ATTACHMENT 2

Title 16. Board of Pharmacy
Proposed Language

Proposal to Add a New Section 1747.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1747.2 Drop Shipments.

For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the "drop shipment" method of sale as defined by that section, the data elements pertaining to transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery thereby, may be omitted from the pedigree, in which case the manufacturer shall convey the pedigree directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug.

Note: Authority cited: Sections 4005, 4034, and 4163.1, Business and Professions Code. Reference: Sections 4034, 4037, 4163, 4163.1, 4170, 4180, and 4190, Business and Professions Code.

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October 24, 2013

VIA E-MAIL [Debbie.Damoth@dca.ca.gov]
FOLLOWED BY U.S. MAIL

Ms. Debbie Damoth
Drop Shipment Regulation Coordinator
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: Support for Board of Pharmacy Proposed Regulation 1747.2 "Drop Shipments" Notice Published September 13, 2013

On behalf of our client, Millennium Pharmaceuticals, Inc. ("Millennium), we are pleased to submit comments in support for the California State Board of Pharmacy ("Board") adoption of its proposed new regulation at Title 16, California Code of Regulations, Section 1747.2 – "Drop Shipments."

Millennium has worked closely with the Board to encourage its focus on a unique distribution model in the prescription drug supply chain, and one for which customized rulemaking is authorized in the state's electronic pedigree ("e-pedigree") statute at Section 4163.1(b) of the California Business and Professions Code.

Millennium supports the Board's proposal to specify that when a manufacturer utilizes the "drop shipment" method of distribution for a dangerous drug, the manufacturer may omit data elements from the pedigree showing transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery of the drug by the wholesaler. Pedigree would then be required to be conveyed directly from the manufacturer or its designated distributor to the authorized purchaser prior to or contemporaneously with the delivery of the dangerous drug.

As the Board knows from our previous testimony and written submissions on this question, Millennium utilizes a "drop-shipment" distribution model that provides treating physicians and their patients with timely and efficient access to critical and time-sensitive therapies for cancer. This

model allows our client to facilitate the direct shipment of medications to a healthcare provider's office, and ultimately to the patient, within a day of placing an order.

In this model, wholesalers place orders for the product and consequently take title to the ordered product, but never take possession or physical control of the product. The role of the wholesaler in this model is thus limited to facilitating administrative services, such as the processing of orders and payments.

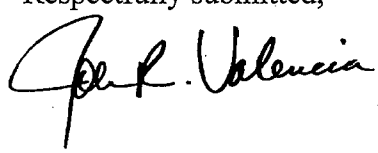
Section 4163.1(b) of the California Business and Professions Code expressly permits the Board to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in California law is to provide the capability to track and trace drug shipments. As a result, only those stakeholders that actually take possession or physical control of the drugs are best positioned to satisfy the objectives of the law's pedigree requirements.

In the context of a drop shipment distribution model, pedigree information should include records of any shipments directly from manufacturers (or their designated distributors) to dispensers, as well as any returns. However, pedigree requirements need not apply to wholesale distributors who take only legal title of a drug product, but take neither possession nor physical control. Ensuring entities that *never* physically handle the product are not subject to the reporting requirements will allow companies, like Millennium, to maintain important efficiencies in its distribution system without subjecting its wholesalers to unnecessary regulation. All the while, the accurate tracking of pharmaceutical products throughout this unique chain of physical custody is ensured.

On behalf of Millennium, we wish to express our thanks to the Board and its staff for its sustained focus, and proposed action, on this important aspect of "e-pedigree." Millennium reiterates its support for the adoption of this regulation.

Should the Board require any additional information, please don't hesitate to contact me at (916) 441-2430.

Respectfully submitted,



JOHN R. VALENCIA

JRV:mb
Enclosures: Exhibits "A" & "B"
1020420.1

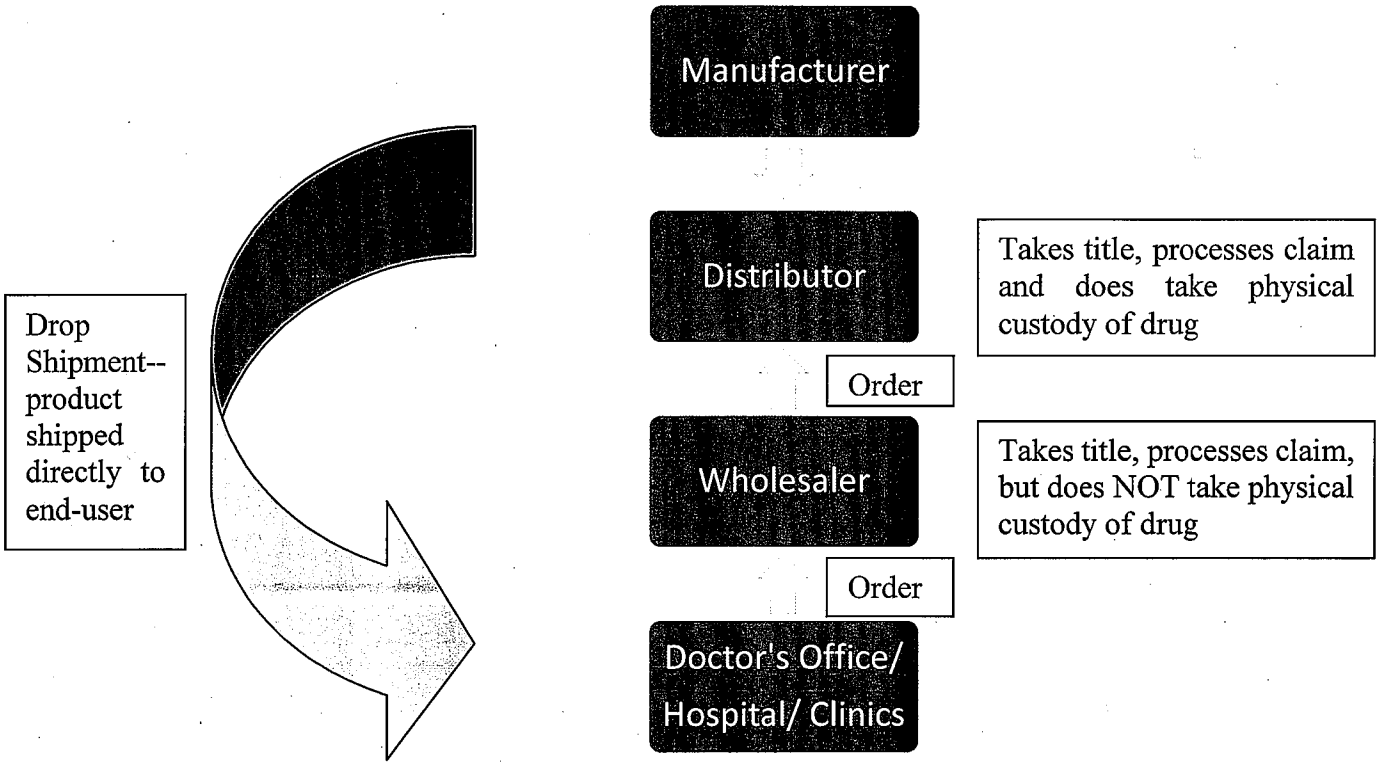
Exhibit "A"

