescriber who dispenses drugs and fails to store all drugs to be dispensed in an area that is secure;
- H&S Code section 11165.1(a)(1)(A)(i), requiring health care practitioners authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances to submit an application before July 1, 2016, to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient maintained in the CURES database;
- H&S Code section 120370(a), relating to physicians providing a parent or guardian of a child a written statement indicating that the physical condition of a child, or the medical circumstances relating to the child, are such that immunization is not considered safe; and
- 16 CCR section 1355.4, relating to any licensee that practices medicine and fails to provide proper notice to each patient of the fact that the licensee is licensed and regulated by the Board.

Adding these sections of law and regulation as citable offenses is necessary to provide the Board with an administrative tool to bring licensees into compliance with these sections, furthering consumer protection.

Additionally, this proposed rulemaking reorganizes and renumbers section 1364.11(a) so that it is easier for interested parties to locate citable offenses, and also makes technical changes as follows:

- B&P Code sections 655.6 and 2265 have been repealed in statute, and these sections will be deleted as citable offenses.
- B&P Code section 802(b) is currently listed as a citable offense, but subsection (b) falls under the jurisdiction of the Board of Behavioral Sciences. The citable offense has been corrected to reflect B&P Code section 802(a) in the proposed amendments, as this subsection applies to physicians and surgeons.
- B&P Code section 2630 now falls under the Physical Therapy Board's jurisdiction, and will be stricken as a citable offense by this rulemaking.
- B&P Code section 2097 was renumbered by the legislature to B&P Code section 2426, and that change will be reflected in the amendment to this section.

These technical changes are necessary to improve the clarity of this section.

Finally, this proposed rulemaking adds a subsection (e) to specify that a citation issued under this section is separate from and in addition to any other administrative, civil, or criminal remedies. This change is necessary to improve

the clarity of the section.

Proposed Amendments to 16 CCR 1364.13

Under existing law, CCR 1364.13 authorizes a Board official to issue citations containing orders of abatement and fines against individuals, partnerships, corporations or associations, who are performing or who have performed services for which licensure as a physician and surgeon is required under the Medical Practice Act. However, individuals, partnerships, corporations or associations who are performing or who have performed services as unlicensed midwives and polysomnographic technologists, technicians, and trainees are not currently covered by the Board's citation and fine regulations.

This proposed rulemaking will amend this section to indicate that a Board official is authorized to issue citations with orders of abatement and fines to individuals, partnerships, corporations or associations, who are performing, or who have performed, services for which licensure as a licensed midwife or registration as a polysomnographic technologist, technician, or trainee is required. These amendments are necessary for the Board to be able to issue citations with orders of abatement and fines to these individuals and entities who practice without obtaining the required license or registration. Such authority furthers the Board's mission of consumer protection.

Thus, this proposed rulemaking specifies that a Board official is authorized to issue citations containing orders of abatement and fines against persons, partnerships, corporations or associations who are performing or who have performed services for which licensure as a physician and surgeon licensed under Chapter 5 of the code (commencing with section 2000) or as a licensed midwife licensed under Chapter 5 of the code (commencing with section 2505), or registration as a polysomnographic technologist, technician, or trainee registered under Chapter 7.8 (commencing with section 3575) is required.

Additionally, this rulemaking proposes to strike the reference to the Medical Practice Act from CCR section 1364.13, since allied health care providers are being added, and each licensee's or registrant's authorizing code section under the B&P Code is specified. CCR section 1364.13 will be further clarified by indicating that the provisions of CCR sections 1364.10 and 1364.12 apply to the issuances of citations for unregistered as well as unlicensed activity, since polysomnographic technologists, technicians, and trainees are required to be registered, not licensed.

Finally, existing law under CCR section 1364.13 indicates that any sanction under this section is separate and in addition to any other civil or criminal remedies. This rulemaking will add administrative remedies to that list to clarify that any sanction under this section is separate and in addition to any other administrative, civil, or criminal remedies.

This proposed rulemaking is necessary to amend CCR section 1364.13 to allow the Board to issue citations with orders of abatement and fines to these unlicensed/unregistered individuals and entities who violate the law, thereby giving the Board an administrative tool to further its mission of consumer protection.

