State of California
Office of Administrative Law

In re: **Board of Pharmacy**	**DECISION OF DISAPPROVAL OF REGULATORY ACTION**
Regulatory Action: Title 16 **California Code of Regulations**	**Government Code Section 11349.3**
Adopt sections: 1747, 1747.1 **Amend sections:** **Repeal sections:**	**OAL File No. 2013-0913-06 S**

SUMMARY OF REGULATORY ACTION

The Board of Pharmacy (Board) proposed this action to add Article 5.5 entitled "Pedigree Requirements" to title 16 of the California Code of Regulations and to adopt sections 1747 and 1747.1, which establish requirements for serialized electronic pedigrees of dangerous drugs.[1] The purpose of the drug pedigree legislation and related regulations is to prevent the introduction of counterfeit, altered, diverted, misbranded, or expired drugs from entering into California's pharmaceutical drug supply chain.

Among other things, proposed section 1747.1 establishes dates by which a manufacturer that distributes a dangerous drug in California shall submit to the Board declarations related to the manufacturer's readiness to comply with statutory electronic pedigree requirements, as well as information that is to be contained in those declarations, pursuant to Business and Professions Code sections 4163.5. Proposed section 1747.1 also sets forth requirements for manufacturers, wholesalers, repackagers, pharmacies, and pharmacy warehouses to submit specified declarations to the Board in order to designate dangerous drugs that they possess as not subject to the serialized electronic pedigree requirements, as provided in Business and Professions Code sections 4163.2 and 4163.4, as well as information that is to be contained in those declarations. All declarations required by proposed section 1747.1 are required to be signed under penalty of

[1] As defined in Business and Professions Code section 4034(a) "pedigree" means the following:

> (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.
> ...

perjury by an owner, officer, or employee with authority to bind the entity submitting the declaration.

DECISION

On September 13, 2013, the Board submitted the above-referenced regulatory action to the Office of Administrative Law (OAL) for review in accordance with the Administrative Procedure Act (APA). On October 25, 2013, OAL notified the Board that OAL disapproved the proposed action because the Board failed to provide a sufficient economic impact assessment that complied with Government Code section 11346.3(b)(1) and failed to meet the necessity standard of Government Code section 11349.1.

DISCUSSION

The Board's regulatory action must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.)

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and for compliance with the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy APA standards, a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review, OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

A. The Board Failed to Provide in the Rulemaking Record a Sufficient Economic Impact Assessment that Complies with Government Code Section 11346.3(b)(1).

On September 21, 2012, the Board commenced the proposed regulatory action by publishing a public notice as required by the APA. At that time, Government Code section 11346.3(b)(1) provided the following:

> (b)(1) All state agencies proposing to adopt, amend, or repeal a regulation ... shall prepare an economic impact analysis[2] that assesses whether and to what extent it will affect the following:
> (A) The creation or elimination of jobs within the State of California.

[2] In S.B. 1520 (Stats. 2012, c. 766; eff. Sept. 29, 2012), nonsubstantive amendments were made to Government Code section 11346.3(b)(1). Among these amendments, "economic impact assessment" was substituted for "economic impact analysis" in subdivision (b)(1). OAL uses the current term "economic impact assessment" in this decision.

> (B) The creation of new businesses or the elimination of existing businesses within the State of California.
> (C) The expansion of businesses currently doing business within the State of California.
> (D) The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment.

The economic impact assessment (EIA) required by Government Code section 11346.3(b)(1) mandates an assessment of any economic impacts described in subdivisions (b)(1)(A) through (C) and the benefits of the regulation described in subdivision (b)(1)(D). The EIA that the Board provided to OAL in the rulemaking record is not sufficient because it fails to comply with all of the elements addressed by subdivisions (b)(1)(A) through (D) of Government Code section 11346.3(b). The EIA provided only addresses the benefits of the regulation described in subdivision (b)(1)(D); however, it does not contain the economic impact assessments that are required in subdivisions (b)(1)(A) through (C) of Government Code section 11346.3. In its EIA, the Board must perform an analysis explaining why and how it made the initial determinations stated in its 45-day notice that the proposed regulatory action would not have a significant impact on the creation or elimination of jobs (subdivision (b)(1)(A)) or existing businesses (subdivision (b)(1)(B)), or the expansion of businesses (subdivision (b)(1)(C)) in the State of California to address the missing elements of its EIA.

In discussing this issue with the Board, the Board has indicated it will prepare an addendum to its EIA that addresses the economic impacts described in subdivisions (b)(1)(A) through (C) of Government Code section 11346.3. The Board must then make this document available to the public for at least 15 days prior to the Board adopting the regulations and resubmitting these regulations to OAL. (Gov. Code, sec. 11347.1.) Additionally, any comments made in relation to this addendum to the Board's EIA must be considered by the Board, and summarized and responded to in the final statement of reasons. (Gov. Code, sec. 11347.1, subd. (d).)

B. The Requirement in Proposed Section 1747.1 that Certain Declarations be Signed under Penalty of Perjury Fails to Meet the Necessity Standard.

