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 <u>Contact Person</u> 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.

<u>Authority and Reference:</u> 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 midwifes 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 <u>licensed</u> <u>under Chapter 5 of the code (commencing with section 2000) or as a licensed</u> <u>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.</u>

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 <u>unregistered</u> 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 <u>administrative</u> 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 midwifes 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. <u>Consistency and Compatibility with Existing State Regulations</u>

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 midwifes 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 surgeon, 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, midwifes 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.
- <u>Analysis of expansion of business</u>: 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.

 <u>Benefits of the Regulation to the Health and Welfare of California</u> <u>Residents, Worker Safety, and the State's Environment:</u> 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 midwifes and polysomnographic technologists, technicians, and trainees and unlicensed individuals and entities performing services as midwifes 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
Telephone No.:	916-263-2389
Fax No.:	916-263-2387
E-Mail Address:	Christina.delp@mbc.ca.gov

The backup contact person is:

Name: Address:	Kevin A Schunke, Regulations Manager Medical Board of California
	2005 Evergreen St, Ste. 1200
	Sacramento, CA 95815
Telephone No.:	(916) 263-2368
Fax No.:	(916) 263-8936
E-Mail Address:	regulations@mbc.ca.gov

<u>Website Access</u> Materials regarding this proposal can be found at <u>http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations</u>.

MEDICAL BOARD OF CALIFORNIA CITE AND FINE AUTHORITY – ALLIED HEALTH PROFESSIONALS

Specific Language of Proposed Changes

<u>Underlined</u> Indicates proposed additions to the existing regulation.

Strikeout Indicates proposed deletions to the existing regulation

Amend Sections 1364.10, 1364.11, 1364.13 and 1364.15 in Article 6 of Chapter 2, Division 13, of Title 16 of the California Code of Regulations to read as follows:

§1364.10. Citations and Fines.

(a) For purposes of this article, "board official" shall mean the executive director of the board or his or her designee.

(b) 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, licensed midwife, or polysomnographic technologist, technician, or trainee of the statutes and regulations referred to in Section 1364.11.

(c) A citation shall be issued whenever any fine is levied or any order of abatement is issued. Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

Note: Authority cited: Sections 125.9, 148 and 2018, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

§ 1364.11. Citable Offenses.

The amount of any fine to be levied by a board official shall take into consideration the factors listed in subdivision (b)(3) of Section 125.9 of the code and shall be within the range set forth below.

(a) In his or her discretion, a board official may issue a citation under Section 1364.10 for a violation of the provisions listed in this section.

- (1) Business and Professions Code Section 119
- (2) Business and Professions Code Section 125
- (3) Business and Professions Code Section 125.6
- (4) Business and Professions Code Section 475(a)(1)
- (5) Business and Professions Code Section 496
- (6) Business and Professions Code Section 650
- (7) Business and Professions Code Section 650.1
- (8) Business and Professions Code Section 654

(9) Business and Professions Code Section 654.1 (10) Business and Professions Code Section 654.2 (11) Business and Professions Code Section 655.5 (12) Business and Professions Code Section 655.6 (13)(12) Business and Professions Code Section 702 (14)(13) Business and Professions Code Section 730 (15)(14) Business and Professions Code Section 732 (15) Business and Professions Code Section 802(a) (16) Business and Professions Code Section 802.1 (16)(17) Business and Professions Code Section 810 (17)(18) Business and Professions Code Section 2021 (18)(19) Business and Professions Code Section 2052 (19)(20) Business and Professions Code Section 2054 (20)(21) Business and Professions Code Section 2065 (21)(22) Business and Professions Code Section 2066 (22)(23) Business and Professions Code Section 2072 (23)(24) Business and Professions Code Section 2073 (24) Business and Professions Code Section 2097 (25) Business and Professions Code Section 2168 (26) Business and Professions Code Section 2168.4 (27) Business and Professions Code Section 2216.1 (28) Business and Professions Code Section 2221.1 (29) Business and Professions Code Section 2234(h) only for a violation of one of the following: (A) Business and Professions Code Section 802(b) (B) Business and Professions Code Section 802.1 (C) Health and Safety Code Section 102795 (D) Health and Safety Code Section 102800 (E) Health and Safety Code Section 103785 (F) Health and Safety Code Section 109275 (G) Health and Safety Code Section 109277 (H) Health and Safety Code Section 109278 (I) Health and Safety Code Section 109282 (J) Health and Safety Code Section 120250 (K) Health and Safety Code Section 121362 (L) Health and Safety Code Section 121363 (M) Title 17 California Code of Regulations Section 2500 (30) Business and Professions Code Section 2236 (31) Business and Professions Code Section 2238 (32) Business and Professions Code Section 2240 (33) Business and Professions Code Section 2244 (maximum fine \$1000 pursuant to section 2244) (34) Business and Professions Code Section 2243 (35) Business and Professions Code Section 2250 (36) Business and Professions Code Section 2255 (37) Business and Professions Code Section 2256 (38) Business and Professions Code Section 2257 (39) Business and Professions Code Section 2259 (40) Business and Professions Code Section 2261 (41) Business and Professions Code Section 2262 (42) Business and Professions Code Section 2263 (43) Business and Professions Code Section 2264