"Drop Shipment" Distribution Process Summary

A variety of pharmaceutical manufacturers use a "drop-shipment" distribution model that provides treating physicians and their patients with timely and efficient access to drugs. By using a drop-ship model, the manufacturer can facilitate a direct shipment of its drug to a healthcare provider's office. In this model, wholesalers place orders with the manufacturer or a designated distributor for the product and consequently take title to the ordered product, but never take possession or physical control of the product. Instead, the manufacturer or designated distributor ships directly to the physician upon receipt of the order. The role of the wholesaler in this model is thus limited to facilitating drug distribution by providing administrative services, such as the processing of orders and payments.

Exhibit "B"

A 'DROP-SHIPMENT' DRUG DISTRIBUTION MODEL



Title 16. Board of Pharmacy
Proposed Language

Proposal To Amend Section 1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520) ~~four hundred dollars ($400)~~. The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars ($325) ~~two hundred fifty dollars ($250)~~. The penalty for failure to renew is one hundred fifty dollars ($150) ~~one hundred and twenty five dollars ($125)~~.

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325) ~~two hundred fifty dollars ($250)~~.

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105) ~~fifty dollars ($50)~~. The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130) ~~fifty dollars ($50)~~. The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65) ~~twenty-five dollars ($25)~~.

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260) ~~one hundred eighty-five dollars ($185)~~.

(e) The fee for regrading an examination is one hundred fifteen dollars ($115) ~~eighty-five dollars ($85)~~.

(f) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195) ~~one hundred fifty dollars ($150).~~

(g) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars ($195) ~~one hundred fifty dollars ($150)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50) ~~seventy-five dollars ($75)~~.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780) ~~six hundred dollars ($600)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165) ~~one hundred twenty five dollars ($125)~~. The penalty for failure to renew is eighty two dollars fifty cents ($82.50) ~~sixty-two dollars and fifty cents ($62.50)~~.

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330) ~~two hundred fifty dollars ($250)~~. ~~If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars ($110) of the fee.~~ The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195) ~~one hundred fifty dollars~~

~~($150)~~. The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50) ~~seventy-five dollars ($75)~~.

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780) ~~six hundred dollars ($600)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars ($115) ~~seventy-five dollars ($75)~~. The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30) ~~twenty dollars ($20).~~

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520) ~~four hundred dollars ($400)~~. The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) ~~two hundred fifty dollars ($250)~~. The penalty for failure to renew is one hundred fifty dollars ($150) ~~one hundred and twenty five dollars ($125)~~.

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780) ~~six hundred dollars ($600)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330) ~~two hundred fifty dollars ($250)~~. ~~If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($150) of the fee.~~ The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195) ~~one hundred ten dollars ($110)~~. The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50) ~~fifty-five dollars ($55)~~.

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425) ~~four hundred dollars ($400)~~. The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325) ~~two hundred and fifty dollars ($250)~~. The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45) ~~thirty dollars ($30)~~.

(t) The fee for the issuance of a centralized hospital packaging pharmacy shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4127.5, 4128.2, 4196, 4200, 4400, 4401 and 4403, Business and Professions Code.

Order of Adoption

Board of Pharmacy

California Code of Regulations

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(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 July 31, 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:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(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 July 31, 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:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

Virginia Herold
Executive Officer
Board of Pharmacy

Order of Adoption
Board of Pharmacy
California Code of Regulations

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1745. Partial Filling of Schedule II Prescriptions.
(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ <u>or</u> on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The

remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

~~(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.~~

(b) ~~(c)~~ Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(c) ~~(d)~~ Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

Title 16. Board of Pharmacy
Proposed Language

To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse

Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Title 16. Board of Pharmacy
Proposed Language

To Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements
(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.
(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions under ~~$300~~ $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.
(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Add Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.
(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Amend Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.
(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her

fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Title 16. Board of Pharmacy
Proposed Language

To Add Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, 4301, Business and Professions Code