State of California
Office of Administrative Law

In re: **Medical Board of California**	**DECISION OF DISAPPROVAL OF REGULATORY ACTION**
Regulatory Action: Title 16 **California Code of Regulations**	**Government Code Section 11349.3**
Adopt sections: 1333, 1333.1, 1333.2, 1333.3	**OAL File No. 2012-0210-04 S**

SUMMARY OF REGULATORY ACTION

In this regulatory action, the Medical Board of California (Board) proposed to adopt regulations pertaining to "Sponsored Free Health Care Events." These regulations implement Business and Professions Code section 901 which was enacted in Statutes of 2010, Chapter 270 (A.B. 2699). Under this legislation, California's healing arts boards are generally authorized to adopt regulations under which a health care practitioner licensed or certified and in good standing in another state, district or territory of the United States (an out-of-state practitioner) under specified conditions may offer or provide the health care services in California without obtaining California licensure. The out-of-state health care practitioner must provide the services on a voluntary basis and without charge to uninsured or underinsured persons, at a sponsored health care event, and for a period of 10 calendar days or less per event.

Pursuant to statutory requirements in Business and Professions Code section 901, the Board's proposed regulations set forth a process for an out-of-state practitioner licensed or certified to practice medicine in another state, district or territory of the United States to obtain authorization from the Board to participate in a sponsored event in California, including the specification of a "request for authorization" form and setting of the amount of a processing fee. The Board's proposed regulations further set forth the process for the "sponsoring entity" of a sponsored event to register with the Board in advance of the event, including the specification of a "registration of sponsoring entity" form. Additional provisions of the proposed regulations include definitions of terms, reporting and recordkeeping requirements, and provisions pertaining to the termination of out-of-state practitioner authorization and appeals.

DECISION

On March 13, 2012, the Office of Administrative Law (OAL) notified the Board of the disapproval of this regulatory action. The reasons for the disapproval were the following: (1) failure to comply with the "Clarity" standard of Government Code section 11349.1, (2) failure to comply with the "Necessity" standard of Government Code section 11349.1, (3) failure to comply with all required Administrative Procedure Act procedures (defective rulemaking file documents).

DISCUSSION

Regulations adopted by the Board must generally be adopted pursuant to the rulemaking provisions of the California Administrative Procedure Act (APA), Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code (Gov. Code, secs. 11340 through 11361). Any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the APA, unless a statute expressly exempts or excludes the regulation from compliance with the APA (Gov. Code, sec. 11346). No exemption or exclusion applies to the regulatory action here under review. Moreover, Business and Professions Code section 2018, which sets forth the Board's general authority to adopt regulations, specifically states: "The board may adopt, amend, or repeal, in accordance with the provisions of the Administrative Procedure Act, those regulations as may be necessary to enable it to carry into effect the provisions of law relating to the practice of medicine." (Emphasis added.) Consequently, before these regulations may become effective, the regulations and rulemaking record must be reviewed by OAL for compliance with the substantive standards and procedural requirements of the APA, in accordance with Government Code section 11349.1.

A. CLARITY

OAL must review regulations for compliance with the "Clarity" standard of the APA, as required by Government Code section 11349.1. Government Code section 11349, subdivision (c), defines "Clarity" as meaning "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The "Clarity" standard is further defined in section 16 of title 1 of the California Code of Regulations (CCR), OAL's regulation on "Clarity," which provides the following:

> In examining a regulation for compliance with the "clarity" requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
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> (a) A regulation shall be presumed not to comply with the "clarity" standard if any of the following conditions exists:
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> (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or

(2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
(3) the regulation uses terms which do not have meanings generally familiar to those "directly affected" by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
(4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
(5) the regulation presents information in a format that is not readily understandable by persons "directly affected;" or
(6) the regulation does not use citation styles which clearly identify published material cited in the regulation.

(b) Persons shall be presumed to be "directly affected" if they:
(1) are legally required to comply with the regulation; or
(2) are legally required to enforce the regulation; or
(3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
(4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

In this "Sponsored Free Health Care Events" rulemaking, a number of provisions of the proposed regulations fail to comply with the "Clarity" standard. Two "Clarity" problems are discussed below. Additional "Clarity" concerns (such as minor wording problems) have been discussed with Board staff and will also need to be corrected in any resubmission of this rulemaking.

1. Regulation section 1333.1 and the "registration of sponsoring entity" form – Subsections (a) and (b) of proposed regulation section 1333.1 set forth the requirements for a sponsoring entity of a sponsored health care event to register with the Board prior to the event. This registration process is required pursuant to Business and Professions Code section 901, subdivision (d). The proposed regulations incorporate by reference a form for this purpose which is identified as "Form 901-A (MBC/2011)." Specifically, subsections (a) and (b) of proposed regulation section 1333.1 state:

> (a) Registration. A sponsoring entity that wishes to provide, or arrange for the provision of, health care services at a sponsored event under section 901 of the [Business and Professions Code] shall register with the board not later than 90 calendar days prior to the date on which the sponsored event is scheduled to begin. A sponsoring entity shall register with the board by submitting to the board a completed Form 901-A (MBC/2011), which is incorporated by reference.
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> (b) Determination of Completeness of Form. The board may, by resolution, delegate to the Department of Consumer Affairs the authority to receive and process Form 901-A (MBC/2011) on behalf of the board. The board or its delegatee shall inform the sponsoring entity in writing within 15 calendar days of receipt of the form that the form is either complete and the sponsoring entity is registered or that the form is deficient and what specific information or documentation is required to complete the form and be

> registered. The board or its delegatee shall reject the registration if all of the identified deficiencies have not been corrected at least 30 days prior to the commencement of the sponsored event.

The referenced registration form, Form 901-A, is entitled "Sponsored Free Health Care Events Registration of Sponsoring Entity under Business & Professions Code Section 901." A key provision on page 1 of the form states: "Only one form (per event) should be completed and submitted to the Department of Consumer Affairs. The Department of Consumer Affairs will forward a copy of the completed registration form to each of the licensing authorities indicated on the form." (Emphasis added.) Pages 3 and 4 of the form contain a list of the various California healing arts boards (licensing authorities) within or associated with the Department of Consumer Affairs, including the Medical Board of California and 19 other healing arts licensing authorities, with a place to check which of the licensing authorities will have jurisdiction over an out-of-state licensed health practitioner who intends to participate in the sponsored event. Page 4 of the form gives a Department of Consumer Affairs address for submission of the completed form and form attachments. It is evident then, that the Board has made the delegation to the Department of Consumer Affairs to receive the Form 901-A, the registration of sponsoring entity form. The "only one form per event" provision appears to indicate that a single registration of sponsoring entity form is to be submitted to the Department of Consumer Affairs per event to cover all of the applicable healing arts licensing authorities identified on pages 3 and 4 of the form.

The Initial Statement of Reasons in the Board's rulemaking file contains (on page 2) the following explanation of the "delegation to the Department of Consumer Affairs" provisions:

> Because sponsoring entities may be required to register with multiple boards under § 901(d), the proposed regulation allows the board to delegate the authority to receive and process the registration form to the Department of Consumer Affairs. Assuming that all applicable boards make this delegation, the sponsoring entity need only file one registration form and the Department will notify the boards that the sponsoring entity submitted a compete form.

The primary "Clarity" problem here relates to the specific content of the Board's Form 901-A in relation to the content of similar forms being proposed by other healing arts boards within the Department of Consumer Affairs.

OAL is, concurrently with the review of the Board's regulations, reviewing proposed regulations implementing Business and Professions Code section 901 from two of the other healing arts boards within the Department of Consumer Affairs. These regulations are from the Board of Vocational Nursing and Psychiatric Technicians (BVNPT; OAL File No. 2012-0207-02S) and from the Board of Occupational Therapy (BOT; OAL File No. 2012-0209-03S). The BVNPT and BOT regulations and forms are similar to, but not the same as, the Board's regulations and forms. The BVNPT and BOT regulations each contain regulatory language similar to the Board's regulatory language about the incorporation by reference of a Form 901-A (although the specific designations and dates of the forms are different) for the purpose of the registration of sponsoring entities, and the BVNPT and BOT regulations each contain similar language

providing for the delegation of authority to the Department of Consumer Affairs to receive and process the Form 901-A.

Looking at the referenced forms incorporated by reference in the proposed BVNPT and BOT regulations, the Form 901-A for each of the BVNPT and BOT regulations contains language similar to that on the Board's form indicating that only one registration form per event should be completed and submitted to the Department of Consumer Affairs. The BVNPT and BOT forms, like the Board's form, each includes a listing of the healing arts boards (licensing authorities) within or associated with the Department of Consumer Affairs with a place to check which of the licensing authorities will have jurisdiction over an out-of-state licensed health practitioner who intends to participate in the sponsored event. The BVNPT and BOT forms, like the Board's form, each set forth a Department of Consumer Affairs mailing address for the completed form.

The "Clarity" problem principally relates to the fact that, despite the many similarities in the regulations and forms of the three agencies, somewhat different versions of the Form 901-A were in fact incorporated by reference by the Board, the BVNPT, and the BOT in their respective regulations. Examples of differences in the three versions of the Form 901-A include: (1) the Board's Form 901-A and the BVNPT's Form 901-A state that the form shall be completed and submitted by the sponsoring organization at least 90 calendar days prior to the sponsored event, while the BOT's Form 901-A provides for form completion and submission at least 60 calendar days before the sponsored event; (2) the BVNPT's Form 901-A adds "fax number" requirements for organizational contacts and for officers and officials of the organization which are not on the Board's form or on the BOT's form; (3) the statements about recordkeeping requirements for the sponsoring entity are not the same on the three forms; (4) the mailing address for the Department of Consumer Affairs to which the Form 901-A and attachments are to be submitted is stated differently on the three forms; and (5) the "certification under penalty of perjury" statement at or near the end of each form is worded differently on the BOT form than it is on the Board and BVNPT forms.

Consequently, there is not one common form with a uniform set of regulatory requirements which would with certainty allow for the filing of a "single, common form" that meets the regulatory requirements of all three agencies. It is not easy to understand how the "only one form per event" provision on each of the forms would work in practice. With the differing versions of the Form 901-A, there is the potential for confusion and uncertainty among sponsoring entities legally required to comply with the regulations.

Would the Board accept as meeting its requirements a Form 901-A submission with the Department of Consumer Affairs if the submission were the version from the BVNPT regulations or the BOT regulations? All three versions of the Form 901-A indicate that "only one form per event" should be submitted, and that the Department of Consumer Affairs will then forward a copy of the completed registration form to each of the licensing authorities indicated on the form. This language implies that only one Form 901-A submission is necessary to meet the requirements for all of the applicable healing arts boards. However, in proposed regulation section 1333.1(a), the Board incorporates by reference and requires "Form 901-A (MBC/2011)," which is the Board's own particular version of the form. Given the differing versions of the Form 901-A, there is tension between the section 1333.1(a) language and the "only one form per

event" provision on the form, resulting in an ambiguity regarding what exactly will be acceptable. If an identical version of the Form 901-A were to be incorporated by reference by each of the healing arts boards, then this ambiguity would potentially be resolved.

In addition, we note that the Board's proposed regulation section 1333.1(b) includes the following statement regarding the evaluation of a submitted Form 901-A: "The board or its delegatee shall inform the sponsoring entity in writing within 15 calendar days of receipt of the form that the form is either complete and the sponsoring entity is registered or that the form is deficient and what specific information or documentation is required to complete the form and be registered." (Emphasis added.) The BVNPT regulations include a very similar statement with the same 15-calendar-day response period for the BVNPT or its delegatee. However, the BOT regulations include a similar statement but with a 20-calendar-day response period for BOT or its delegatee. In the event that the Department of Consumer Affairs (as delegatee) intends, upon receipt of a Form 901-A, to provide a single response to the sponsoring entity on behalf of each of the delegating healing arts boards, then it is confusing as to whether a 15-calendar-day response period or a 20-calendar-day response period would be applicable.

2. Regulation section 1333.2(d) – Proposed regulation section 1333.2, which sets forth the process and requirements for an out-of-state practitioner to obtain authorization to participate in a sponsored event, includes an appeal provision in section 1333.2(d) which reads as follows: "(d) Appeal of Denial. An applicant requesting authorization to participate in a sponsored event may appeal the denial of such request by following the procedures in section 1333(d)." (Emphasis added.) The Board does not have an existing regulation section 1333, and the new section 1333, entitled "Definitions," proposed to be adopted in this rulemaking includes only subsections (a) and (b) and does not pertain to appeal procedures. Consequently this cross-reference to "section 1333(d)" does not make sense and is not clear. It is likely that the Board instead intended to refer to "section 1333.3(d)" which references appeal rights and procedures that apply upon the termination of an out-of-state practitioner's authorization.

B. NECESSITY

OAL must review regulations for compliance with the "Necessity" standard of Government Code section 11349.1. Government Code section 11349, subdivision (a), defines "Necessity" as meaning: "the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion."

To further explain the meaning of substantial evidence in the context of the "Necessity" standard, subdivision (b) of section 10 of Title 1 of the CCR provides:

> In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
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> (1) a statement of the specific purpose of each adoption, amendment, or repeal; and

> (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.

In order to provide the public with an opportunity to review and comment upon an agency's need for a regulation, the APA requires that a rulemaking agency describe the need for the regulation and identify documents relied upon in proposing the regulation in the Initial Statement of Reasons, pursuant to Government Code section 11346.2, subdivision (b).

The $25 processing fee in regulation section 1333.2(a)(1) -- While the Board's rulemaking file in most respects satisfies the "Necessity" standard, the showing of "Necessity" is insufficient in relation to the $25 processing fee required of applicant out-of-state practitioners, as discussed below.

Proposed regulation section 1333.2, which sets forth the process and requirements for an out-of-state practitioner to obtain authorization to participate in a sponsored event, includes the following provision in subsection (a)(1): "An applicant shall request authorization by submitting to the board a completed Form 901-B (MBC/2011), which is incorporated by reference, accompanied by a non-refundable, non-transferrable processing fee of $25." (Emphasis added.)

Business and Professions Code section 901, subdivision (b)(1)(C), sets forth the requirement for a processing fee, by providing that one of the requirements for an applicant out-of-state practitioner is that the practitioner "pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request."

In its Initial Statement of Reasons for this rulemaking, the Board references (on page 3) the statutory requirement of a processing fee and then provides only the following very general explanation of the proposed processing fee amount of $25: "The processing fee of $25 shall cover the cost of developing the authorization process and processing the request of the health care practitioner." The only other explanation or discussion of the $25 processing fee in the rulemaking file is on the STD. 399 form, the "Economic and Fiscal Impact Statement." On this form, the Board indicates that it has set fees at a level to allow for "cost-neutral implementation" of the rulemaking (but the STD. 399 does not provide any specific cost data). An attachment to the STD. 399 references a projected annual economic impact and fiscal revenue impact from the processing fee of $5,000 (based upon 10 events per year with approximately 20 out-of-state physicians participating in each event), but again no cost information is provided. In summary, the rulemaking file does not include data or other information showing how the Board actually determined (calculated) the $25 fee amount based upon the estimated costs of developing the authorization process and processing the request.

In order to meet the "Necessity" standard, the rulemaking file needs to include additional information showing how the Board determined (calculated) the processing fee amount of $25 based upon estimated regulatory program costs. In raising this concern, we are mindful of the substantial body of judicial decisions in California relating to fees and particularly "regulatory fees." See, for example, the recent California Supreme Court decision in California Farm Bureau Federation v. State Water Resources Control Board 51 Cal.4th 421, 121 Cal.Rptr.3d 37 (2011).

The Board needs to add to the rulemaking file information explaining how the $25 processing fee amount was determined (calculated), and the information then needs to be made available to the public pursuant to Government Code section 11347.1.

C. INCORRECT PROCEDURES (DEFECTIVE DOCUMENTS)

In addition to the problems discussed above, this rulemaking raises two problems relating to compliance with APA procedural requirements because of defective documents in the rulemaking file. Each of these problem areas is discussed below.

1. Table of Contents – Government Code section 11347.3, subdivision (b)(12), provides that a rulemaking file shall include: "An index or table of contents that identifies each item contained in the rulemaking file. The index or table of contents shall include an affidavit or a declaration under penalty of perjury in the form specified by Section 2015.5 of the Code of Civil Procedure by the agency official who has compiled the rulemaking file, specifying the date upon which the record was closed, and that the file or the copy, if submitted, is complete."

The Board's rulemaking file includes a Table of Contents that identifies each item contained in the rulemaking file. However, the affidavit or declaration (certification) at the end of the Table of Contents does not fully comply with the statutory requirements of Government Code section 11347.3, subdivision (b)(12). First, the certification is not "under penalty of perjury in the form specified by Section 2015.5 of the Code of Civil Procedure." Second, the certification does not include the required statement that the file (or the copy of the file) is complete.

2. Final Statement of Reasons – Government Code section 11346.9, subdivision (a), provides that an agency adopting regulations shall prepare and submit to OAL a "Final Statement of Reasons," which is one of the supporting documents included in the rulemaking file. While the Board's rulemaking file includes a Final Statement of Reasons which generally meets the requirements of Government Code section 11346.9, subdivision (a), the document contains a number of errors and inaccuracies which need to be corrected. For example, a citation to "Section 1332(a)(2)" on page 2 of the Final Statement of Reasons is incorrect (and was probably intended to be a reference to "Section 1333.2(a)(2)"). Similarly, a citation to "Section 1333.2(c)(2)(e) on page 2 of the Final Statement of Reasons is incorrect (and was probably intended to be a reference to "Section 1333.2(e)"). Additional problems with the Final Statement of Reasons of a relatively minor nature have been discussed with Board staff and will also need to be corrected in any resubmission of this rulemaking.

CONCLUSION

For the reasons set forth above, OAL has disapproved this regulatory action. If you have any questions, please contact me at (916) 323-6225.

Date: March 13, 2012

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