(44) Business and Professions Code Section 2265 (45)(44) Business and Professions Code Section 2266 (46)(45) Business and Professions Code Section 2271 (47)(46) Business and Professions Code Section 2272 (48)(47) Business and Professions Code Section 2273 (49)(48) Business and Professions Code Section 2274 (50)(49) Business and Professions Code Section 2285 (51)(50) Business and Professions Code Section 2286 (52)(51) Business and Professions Code Section 2305 (53)(52) Business and Professions Code Section 2400 (54)(53) Business and Professions Code Section 2415 (54) Business and Professions Code Section 2426 (55) Business and Professions Code Section 2439 (56) Business and Professions Code Section 2440 (57) Business and Professions Code Section 2441 (58) Business and Professions Code Section 2507 (59) Business and Professions Code Section 2508 (60) Business and Professions Code Section 2510 (61) Business and Professions Code Section 2514 (62) Business and Professions Code Section 2519 (58) Business and Professions Code Section 2630 (59)(63) Business and Professions Code Section 3516 (64) Business and Professions Code Section 3575 (65) Business and Professions Code Section 3576 (60)(66) Business and Professions Code Section 4080 (61)(67) Business and Professions Code Section 4081(a) (68) Business and Professions Code Section 4172 (62)(69) Business and Professions Code Section 17500 (65)(70) Civil Code Section 56.10 (66)(71) Health and Safety Code Section 1248.15 (72) Health and Safety Code Section 11165.1(a)(1)(A)(i) (73) Health and Safety Code Section 102795 (74) Health and Safety Code Section 102800 (75) Health and Safety Code Section 103785 (76) Health and Safety Code Section 109275 (77) Health and Safety Code Section 109277 (78) Health and Safety Code Section 109278 (79) Health and Safety Code Section 109282 (80) Health and Safety Code Section 120250 (81) Health and Safety Code Section 120370(a) (82) Health and Safety Code Section 121362 (83) Health and Safety Code Section 121363 (67)(84) Health and Safety Code Section 123110(a), (b) (68)(85) Health and Safety Code Section 123148 (69)(86) Penal Code Section 11166 (63)(87) Title 16 California Code of Regulations Section 1338(c) (88) Title 16 California Code of Regulations Section 1355.4 (64)(89) Title 16 California Code of Regulations Section 1399.545 (90) Title 17 California Code of Regulations Section 2500 (b) In his or her discretion, a board official may issue a citation under Section 1364.10 to a licensee for a violation of a term or condition contained in the decision placing that licensee on

probation.

(c) A citation may include a fine from \$100 to \$2500. However, a citation may include a fine up to \$5,000 if one or more of the following circumstances apply:

(1) The cited person has received two or more prior citations for the same or similar violations;

(2) The citation involves multiple violations that demonstrate a willful disregard for the law.

(d) In his or her discretion, a board official may issue a citation with an order of abatement without levying a fine for the first violation of any provision set forth above.

(e) The sanction authorized under this section shall be separate from and in addition to any other administrative, civil, or criminal remedies.

Note: Authority cited: Sections 125.9, 148 and 2018, Business and Professions Code. Reference: Sections 125.9, 148, 2227, 2228, 2229 and 2234, Business and Professions Code.

§ 1364.13. Citations for Unlicensed Practice.

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 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. under the Medical Practice Act. Each citation issued shall contain an order of abatement. Where appropriate, a board official shall levy a fine for such unlicensed activity in accordance with subdivision (b)(3) of Section 125.9 of the code. The provisions of Sections 1364.10 and 1364.12 shall apply to the issuance of citations for unlicensed <u>or unregistered</u> activity under this subsection. The sanction authorized under this section shall be separate from and in addition to any other <u>administrative</u>, civil, or criminal remedies.

Note: Authority cited: Sections 125.9, 148 and 2018, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

§ 1364.15. Public Disclosure; Record Retention.

Every citation that is issued pursuant to this article shall be disclosed to an inquiring member of the public. Citations that have been resolved, by payment of the administrative fine or compliance with the order of abatement, shall be purged five (5) three (3) years from the date of resolution. A citation that has been withdrawn or dismissed shall be purged immediately upon being withdrawn or dismissed.

Note: Authority cited: Sections 125.9, 148, and 2018, and 2027, Business and Professions Code. Reference: Sections 125.9, and 148, and 2027, Business and Professions Code.

MEDICAL BOARD OF BOARD

INITIAL STATEMENT OF REASONS

Hearing Date: October 28, 2016

Subject Matter of Proposed Regulations: Citation and Fine Authority – Allied Health Professionals

Section(s) Affected: Title 16, Division 13, Chapter 2, Article 6, California Code of Regulations (CCR), Section(s) 1364.10, 1364.11, 1364.13 and 1364.15

Introduction:

The Medical Board of California (Board) licenses and regulates physicians and surgeons and certain allied health care professionals, including licensed midwives and polysomnographic technologists, technicians, and trainees.