Proposed Amendments to 16 CCR 1364.15

Under existing law, CCR section 1364.15 states every citation that is issued pursuant to this article shall be disclosed to an inquiring member of the public, and citations that have been resolved by payment of the administrative fine or compliance with the order of abatement shall be purged five (5) years from the date of resolution.

Effective January 1, 2015, pursuant to amendments to B&P Code section 2027(b)(9), the Board shall post on its website all historical information in its possession, custody, or control regarding all current and former licensee to include citations issued within the last three (3) years that have been resolved by payment of the administrative fine or compliance with the order of abatement.

This proposed rulemaking will change the citation purge date from five years to three years to be consistent with B&P Code section 2027(b)(9). This proposed amendment is necessary to make CCR section 1364.15 consistent with the three-year time period set forth by B&P Code section 2027(b)(9).

Board Authorization

On May 6, 2016, at the Board's quarterly meeting, Board staff requested the Board authorize staff to prepare the necessary regulatory documents to submit to the Office of Administrative Law (OAL) to formally notice the proposed regulatory amendments and schedule a hearing on the rulemaking. The Board granted the request to initiate the rulemaking process to amend CCR sections 1364.10, 1364.11, 1364.13 and 1364.15 and authorized a hearing to be held after the 45-day comment period.

At the July 29, 2016, quarterly Board meeting, Board staff readdressed its May 6, 2016, request to authorize staff to prepare the necessary regulatory documents to submit to the Office of Administrative Law (OAL) to formally notice the proposed regulatory amendment and schedule a hearing on the rulemaking. The purpose of the proposal was to add H&S Code section 120370(a) to the list of citable offenses due to the recent enactment of Senate Bill 277 relating to medical exemptions for vaccinations.

B. Policy Statement Overview/Anticipated Benefits of Proposal

The proposed amendments will authorize the Board to issue citations containing orders of abatement and fines to licensed midwives and polysomnographic technologists, technicians, and trainees, in addition to licensed physicians and

surgeons, and to unlicensed or unregistered individuals performing services that require a license or registration. Moreover, the proposed amendments add additional statutes for which the Board is authorized to issue citations containing orders of abatement and fines to California health care professionals who violate specified provisions of the B&P Code, the H&S Code, and the CCR, and will align the timeframe for retaining citations with current statute. Such amendments give the Board necessary tools to bring individuals into compliance with the law, and further the Board's mission of consumer protection pursuant to B&P Code section 2001.1. It also furthers the Board's goal of rehabilitation of licensees, when rehabilitation is not inconsistent with the Board's priority of public protection pursuant to B&P Code section 2229.

C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

Additional provisions of the B&P and H&S Codes and CCR have been added to the list of citable offenses to authorize the Board to issue citations with orders of abatement and fines to licensees found in violation of those sections. The proposed amendments also give the Board the authority to issue citations with orders of abatement and fines to licensed midwives and polysomnographic technologists, technicians, and trainees. The cost and workload to the Board is minimal and absorbable. It is anticipated that licensed midwives, polysomnographic technologists, technicians, and trainees will generate an average of \$5,872 in annual revenue to the Board from citations and fines. Over the life of this regulation, the Board anticipates receiving approximately \$58,720 in revenue from citations and fines issued to allied health professions, and for those practicing in these areas without the required license or registration.

Further, the Board anticipates collecting approximately \$107,216 in annual citation and fine revenue from physicians and surgeons, which include citations and fines for violations of the proposed additional code sections. Over the life of this regulation, the Board anticipates receiving approximately \$1,072,160 in revenue from citations and fines issued to physicians and surgeons, and for those practicing medicine without a license. The Board's attachment to the STD 399 outlines the estimated revenue anticipated.

The Board has determined that this proposed rulemaking will not cause a cost or savings in federal funding to the state, since the regulation of the licenses and registrations of health care providers is a state function.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None

Business Impact:

The Board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that individuals who are in compliance with the law will not be impacted by the proposed amendments. Further, very few individuals are issued citations with orders of abatement and fines. For example, the Board issued 158 citations and fines for fiscal year (FY) 2012/2013 to physicians and surgeons, which was approximately .002% of the California licensed physician and surgeon population. In FY 2013/2014, the Board issued 50 citations and fines to physicians and surgeons, which was approximately .0004% of the California licensed physician and surgeon population. The Board's allied health care professionals comprise less than 1% of the total population of the Board's licensees, and the Board anticipates issuing only one to two citations per year for allied health professionals, and fewer for unlicensed individuals and entities.