Government Code section 11349.1 (a)(1) requires OAL to review all regulations for compliance with the necessity standard. Government Code section 11349 (a), defines "necessity" to mean:

> (a) ... 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, title 1, California Code of Regulations, section 10(b) provides:

> (b) In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:

> (1) A statement of the specific purpose of each adoption, amendment, or repeal; and
> (2) information explaining why each provision of the adopted regulations 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 perceived need for a regulation, the APA requires that the agency describe the need for the regulation in the initial statement of reasons. Specifically, Government Code section 11346.2(b)(1) states, in part:

> (b) An initial statement of reasons ... shall include ... :
> (1) A statement of the specific purpose of each adoption, amendment, or repeal, the problem the agency intends to address, and the rationale for the determination by the agency that each adoption, amendment, or repeal is reasonably necessary to carry out the purpose and address the problem for which it is proposed. The statement shall enumerate the benefits anticipated from the regulatory action, including the benefits or goals provided in the authorizing statute.

In short, the Board's initial statement of reasons for this action must state the problems the Board intends to address, the purpose for the adoption or amendment, and the rationale for the adoption or amendment for each regulatory provision. More simply put, the initial statement of reasons must include a statement, for each regulatory provision, explaining "why" the proposed regulation is needed and "how" this regulation fills that need. The initial statement of reasons must then be submitted to OAL with the initial notice of the proposed action and made available to the public during the public comment period, along with all the information upon which the proposal is based. (Gov. Code, sec. 11346.2, subd. (b) and sec. 11346.5, subds. (a)(16) and (b).) In this way the public is informed of the basis of the regulatory action and may comment knowledgeably.

Here, the Board failed to comply with the necessity standard. All of the declarations required by proposed section 1747.1, to be submitted to the Board by manufacturers, repackagers, wholesalers, pharmacies, and pharmacy warehouses, are required to be signed under penalty of perjury by an owner, officer, or employee with authority to bind the entity submitting the declaration. The Board's initial statement of reasons does not provide any rationale to explain why the declaration under penalty of perjury requirements are needed for subdivisions (a)(1), (a)(2), (b), and (c) of proposed section 1747.1.

Subdivisions (a)(1) and (a)(2) of proposed section 1747.1 requires a manufacturer of dangerous drugs to submit a declaration under penalty of perjury for purposes of notifying the Board of the required portions of their drug inventory, as specified, that are ready to comply with the pedigree

requirements by certain deadlines. These subdivisions implement Business and Professions Code section 4163.5, which only refers to notifications by manufacturers as follows:

> ... Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.
> [See Bus. & Prof. Code, sec. 4163.5, subds. (b) and (c).]

Accordingly, since there is no statutory requirement that a manufacturer provide a declaration, let alone a declaration under penalty of perjury, the Board's initial statement of reasons should have explained why the declaration under penalty of perjury requirements are needed.

Similarly, subdivisions (b) and (c) of proposed section 1747.1 require any manufacturer, repackager, wholesaler, pharmacy, or pharmacy warehouse to submit to the Board declarations signed under penalty of perjury to declare certain drugs as exempt from the pedigree requirements by specified deadlines. Both of these subdivisions implement Business and Professions Code sections 4163.2 and 4163.4 and provide as follows:

> (b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:
> ...
> (c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:
> ...
> [Emphasis added.]

Business and Professions Code section 4163.2 expressly requires one type of declaration to be made under penalty of perjury, which is a declaration made by any of the specified entities designating certain drugs in their inventory are not subject to the pedigree requirements, as specified therein. Because this single type of declaration is already statutorily required to be signed under penalty of perjury, there is no need to establish necessity in the initial statement of reasons for the penalty of perjury requirement for a declaration made pursuant to Business and Professions Code section 4163.2. However, the type of declaration required by Business and Professions Code section 4163.2 is covered only by a portion of proposed section 1747.1(b) and (c).

Subdivisions (b) and (c) of proposed section 1747.1 also refer to declarations made for purposes of Business and Professions Code section 4163.4. This section of the Business and Professions Code creates an additional exemption to the pedigree requirements but does not specify whether any declaration needs to be made to the Board, let alone a declaration under penalty of perjury. Accordingly, the Board must establish necessity in the rulemaking file explaining why a portion of proposed section 1747.1(b) and (c) requires declarations to be made pursuant to Business and Professions Code section 4163.4 and why these declarations must be made under penalty of perjury.

Since the Board's initial statement of reasons does not include any statements explaining why the declaration under penalty of perjury provisions are needed, section 1747.1 fails the necessity standard. There is neither a statement of the problem the Board intends to address nor any statements of the purpose and the rational for the declaration under penalty of perjury requirements in section 1747.1. In other words, the Board did not answer "why" the requirement is needed and "how" the requirement fills that need.

Thus, before this regulatory action is resubmitted to OAL, the Board must draft a supplemental statement of reasons to correct the lack of necessity in the initial statement of reasons for the declaration under penalty of perjury provisions under proposed section 1747.1. Pursuant to Government Code section 11347.1, this supplemental statement of reasons, which would provide the necessity missing from the initial statement of reasons, must be made available to the public for at least 15 days prior to the Board's adoption of the proposed regulations. Additionally, any comments made in relation to the supplemental statement of reasons must be considered by the Board, and summarized and responded to in the final statement of reasons prior to resubmitting the regulations to OAL. (Gov. Code, sec. 11347.1, subd. (d).)

CONCLUSION

OAL disapproved this proposed regulatory action for the reasons set forth above.

Date: October 31, 2013

Richard L. Smith
Senior Counsel

For: Debra M. Cornez
Director

Original: Virginia Herold
Copy: Carolyn Klein