The Board is currently authorized to issue administrative citations with orders of abatement and fines to physicians and surgeons, but the Board's regulations do not currently include an authorization for the Board to issue citations with orders of abatement and fines to allied health care professionals.

Through this proposed rulemaking, the Board seeks to amend the identified regulations to include the authority to issue citations with orders of abatement and fines to licensed midwives and polysomnographic technologists, technicians, and trainees, and to add additional statutes and an additional regulation as citable offenses. This proposed rulemaking also proposes additional conforming changes, and some technical changes to improve the clarity of the regulations at issue, as described below. These changes support the Board's mission of consumer protection.

Specific Purpose of Each Adoption, Amendment, or Repeal and Factual Basis/Rationale:

1. <u>Proposed Amendments to 16 CCR section 1364.10(b)</u>

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.

Business and Professions (B&P) Code section 125.9 authorizes the Board to establish a system by regulation for the issuance of a citation which may contain

an order of abatement or fine to licensees within the Board's jurisdiction. Pursuant to B&P Code section 23.7, "license" means license, certificate or registration. 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 rulemaking adds licensed midwives and polysomnographic technologists, technicians, and trainees under CCR section 1364.10(b) as individuals to whom the Board may issue citations containing orders of abatement and fines.

The proposed amendments are necessary for the Board to be able to issue citations with orders of abatement and fines when these allied health care professionals violate statutes or regulations referenced in CCR section 1364.11.

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.

This amendment is necessary to provide clarity to this section, which furthers the Board's mission of consumer protection.

2. Proposed Amendments to 16 CCR section 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. Additional provisions of the B&P and Health and Safety (H&S) Codes and the CCR need to be 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 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 statutes and regulation as citable offenses is necessary to provide the Board with the administrative authority to bring licensees and registrants into compliance with these sections, furthering consumer protection.

Additionally, under existing law, CCR section 1364.11(a) is not organized by code and section in a logical way that makes citable offenses easy to find. Under the proposed rulemaking, section 1364.11(a) will be reorganized and renumbered so that it is easier for interested parties to locate citable offenses.

Further, technical changes to section 1364.11(a) are proposed in this rulemaking 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.

Existing law under CCR section 1364.11 does not make it clear that citations with orders of abatement and fines are separate from and in addition to any other administrative, civil, or criminal remedies. Thus, the proposed rulemaking adds subsection (e) to CCR section 1364.11 to make it clear that a citation issued under this section is separate from and in addition to any other administrative, civil, or criminal remedies. These changes are necessary to improve the clarity of the section, and to remind recipients of citations that all other remedies to address the wrongful conduct remain available.

3. Proposed Amendments to 16 CCR section 1364.13

Under existing law, CCR section 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 midwifes or unregistered polysomnographic technologists, technicians, and trainees are not currently covered by the Board's citation and fine regulations.

B&P Code section 148 authorizes the Board to establish a system by regulation for the issuance of a citation which may contain an order of abatement or fine to an unlicensed person acting in the capacity of a licensee or registrant within the Board's jurisdiction. 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 <u>unregistered</u> 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 <u>administrative</u> 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.

4. Proposed Amendments to 16 CCR section 1364.15

Existing law under 16 CCR section 1364.15 states that 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. However, 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 the time period specified by 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).

Underlying Data

At the May 6, 2016 quarterly Board meeting, Board staff requested the Board 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 Board adopted a motion to approve staff to begin the regulatory process to formally notice the proposed regulatory amendments and schedule a hearing on the rulemaking to amend Title 16, Division 13, Chapter 2, Article 6, California Code of Regulations, sections 1364.10, 1364.11, 1364.13 and 1364.15.

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 expand the list of citable offenses to include H&S Code section 120370(a) to the list due to the recent enactment of Senate Bill 277 relating to medical exemptions for vaccinations.

Business Impact

The Board has made an initial determination that the proposed regulatory action would 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 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.

Economic Impact Assessment

The Board has made an initial determination that the proposed regulatory action would 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.
- <u>Analysis of expansion of business</u>: 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.
- <u>Benefits of the Regulation to the Health and Welfare of California</u> <u>Residents, Worker Safety, and the State's Environment:</u> 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. Moreover, authorizing the Board to issue citations with orders of abatement and fines to licensed midwifes and polysomnographic technologists, technicians, and trainees and unlicensed individuals performing services as midwifes 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.

Economic Impact for "Major Regulations" (If applicable)

Non-Applicable.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1. Do not seek a change. This alternative was rejected because the amendments are necessary for consumer protection and support the Board's mission to regulate physicians and certain allied health care professionals. Additionally amendments are needed to delete repealed or incorrect references to law, and to provide clarity.

2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate because the proposed changes align with the Board's mission to protect consumers by bringing licensees and registrants into compliance with the law, and taking action against unlicensed or unregistered individuals and entities performing services requiring a license or registration. The proposed changes also improve clarity to the sections at issue.