Cost Impact on Representative Private Person or Business:

The cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action and that are known to the Board are:

There may be minimal cost impact to licensed physicians and surgeons, midwives and polysomnographic technologists, technicians, and trainees and unlicensed individuals and entities performing services for which a license or registration is required as a result of a citation and fine being issued for violating a provision(s) listed in section 1364.11(a) of the CCR. Individuals who are in compliance with the law will not be impacted. Based on data over a two year period, the average citation and fine amount is \$979.

Effect on Housing Costs: None

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

The Board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts:

- Analysis of creation/elimination of jobs: The Board has made an initial determination that this regulatory proposal will not likely have any impact on the creation of jobs or the elimination of jobs in the State of California. This initial determination is based on the fact that individuals who are in compliance with the law will not be impacted by the proposed amendments. Further, very few individuals are issued citations with orders of abatement and fines. For example, the Board issued 158 citations and fines for FY 2012/2013 to physicians and surgeons, which was approximately .002% of the California licensed physician and surgeon population. In FY 2013/2014, the Board issued 50 citations and fines to physicians and surgeons, which was approximately .0004% of the California licensed physician and surgeon population. The Board's allied health care professionals comprise less than 1% of the total population of the Board's licensees, and the Board anticipates issuing only one to two citations per year for allied health professionals, and fewer for unlicensed individuals and entities.
- Analysis of creation/elimination of businesses: The Board has made an initial determination that this regulatory proposal will not likely have any impact on the creation of new businesses or the elimination existing businesses or the expansion of businesses in the State of California. This initial determination is based on the fact that individuals who are in compliance with the law will not be impacted by the proposed amendments. Further, very few individuals are issued citations with orders of abatement and fines. For example, the Board issued 158 citations and fines for FY 2012/2013 to physicians and surgeons, which was approximately .002% of the California licensed physician and surgeon population. In FY 2013/2014, the Board issued 50 citations and fines to physicians and surgeons, which was approximately .0004% of the California licensed physician and surgeon population. The Board's allied health care professionals comprise less than 1% of the total population of the Board's licensees, and the Board anticipates issuing only one to two citations per year for allied health professionals, and fewer for unlicensed individuals and entities.
- Analysis of expansion of business: This proposal is not expected to lead to the expansion of new businesses within California. This initial determination is based on the fact that this proposal gives the Board a tool to bring licensees into compliance with the law if they violate certain

specified statutes or regulations, and it impacts a very small percentage of licensees and unlicensed or unregistered individuals or entities.

- Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: The Board has determined that this regulatory proposal will benefit the health and welfare of California residents because the proposed additions to the list of citable offenses under CCR section 1364.11(a) provides further consumer protection. Additionally, authorizing the Board to issue citations with orders of abatement and fines to licensed midwives and polysomnographic technologists, technicians, and trainees and unlicensed individuals and entities performing services as midwives and polysomnographic technologists, technicians, and trainees, provides an administrative tool to the Board to address consumer complaints that do not warrant formal disciplinary action. This assists in bringing the licensee or unlicensed individual or entity into compliance, furthering consumer protection.

This proposed rulemaking is not anticipated to have an impact on worker safety or the state's environment.

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would not affect small businesses. This initial determination is based on the fact that individuals who are in compliance with the law will not be impacted by the proposed amendments. Further, very few individuals are issued citations with orders of abatement and fines. For example, the Board issued 158 citations and fines for fiscal year (FY) 2012/2013 to physicians and surgeons, which was approximately .002% of the California licensed physician and surgeon population. In FY 2013/2014, the Board issued 50 citations and fines to physicians and surgeons, which was approximately .0004% of the California licensed physician and surgeon population. The Board's allied health care professionals comprise less than 1% of the total population of the Board's licensees, and the Board anticipates issuing only one to two citations per year for allied health professionals, and fewer for unlicensed individuals and entities.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the person designated in the Notice under Contact Person, below, or by accessing the Board's website at http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Christina Delp, Chief of Enforcement
Address:	2005 Evergreen Street, Ste. 1200 Sacramento, CA 95815
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The backup contact person is:

Name:	Kevin A Schunke, Regulations Manager
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Website Access Materials regarding this proposal can be found at
[http://www.mbc.ca.gov/About Us/Laws/Proposed Regulations](http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations).