



California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
D. Timothy Dazé, Board Member
Robert Graul, RPh, Board Member
Kenneth H. Schell, PharmD, Board Member
Stanley Weisser, RPh, Board Member

REGULATION REPORT

Report and Action on Items Discussed at the Legislation and Regulation Committee Meeting of April 11, 2008.

Minutes of the Legislation and Regulation Committee Meeting of April 11, 2008, are provided in **ATTACHMENT 1**.

Item B. Board Regulations – Noticed, Pending Adoption

FOR ACTION:

Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and amendment to 16 CCR § 1751-1751.8 and adoption of 16 CCR §§1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

At the January 2008 board meeting, the board conducted a regulation hearing to hear testimony about the regulation proposal that establishes requirements for pharmacies that compound medications. As a result of this regulation hearing, the board voted to complete a 15-day notice with revised language to address some of the written comments received and oral testimony provided.

Given the significant amount of comments submitted and testimony provided, staff recommends that the board consider withdrawing this rulemaking to allow time to further refine the draft language. **ATTACHMENT 2** contains proposed language for the board to consider for a new 45-day comment period. This language reflects changes as a result of written comments received and public testimony provided.

Item C. Board Approved Regulations – Awaiting Notice

FOR INFORMATION:

1. Proposed Addition to Title 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

A copy of the draft language and form is included in **ATTACHMENT 3**. Staff anticipate initiating the 45-day comment period in advance of the July Board Meeting to allow for action by the board at the July 2008 Meeting.

2. Proposed Amendment to Title 16 CCR §1780 – Update the USP Standards Reference Material

CCR 1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

At the April 2007 Legislation and Regulation Committee Meeting, the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather is seeking input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material. At the June 2007 committee meeting, Dr. Schell offered to facilitate a taskforce to review the USP Standards Reference Material.

3. Proposed Adoption of Title 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

At the July 2007 Board Meeting, the board voted to move this proposal. Staff anticipates initiating the rulemaking process for final adoption by the July 2008 board meeting.

A copy of the language is provided in **ATTACHMENT 4**.

4. Proposed Amendment to Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

A copy of the language is provided in **ATTACHMENT 5**.

ITEM D: Board-Approved – Regulation Language to be Developed

At the October 2007 Board Meeting, the board voted to pursue a regulation proposal to develop an ethics course for pharmacists, modeled after the program used by the Medical Board of California. Staff is working with the Institute for Medical Quality to define the scope of the proposal.

Draft language will be developed in concert with staff counsel for consideration at the Enforcement Committee Meeting scheduled for January 23, 2008.

Attachment 1

*Meeting Summary Legislation and Regulation
Committee Meeting of April 11, 2008*



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ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES**

DATE: April 11, 2008

LOCATION: Los Angeles International Airport
Samuel Greenberg Board Meeting Room
1 World Way
Los Angeles, CA 90045

BOARD MEMBERS

PRESENT: Andrea Zinder, Public Member, Chairperson
D. Timothy Dazé, Esq., Public Member
Kenneth H. Schell, PharmD
Robert Graul, RPh
Stanley C. Weisser, RPh

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Tina Thomas, Analyst

Chairperson Zinder called the meeting to order at 9:30 a.m.

Chairperson Zinder acknowledged Anne Sodergren's return to the board.

Ms. Herold introduced board staff Anne Sodergren and Tina Thomas.

Dr. Weisser acknowledged Mr. Dazé for assisting in providing the conference room for the meeting.

Legislative and Regulatory Proposals for 2008

SB 1307 Electronic Pedigree

Ms. Herold provided updates on the bill. She stated that amendments have been put in place since the last board meeting to establish staggered implementation dates for the e-pedigree requirements. Ms. Herold noted that there are many manufacturers who feel they will be ready for having their products tagged by 1/1/11. She highlighted that the current implementation timeline would leave the supply chain partners without enough time to implement effectively.

The amendment will allow the wholesalers an additional year and pharmacies will have an additional eighteen months behind the 2011 deadline to implement and stated that there are also provisions for the board to develop regulations for inference. Ms. Herold noted that the current language for grandfathering is difficult to understand and may be slightly revised. She stated that the intent with grandfathering is to provide a grace period in order to run out drugs already in the supply chain prevent, and that it is a short-term implementation issue. Ms. Herold stated that the bill was in hearing Monday and was passed with a 6-2 vote. She commented that the next stop is the Appropriations Committee. Ms. Herold stated that there will be additional amendments to bill, as Senator Cedillo had a competing bill (SB 1270). Senator Cedillo's bill does not have amendments yet.

Dr. Schell asked what the intent is on the grandfathering provision. Ms. Herold responded that on 1/1/01, there will still be drugs manufactured that are not serialized or e-pedigree that could still be moved through the supply chain. She noted that a list has to be developed with regard to turnaround of all such drugs.

Comments/Questions from public:

Kathy Lynch (CPHA) noted that they are in support of SB 1307. Ms. Lynch asked the committee to clarify how inference will be handled. Ms. Herold responded that inference will be done during the regulation process if the bill is passed. Ms. Herold stated that inference comes at the expense of serialization, and that the more inference you give, the less value serialization provides to the security of the supply chain. Ms. Lynch pointed out that they have great concern for the liability involved for their stores. She stated that they appreciate the extra time being provided in order for the pharmacies to comply. Ms. Lynch also stated that she requested that the technology be sightless. Dr. Schell asked if CPHA will be working on developing thoughts around the inference issue, as they should be starting that now. Ms. Lynch responded that they are. Ms. Herold stated that the board shares CPHA's concern about a product going from all the way from the manufacturer to a pharmacy without ever being electronically read, and the issue will be addressed.

SB 1779 (Omnibus Provisions)

Chairperson Zinder stated there have been no new provisions proposed since the last discussion.

Questions/comments from the public:

Steve Gray (Kaiser Permanente) referenced language in section 4110 (Temporary Permit Upon Transfer of Ownership). Dr. Gray suggested that a mobile pharmacy should be allowed in a parking lot during remodel. Ms. Herold agreed that this was a reasonable request and that excluding this event from the provisions was unintentional. Dr. Gray stated his concern over the Board's requirement of an approval process for a new pharmacist-in-charge. Ms. Herold clarified the process for a change of PIC, and stated that a pharmacy permit will not be issued or renewed until the PIC is approved.

MOTION: To ensure the remodel situation is clearly set forth in the amendments to Business and Professions code 4110.

M/S: Weisser/Schell

Support: 4 Oppose: 0

Questions/comments from the public:

Cooky Quandt (Long's) referenced section 4113 (d) and asked for clarification that a pharmacy will need to notify the board in all cases of an interim PIC. Ms. Sodergren pointed out that the language is "may", and that it is not mandatory at this point. Ms. Herold stated that when a pharmacy renews its license an interim PIC must be designated on the renewal. This interim PIC has to be reported to the board.

Dr. Gray shared his concern of the 120-day limit on an interim PIC, and that there is often difficulty for hospitals to find someone who will take the role of permanent PIC. He also explained the concern of compensation in relation to the need to find a permanent PIC. Ms. Herold restated the law from the Pharmacy Lawbook that already requires the designation of a permanent PIC after 120 days. She also noted the fact that a permanent PIC is the cornerstone of pharmacy law. Chairperson Zinder noted that a discussion to consider any change to the permanent PIC law is not appropriate now.

Legislation of Interest

Active bills

AB 501 (Swanson) – Pharmaceutical Devices

Ms. Sodergren stated that the bill was carried over from last year. The bill is designed to provide a safe mechanism for people to dispose of hypodermic syringes and needles and prevent them from being found in landfills, playgrounds, etc. Ms. Sodergren explained the options for ultimate disposal by users.

Board Position: Support

AB 865 (Davis) – State agencies: Live customer service agents

Ms. Sodergren explained that the intent of the legislation is to require state agencies to have all phone calls answered within ten rings by a live operator, and to have a zero-out option to reach a live agent with automated systems. Chairperson Zinder felt that we should not change that position. Ms. Herold emphasized the need for the public to feel that the state agencies are reachable.

Board Position: Neutral

AB 1394 (Krekorian) – Counterfeit: Trademarks

Ms. Herold explained that the bill will enhance penalties against anyone involved in counterfeiting. She explained that it is viewed as theft from manufacturers and thus increased penalties on such theft is appropriate. Ms. Herold noted that there was a slight amendment since the last board meeting.

Board Position: Support

AB 1436 (Hernandez) – Nurse Practitioners

Ms. Sodergren explained that bill was initially introduced to expand to the scope of practice for nurse practitioners. She stated that numerous amendments have been made, and the bill now revises educational requirements for nurse practitioners. Initially the board was watching the bill, however the bill has changed significantly in scope.

Board Position: Watch

AB 1587 (De La Torre) – Personal Information: pharmacy

Ms. Sodergren reviewed the bill and that it would allow the pharmacy to provide drug–manufacturer produced information at the time that a prescription was dispensed. She informed the board that the proposal will not be moving forward.

Board position: Oppose

AB 1947 (Emmerson) – Pharmacy Technicians

Ms. Herold explained that the bill would have required that a pharmacy technician applicant would have to pass an exam that met the requirements of California Business and Professions Code 139 and would also require the technician to earn 20 hours of continuing education credits every two years as a condition of renewal. Ms. Herold stated that the bill has been withdrawn.

Phillip Swanger (CSHP) provided an explanation of the reasons for the bill withdrawal, and explained that there is a plan for all stakeholders to meet in the near future to come to an agreement to rerun the bill in 2009. Dr. Graul asked about the nature of the opposition, and Mr. Swanger responded that it involved financial impact on community and chain pharmacies. Dr. Weisser commented that this is an important issue, and that the Board of Pharmacy should continue to be involved in determining continuing education for the technicians, as they are very involved with the patients and community.

Committee Recommendation: None

AB 2516 (Mendoza) – Prescriptions: Electronic transmission

Ms. Sodergren explained that the bill deals with the electronic transmission of prescriptions. Ms. Sodergren explained further that the bill's intent is to have a physician submit prescriptions electronically to the pharmacy of a patient's choice. Ms. Herold commented on the concern regarding the exemption in section 4072.5, which she will be discussing with legal counsel. Dr. Graul asked if the bill is stating that all prescriptions will be prescribed electronically by 2010. This was confirmed by Ms. Herold and Ms. Sodergren.

Questions/comments from the public:

Dr. Gray (Kaiser Permanente) shared concerns with the bill. Dr. Gray first indicated that the law already states that prescriptions are to be sent to the patients' pharmacy of choice. Dr. Gray stated his concern over the intent of the bill and whether liability would lie with the prescriber or the pharmacy when a prescription is not prescribed electronically. Dr. Gray was also concerned over proper enforcement from other boards involved (i.e., Medical, Dental Boards). Dr. Gray also stated concern over the date of the implementation and the lack of technology in place to have all pharmacies receive prescriptions electronically from large hospitals, such as Kaiser Permanente. Dr. Gray and Dr. Graul both raised the issue of poor legibility on faxed handwritten transmissions and other types of transmissions and that it doesn't seem realistic to have e-prescribing in place by the implementation date of the bill. Ms. Herold stated that further investigation of the bill by board staff is necessary.

Stacy Noroni (health care attorney) stated that the regulations are not clear on some issues, including the lack of distinction between new and renewal prescriptions. She also discussed the issue of regulations being specifically addressed towards skilled nursing facilities (but not other entities), which billers are using against the skilled nursing facilities to withhold payments. Ms. Herold requested that Ms. Noroni place her issues in writing and submit them to the board. She noted that the e-prescribing law has been in place since 1994, and that it may be time to take a look at whether the law is still adequate based on current technology. Ms. Noroni stated that

she will submit the issue in writing. It was noted that the board will conduct further analysis on the bill before taking a position, as additional information is needed.

Committee Recommendation: None

AB 2643 (Cook) - Drugs and Devices

Ms. Sodergren explained that the bill would have replaced the references to USP to the name of the publication Drug Points. She noted that the hearing was cancelled, and that the sponsor will not be moving on this legislation

Committee Recommendation: None

AB 2756 (Duvall) – Pharmacists: Furnishing Drugs During and Emergency

Ms. Herold invited the California Retailers Association to speak on behalf of the bill, as they are the sponsor of the bill. Heidi Barsuglia (CRA) explained that the bill is currently a spot bill, but amendments should be in print by Monday. She explained the details of the bill as it relates to natural disasters and the ability to dispense in such an event, rather than having to wait until a Governor declaration is issued. Dr. Schell asked who would determine the emergency. Ms. Barsuglia clarified that this would refer to the natural disaster, rather than an emergency. Dr. Graul clarified that the changing of language would involve adding “natural disaster” to the current language. Ms. Herold recommended that the board wait until we have the bill in front of us before taking a position.

Committee Recommendation: None

SB 963 (Ridley – Thomas) – Regulatory Boards: Operations

Ms. Herold explained that the bill deals with the Sunset Review process. She informed the board that there will be changes in the bill, and that amendments are not yet available. Ms. Herold recommended that the board not take a position until we have the changes. She stated that the information provided is for information only. Ms. Herold did emphasize the importance of bill.

Committee Recommendation: None

SB 1096 (Calderon) – Medical Information

Ms. Sodergren explained that the bill would allow a pharmacy, or an entity authorized by a pharmacy, to mail written communications to a patient pertaining to the prescribed course of their treatment, without patient authorization. Ms. Sodergren noted that the board took an oppose position at the January 2008 board meeting and concerns from the board are detailed in the comments of the bill analysis.

Comments from the sponsor:

Dan Ruben (Adheris), sponsor of the bill, provided the background and purpose for the bill. Mr. Ruben reviewed specific points they would like the board to keep in mind when evaluating the bill, including the issue of lack of patients’ adherence to taking their medications, the need for ongoing management of chronic health, and programs providing education and reminder messaging about patients’ prescribed therapy. Mr. Ruben also listed programs not being offered to citizens in California. Mr. Ruben emphasized several requirements that must be met before the written communications would occur. He also stated that Adheris disagrees with concern by some parties that the written communication programs could interfere with the patient-physician

relationship, by pointing out that the information being provided in writing only relates to drugs already prescribed by the physician.

Dr. Graul confirmed that the program is an “opt out” program. He asked what the time frame is for opting patients out currently under the program. Mr. Ruben indicated that a toll-free phone number is available for the patient to call in order to opt-out, at which point they are removed from any further written communication immediately. Dr. Graul also asked about the confidentiality concern over written communication being sent. Mr. Ruben stated that all written communication is sent by first class mail. Dr. Graul also confirmed with Mr. Ruben that the program is currently being funded by pharmaceutical companies.

Dr. Schell asked if they have any evidence that suggests a greater problem with medication adherence in California compared to the rest of the United States. Mr. Ruben responded that he doesn't think it is better or worse. Dr. Schell commented that maybe the reason adherence is not worse in California is because such patient mailings do not work. Mr. Ruben clarified that he was speaking globally.

Mr. Dazé asked about the option of doing an “opt-in” program rather than an “opt-out”. Mr. Ruben responded that no bill is needed for an “opt-in” program, but there are limitations to such a program. He stated that in the case of an “opt-in” program, it is difficult to get patients to “opt-in,” and they tend to be only the most compliant patients. Mr. Dazé stated that people simply may not want the information, and that is why they wouldn't “opt-in” if they have the choice.

Chairperson Zinder asked what additional information is provided through Adheris's service that is not provided at the pharmacy. Mr. Ruben responded that additional information includes the printing out of a drug monograph in a more patient-friendly manner. He also stated that refill reminders will come in the mail to them as well. Ms. Herold requested copies of the letters that are used for written communication in other states. The board agreed on the request. Mr. Ruben will send this material to the board.

Dr. Schell requested a better overview on how the system knows to stop sending information when there are no refills. Mr. Ruben that all the communications are triggered based on refills remaining. He also noted that an additional letter may be sent out for patients using medication on a long-term basis, indicating the recommendation to contact their physician routinely. Chairperson Zinder asked who the mailing comes from. Mr. Ruben indicated that it appears to come from the pharmacy.

Dr. Graul asked for the “opt-out” rate. Mr. Ruben indicated it was 3 percent. Ms. Sodergren and Mr. Dazé asked if Adheris receives the patient information, and whether that is without the acknowledgement of the patient. Mr. Ruben responded that that is correct in some cases. Dr. Graul how much money is involved in the transactions, and whether it is a significant cash flow to the pharmacies. Mr. Ruben responded that there is reimbursement for services involved for help in printing out the letters.

Questions/comments from the public:

Dr. Gray voiced Kaiser Permanente's concern over the bill. He stated that Kaiser Permanente's view is that the bill places severe limitations on written communication to patients from the pharmacy, and limits that communication to only being that which has prior authorization. Dr. Gray pointed out that they cannot provide non-drug information or information on other drugs not prescribed, and can only provide what's in the medication insert of the drug being prescribed. Dr. Gray noted that the confidentiality law is extremely complex, but Kaiser

Permanente is concerned that this bill would inhibit pharmacies to participate fully in what they can and cannot communicate in writing. Dr. Gray encouraged the board to look at this bill carefully, and feels that there should be more communication, not less.

Mr. Dazé asked if Kaiser Permanente has communicated their concerns with the sponsor. Dr. Gray responded that they have not, but they are beginning that process. Mr. Dazé noted that if there is a positive impact to mailings, then we should take a look at it. However, the board needs to address this if it will hinder the other types of communications Dr. Gray mentioned, including medication adherence. Dr. Graul clarified that this bill would narrow the scope of communication between a pharmacy and a patient to one drug being prescribed, and would not allow the pharmacist to discuss other drug options or otherwise, for example. Dr. Graul stated that he is not opposed to compliance programs, but that something is needed to improve and protect the patients when they don't know that they should not continue on a drug. Dr. Gray stated that substantial funding for some of those programs comes from the pharmaceutical companies, and it usually comes from a company of a patented, branded drug. They are rarely sponsored by a generic drug company. This raises the question of intention of some of the trade name companies, so that the pharmacists are unable to communicate generic drugs options to patients in low-income situations.

Mr. Ruben responded to Dr. Gray's comments, and stated that there was nothing in the bill which was meant to limit what can be done. They viewed the bill as a starting point, and are not against allowing other communication. Mr. Ruben defended the concern over any intention of branded companies to disallow communication on generic drugs.

Mr. Dazé suggested that Adheris and Kaiser Permanente work together to address the concerns. Mr. Dazé also noted that no one is opposed to having information going to consumer, or to have information restricted to only one channel.

Chairperson Zinder noted that the board has taken an opposed position. Ms. Herold explained the reason for the opposed position involved (1) financial reimbursement to the pharmacy for providing this service, compromising the role of the pharmacist, (2) the opt-out nature of the process and as well as (3) patient confidentiality being violated by a third party.

Questions/comments from the public:

Dr. Gray addressed the board's concern regarding the sharing of information to third parties. He feels that this issue is already well regulated, and Kaiser Permanente's opposition to the bill is not related to this. Dr. Gray noted Kaiser Permanente's communications to patients in an attempt to discourage patients to continue on medication that they should not be using, and that this is another reason for their opposition

Board Position: Oppose

SB 1270 (Cedillo) – Pharmacy: Dangerous Drug and Devices Pedigree

Ms. Herold summarized the bill. She stated that the bill was amended on March 27th, and explained that it deals with the normal distribution channel of e-pedigree. She noted that amendments to the bill just came out April 11th, and that the bill will be heard by the Business & Professions Committee on April 14th. Ms. Herold stated that everything in the bill related to normal distribution channels has been removed, and replaced with a task force to help aid the board in advising it about implementation of e-pedigree requirements. Ms. Herold advised the committee to wait to take a position on the bill until the amended copy is available to review.

Committee Recommendation: None

SB 1504 (Ridley – Thomas) – Antiepileptic Drug Products: Substitution

Ms. Sodergren explained that the bill dealt with prohibiting generic substitutions for antiepileptic drugs. She stated that the bill is not moving forward.

Committee Recommendation: None

SB1594 (Steinberg) – Bleeding Disorders Clotting Products

Ms. Herold explained that the bill involves specific regulations on blood clotting products for home use. The Senate Health Committee had requested that amendments be added to allow the Pharmacy Board to enforce the regulations with respect to pharmacies. Ms. Herold that the board staff should be able to ensure the safety of these patients. Ms. Herold stated that the bill was amended on April 9th, and the board has not had a chance to work with the Dept. of Health Care Services to work out the details. Ms. Herold suggested not recommending a position on the bill.

Dr. Graul raised the question of whether the bill would allow for jurisdiction by the Board of Pharmacy over non-licensed persons involved as well.

Dr. Schell asked what the genesis of the bill is. Ms. Herold responded that the bill aimed at improving the quality of service for patients that require hemophilia drugs. Dr. Schell questioned whether the quality of services is currently an issue. Kathy Lynch (CPhA) indicated that CPhA is taking a neutral/watch position on this bill right now. She explained the issues behind the bill with respect to the container of the drug, as well as the need for standards. CPhA feels that the pharmacies are already abiding by these standards, and that it is the hemophilia groups' intention to have something in place that will be enforced. Dr. Schell's shared his concern on overregulation, and that we may simply be adding another, and an unnecessary layer. Ms. Lynch pointed out that standards similar to those being attempted in California have been set in other states. She also noted that hemophiliac groups are seeking some amendments, but she is not sure what they are.

Dr. Gray provided background on hemophiliac drugs, including cost. He noted that a very well organized consumer group is involved in developing this bill.

Ms. Lynch described an instance where a specialty pharmacy was trying to force a patient to move over to another drug because they did not want to supply the original drug that the patient has been taking for many years. She stated that this is an important aspect to consider for this bill and group.

Ms. Herold wants to clarify specifics around this bill by those with expertise in this area, so that the board can properly enforce regulations for these sensitive patients. Ms Herold added that the board does not need to be the lead agency, but that we should participate. The committee indicated that they will need more information before taking a position on the bill.

Committee Recommendation: None – seeking more information

AB 2122 (Plescia) – Surgical Centers: Licensure

Ms. Sodergren noted that the bill is similar to AB 543 from 2006, which the board had supported. Ms. Sodergren explained that the bill standardizes the operating standards for a

surgical clinic, and would allow the board to issue a surgical clinic license to anyone who is accredited by an approved agency or is certified to participate in the Medicare program.

Dr. Graul asked if the bill cleared the bar that the Governor has set in his veto message, or whether the language is substantially different. Ms. Sodergren stated that the language is very similar to AB 543. Ms. Herold and Ms. Sodergren provided more clarification on the details of the bill. Dr. Weisser asked for clarification on language of “operation staffing” and acute facilities. Dr. Weisser stated his concern over an attempt by this bill to dictate staffing ratios in acute facilities.

Dr. Gray provided background on the bill with relation to licenses and staffing. Dr. Gray encouraged the board to support the bill.

Motion: Support AB 2122.

M/S: Graul/Dazé

Support: 4 Oppose: 0

AB 2425 (Coto) – Dept. of Public Health: Water Quality: Purity

Ms. Sodergren summarized the bill, which would require any pharmaceutical manufacturer doing business in California whose products have been detected in the drinking water, to file a report with the State Public Health Officer as specified. She explained that the intent is to determine how pharmaceuticals are entering the water supply and then what will be done to remove them. She noted that there is a six-year window for this process.

Ms. Herold noted that this bill was intended for information purposes.

Dr. Graul stated a concern with subsection b in regards to the methods of preventing the drugs from entering the water, as it is unclear how that will be identified. Ms. Sodergren responded that the intention is for the manufacturers to make recommendations on how to prevent residue from occurring.

Committee Recommendation: None

Public Requests for Future Legislation and Regulatory Proposals:

Heidi Barsuglia (CRA) asked the committee to put SB 1702 (Machado) on their watch list. She explained that it would trigger additional MediCal audits of any MediCal provider who supply a service or product to a certain percentage of out-of-county MediCal beneficiaries. Pharmacists are concerned that if they have patients near a county line, patients would be effected. The recommendation has been to address the issue as a “service area” instead.

Dr. Gray (Kaiser Permanente) asked the board to put AB 2661 on a watch list. He explained that this bill changes the definition of California law on telemedicine, and removes the exemption of phone calls. He stated that this would instead impose requirements on how telemedicine could be done, records kept, etc.

Phillip Swanger (CSHP) spoke regarding their sponsorship of AB 1947 (Emmerson). Mr. Swanger provided a brief history as well as an explanation for their language of the bill. He detailed the creation of a task force, and their development on addressing the requirements for

pharmacy technician training and education. Mr. Swanger reviewed issues determined by the task force, including having pharmacy technicians pass a certification exam, and completion of standardized training. CSHP is asking the board to consider co-sponsoring the bill to protect consumers.

Board Approved Regulations – Awaiting Notice (Status Update:)

Repeal of Title 16, CCR sections 1716.1 and 1716.2 and amendment to sections 1751-1751.8 and adoption of sections 1735-1735.8.

Ms. Sodergren stated that there was a vote on the compounding regulations at the January 2008 board meeting to do a 15-day notice, which has not yet been done.

Ms. Sodergren reviewed the regulations awaiting notice as:

Title 16 CCR section 1785 – Self-Assessment of a Veterinary Food-Animal Drug retailer.

Title 16 CCR section 1780 – Update the USP Standards Reference Material

Title 16 CCR section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Title 16 CCR sections 1721 and 1723.1 – Dishonest conduct during a Pharmacist's Licensure Examination/Confidentiality.

Ms. Sodergren noted that all of the regulations are awaiting notice, and that the specific language is provided.

Regulations Currently Noticed (Status Update)

Ms. Sodergren stated that the Disciplinary Guidelines are currently noticed, that the comment period was reopened until the regulation hearing, which will occur at the April Board Meeting.

Board approved – Regulation Language to be Developed

Ms. Sodergren explained that the language needs to be developed for the ethics course. She stated that the concept was approved at the board meeting in October 2007.

Chairperson Zinder adjourned the meeting at 12:08 p.m.

Attachment 2

*Revised Proposed Language for Requirements
for Pharmacies that Compound*

Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile Injectable Compounding; Compounding Area.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

(b) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- (6) A sink shall be included in accordance ~~in~~ with Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
- (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§~~1751.3.~~ 1751.1. Sterile Injectable Recordkeeping Requirements.

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, have make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
 - (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.
 - (3) Certification of the sterile compounding environment.
 - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
 - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
 - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years~~ Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

In addition to ~~existing labeling requirements~~ to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.02. 1751.3. Sterile Injectable Policies and Procedures.

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:
- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.
- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- (d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.

- (E) Personnel access and movement of materials into and near the controlled area.
- (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
- (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
- (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.
- (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- (J) Sterilization.
- (K) End-product evaluation and testing.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.01. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~ compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- (e) Pharmacies preparing parenteral cytotoxic agents shall be do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for

certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.1. Laminar Flow Biological Safety Cabinet.~~

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.~~

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.3. Recordkeeping Requirements.~~

- ~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~
- ~~(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
 - ~~(1) The training and competency evaluation of employees in sterile product procedures.~~
 - ~~(2) Refrigerator and freezer temperatures.~~~~

- ~~(3) Certification of the sterile compounding environment.~~
- ~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
- ~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
- ~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~

~~(e) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.
- (c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.5. 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
 - (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
 - (A) Aseptic technique.
 - (B) Pharmaceutical calculations and terminology.
 - (C) Sterile product compounding documentation.
 - (D) Quality assurance procedures.
 - (E) Aseptic preparation procedures.
 - (F) Proper gowning and gloving technique.
 - (G) General conduct in the controlled area.
 - (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
 - (I) Sterilization techniques.
 - (J) Container, equipment, and closure system selection.
 - (2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

~~Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.~~

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
- (1) Cleaning and sanitization of the parenteral medication preparation area.
 - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials ~~are~~ must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and

Attachment 3

*Proposed Addition to CCR §1785 – Self-
Assessment of a Veterinary Food-Animal Drug
Retailer*

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food-animal drug retailer permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-40 entitled "Veterinary Food-Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.

(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.



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STATE AND CONSUMERS SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

VETERINARY FOOD-ANIMAL DRUG RETAILER SELF ASSESSMENT

All legal references used throughout this self-assessment form are explained on Page 17
 All references to “drugs” throughout this self–assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&P) section 4022.
 (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals.

Definitions:

”Veterinary Food-Animal Drug Retailer” (vet retailer) is an area, place or premises, other than a pharmacy that holds a valid license from the California State Board of Pharmacy as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed Veterinarian. It is a separate and additional license from a wholesaler license. Veterinary food–animal drug retailer includes but is not limited to any area, place or premises described in a permit issued by the board wherein veterinary food-animal drugs (as defined in Business & Professions Code section 4042) are stored, possessed, or repackaged, and from which veterinary drugs are furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

“Veterinary Food–Animal Drugs” include any drug to be used in food-producing animals bearing the legend “Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian” or words of similar import. Also included is any drug as defined in Section 14206 of the Food and Agriculture Code that is used in a manner that would require a veterinary prescription.

Veterinary Food-Animal Drug Retailer Name _____

Address _____

Phone _____

E-mail address (optional) _____

Ownership: Please mark one

- Sole owner Partnership Corporation LLC
 Non-licensed owner other (please specify) _____

CA Veterinary Food-Animal Drug Retailer Permit # _____ Expiration Date _____

CA Wholesaler Permit # _____ Expiration Date _____

DEA Registration # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Daily _____ Sat _____ Sun _____ 24 hours _____

Designated representative-in charge (DRIC) /pharmacist (RPH) _____

DRIC License # / RPH License # _____ Expiration Date _____

Licensed Veterinary Food-Animal Drug Retailer Staff (designated representative (DRep,
pharmacist):

1. _____ DRep/RPH# _____ Exp. Date _____

2. _____ DRep/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

Review the current veterinary food-animal drug retailer permit for this business. Are the listed owners correct and is the listed address correct? If either is incorrect, notify the board in writing. (B&PC 4196 [a] [d])

Attach a copy of the notification letter to the board to this document.

CORRECTIVE ACTION OR ACTION PLAN _____

2. Facility

Yes No N/A

Are only pharmacists, intern pharmacists, designated representatives, and authorized officers of the law, or a person authorized to prescribe, permitted in the area place or premises described in the permit as a veterinary food-animal drug retailer without supervision? (B&P 4196[c])

Is a pharmacist or designated representative responsible for any person who enters the premises for clerical, inventory control, housekeeping, delivery, maintenance, or similar functions related to the business of a veterinary food animal drug retailer? (B&P 4196[c])

Are all veterinary food-animal drugs stored in a secure, lockable area? (B&P 4197[a][1])

Premises, Fixtures and equipment: (B&P 4197[a][2])

Fixtures and equipment -Clean and orderly

Premises - dry

Premises - well ventilated

Premises - Adequately lighting

CORRECTIVE ACTION OR ACTION PLAN _____

3. Designated Representative-in-Charge/Owner Responsibilities

Yes No N/A

Are the owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory? (B&P 4081[b])

Is the designated representative-in-charge responsible for the veterinary food-animal drug retailer's compliance with all state and federal laws related to practice as a veterinary food-animal drug retailer? (B&P 4196[d]).

Has the owner notified the board within 30 days of the termination of the designated representative-in-charge or pharmacist? (B&P 4305.5[a])

Has the owner identified and notified the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge? (B & P 4196[d], 4331[b]. The appropriate form for this notification is a "Change of Designated Representative-in-Charge", which is available on the board's web site.

Has any designated representative-in-charge who ends his or her employment at a wholesaler, notified the board within 30 days? (B & P 4305.5[c], 4101[b]. This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative/Pharmacist

Yes No N/A

Does your veterinary food-animal drug retailer operate only when a pharmacist or veterinary designated representative is on the premises? (4053[c])

Is the address of the veterinary designated representative(s) current on their printed permit? (B&P4100,1704)

If a veterinary designated representative or pharmacist changes his/her name or personal address of record, he/she will notify the board in writing within 30 days? (B&P 4100, CCR 1704)

A pharmacist or veterinary retailer designated representative only dispenses drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian? (CCR 1780.1[d])

Only a pharmacist or the veterinary designated representative receives an oral order for a veterinary food-animal drug from the veterinarian? (CCR 1780.1[d])

Yes No N/A

A written copy of any oral prescription is sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&P 4163[b], 4169)

CORRECTIVE ACTION OR ACTION PLAN _____

6. Receipt of Drugs by this Business

Yes No N/A

When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B&P 4059.5[a])

CORRECTIVE ACTION OR ACTION PLAN _____

7. Drug Stock

Yes No N/A

Is all drug stock open for inspection during regular business hours? (B&P 4081[a])

Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&P 4342[a])

If dangerous drugs, legend drugs or extra label use drugs are returned to the veterinary food-animal drug retailer from a client are they treated as damaged or outdated prescription drugs and stored in the quarantine area specified in California Code of Regulations section 1780(3)(1) and are not returned to stock, or dispensed, distributed or resold? (CCR 1780.1)

8. Prescription Dispensing

Yes No N/A

Are dangerous drugs and extra label use drugs for use on food producing animals dispensed to clients pursuant to a prescription written by a veterinarian? (CCR 1780.1[a][d])

Are dangerous drugs, and extra label use drugs prepared and labeled by a pharmacist or designated representative only? (CCR 1781.1[d])

A veterinarian's prescription for a food-producing animal can only be refilled if the initial prescription issued indicated a specific number of refills. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead a new prescription must be obtained from the veterinarian? (CCR 1780.1[g][1])

No veterinary food-animal drug prescriptions are refilled over six months from the date of issuance of the initial order? (CCR 1780.1[g][2])

Are prescriptions partially filled? If unable to fill the full quantity of drugs prescribed, fill and ship a portion of the order, so long as the full quantity is shipped within 30 days? (CCR 1780.1[j])

When partially filling a prescription, does the pharmacist or veterinary designated representative note the following information on the written prescription for each date the drugs are shipped: (CCR 1780.1[j])

Quantity shipped?

Date shipped?

Number of containers shipped?

If multiple containers, each container must be sequentially numbered?

If unable to fill the full quantity of a prescription within 30 days, has a new veterinarian's prescription been written to fill the remainder of the drugs originally prescribed? (CCR 1780.1[j])

9. Prescription Labeling

Yes No N/A

Does only a pharmacist or veterinary designated representative prepare and affix the label to a veterinary food-animal drug product?

Pursuant to a veterinarian’s prescription, are prescription labels affixed to all drug containers that include: (CCR 1780.1[h][1-14])

Active ingredients or the generic name(s) of the drug?

Manufacturer of the drug?

Strength of the drug dispensed?

Quantity of the drug dispensed?

Name of the client?

Species of food-producing animal for which the drug is described?

Condition for which the drug is prescribed?

Directions for use?

Withdrawal time?

Cautionary statements, if any?

Name of the veterinarian prescriber?

Date dispensed?

Name and address of the veterinary food-animal drug retailer?

Prescription number or another means of identifying the prescription?

If an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription? (container 1 of 6, container 2 of 6)

Manufacture’s expiration date?

CORRECTIVE ACTION OR ACTION PLAN _____

10. Repackaging

Definition - Repackaging within the meaning of B&P 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a) or extra label use drugs, so long as the seals on the individual containers are not broken.

Yes No N/A

Are only sealed original manufacturer’s containers labeled for distribution to clients? Veterinary retailers or wholesalers cannot open a container and count out or measure out any quantity of a dangerous legend or extra label use drug. (CCR 1780.1[b])

11. Sale or Transfer of Drugs by this Business

Yes No N/A

Are all dangerous drugs and extra label drugs that are sold, only sold pursuant to a prescription issued by a veterinarian to a veterinarian's client for use on food-producing animals? (CCR 1780.1[a])

No dangerous drugs or extra label drugs are sold, traded or transferred at wholesale by the veterinary retailers? (B&P 4041)

Are practices in place to prevent dangerous drugs from being sold, traded or transferred if the vet retailer or wholesaler knew or reasonably should have known the drugs were adulterated as defined by CA Health & Safety Code section 111250, misbranded as defined by CA Health & Safety Code section 111335, or beyond the use date on the label? (B&P 4169[a])

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

 Do your advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&P 4341, 4651, CCR 1766)

Do you offer any rebates, refunds, commissions or preferences, discounts, or other considerations for referring clients? If your business has any of these arrangements, please list with whom? (B&P 650)

If your business sells, transfers or delivers dangerous drugs outside of California, either to another state within the United States or a foreign country, do you comply with:

All CA pharmacy and veterinary laws related to the distribution of drugs?

The pharmacy law and veterinary laws of the receiving state within the United States?

The statutes and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration?

All laws of the receiving foreign country related to drugs for food producing animals?

Yes No N/A

All applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a client in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&P 4059.5[e])

CORRECTIVE ACTION OR ACTION PLAN _____

12. Delivery of Drugs

Yes No N/A

Upon delivery of appropriately labeled prescription drugs or extra label drugs to a client, pursuant to a veterinarian’s prescription, do you obtain the signature of the client, or the client’s agent, on the invoice with notations of any discrepancies, corrections or damage? (CCR 1780.1[k])

CORRECTIVE ACTION OR ACTION PLAN _____

13. Controlled Substances

Yes No N/A

If a controlled substance is dispensed, are the labels on the containers countersigned by the prescribing veterinarian before being provided to the client? (CCR1780.1[e])

Note: Please refer to “Controlled Substances” section of the Wholesaler Self Assessment for additional controlled substance statutes, regulations, and requirements your business must follow

CORRECTIVE ACTION OR ACTION PLAN _____

14. Consultant Pharmacist

Yes No N/A

Does your consulting pharmacist assure compliance with all statutes and regulations governing veterinary food-animal drug retailers? (B&P 4198[e])

Yes No N/A

Does your consultant pharmacist visit routinely, but at least quarterly? (B&P 4198[e])

Does your consultant pharmacist: (B&P 4198[e])

Review and revise policies and procedures?

Assure compliance with state and federal statutes and regulations for labeling, storage and dispensing of veterinary food-animal drugs?

Provide a written report twice yearly certifying whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter?

Are these written reports readily available for inspection upon request?

CORRECTIVE ACTION OR ACTION PLAN _____

15. Designated Representative Training.

Yes No N/A

Does your business prepare and maintain records of training and demonstrated competence for each individual employed or retained by you? (B&P 4198[b])

Are records of training and demonstrated competence for each employee maintained for 3 years after the last date of employment? (B&P 4198[b])

CORRECTIVE ACTION OR ACTION PLAN _____

16. Quality Assurance Program

Does your business have an ongoing, documented quality assurance program, which includes but is not limited to: (B&P 4198 [c])

Yes No N/A

Monitoring personnel performance?

Storage of veterinary food-animal drugs?

Maintenance of equipment?

Dispensing of veterinary food-animal drugs?

CORRECTIVE ACTION OR ACTION PLAN _____

17. Policies and Procedures

Does your business maintain and adhere to policies and procedures for: (B&P 4198)

Yes No N/A

- Handling of veterinary food animal drugs?
- Dispensing of veterinary food animal drug?
- Staff training records?
- Cleaning of equipment?
- Storage and maintenance of veterinary food –animal drugs?
- Storage and maintenance of equipment?
- Record keeping requirements?
- Storage requirements?
- Security requirements?
- Quality assurance?

CORRECTIVE ACTION OR ACTION PLAN _____

18. Record Keeping Requirements

Purchase and Sales Records

Yes No N/A

- Are all records of acquisition and disposition of dangerous drugs, retained on the premises, open for inspection, during regular business hours? (B&P 4081, 4332, CCR 1718)
- Are all prescription documents and other disposition records for dangerous drugs or extra label use drugs dispensed by a vet food-animal drug retailer kept on file and maintained on the premises for 3 years? (B&P 4198[b])
- Are all records of prescription refills retained by your business on the premises for 3 years? (CCR1780.1[I], B&P 4081[a], 4332)
- Are all purchase and sales records retained in a readily retrievable form? (B&P 4105[a])

Yes No N/A

- Are records of shipment of labeled dangerous drugs to clients (also known as an expanded invoice) included in the client’s shipment? This document includes: (CCR1780.1[i])
 - Drug name?
 - Quantity shipped?
 - Manufacturer’s name and lot number?

Yes No N/A

Date of shipment?

Name of the pharmacist or vet retailer exemptee who is responsible for the distribution?

Are copies of the records of shipment (also known as the expanded invoice) distributed to the prescribing veterinarian? (CCR 1780.1 [i])

Are copies of the records of shipment (also known as the expanded invoice) of labeled dangerous drugs retained by your business for 3years? (CCR 1780.1[I])

Inventory

Yes No N/A

Is a current, accurate inventory maintained for all dangerous drugs (B&P 4081[a], CCR 1718)

Consultant Pharmacist

Yes No N/A

Are consultant pharmacist semi-annual reports retained by your business for 3 years from the making? (B&P 4198 [e])

Quality Assurance

Yes No N/A

Is quality assurance documentation retained for 3 years from the making? (B&P 4198[d])

Policies and Procedures

Yes No N/A

Are all policies and procedures specified in section 4198(a) maintained for 3 years from the making? (B&P 4198(b))

Are all policies and procedures, documents related to the quality assurance program, and all records of employee training and demonstrated competency open for inspection by authorized officers of the law? (B&P 4198[b])

Temporary removal of records

Yes No N/A

If you temporarily remove purchase or sales records from your business, does your business retain, on your licensed premises at all times, a photocopy of each record temporarily removed? (B&P 4105[b])

Off-site storage waiver

Yes No N/A

Are required records stored off-site only if a board issued written waiver has been granted? (CCR 1707[a])

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below: (CCR 1707[a])

Yes No N/A

If an off-site written waiver is in place, is the storage area secure from unauthorized access? (CCR 1707[b][1])

If an off-site waiver is in place, are the records stored off-site retrievable within 2 business days? (1707[b][1])

CORRECTIVE ACTION OR ACTION PLAN _____

19. Reporting Requirements to the Board

Ownership

Yes No N/A

I understand this veterinary retailer license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted, in addition to an application for a permanent new permit, to the board, if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (B&P 4201[h][I], 4196[b], CCR 1709[b])

Are transfers, in a single transaction or a series of transactions, of 10% or more of the beneficial interest in a business licensed by the board to a person who did not hold beneficial ownership interest at the time of the initial permit was issued, reported in writing to the board within 30 days of the transaction? (CCR 1709[b])

Any transfer of a beneficial interest in a business licensed by the board, in a single transaction or series of transactions, to a person or entity, which results in the transferee holding 50% or more shall constitute of change of ownership and an application must be submitted to the board for a change of ownership. (CCR 1709 [c])

Yes No N/A

When called upon by an inspector, can the business owner or manager, produce information indicating the names of the business owners, managers and employees and a brief statement of the capacity for each person employed by the business? (B&P 4082)

Veterinarian

Yes No N/A

Whenever a veterinary designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, or extra label use drugs prescribed by multiple veterinarians, does the veterinary designated representative contact the prescribing veterinarians for authorization before dispensing any drugs? (CCR 1780.1[f])

Are copies of expanded invoices, documenting sales of dangerous drugs, distributed to the prescribing veterinarian within 72 hours of dispensing? (CCR 1780.1[I]).

Is a written copy of any oral prescription received by either a pharmacist or designated representative of the veterinary food-animal drug retailer sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

Consultant Pharmacist

Yes No N/A

Does the consultant pharmacist provide written certification every 6 months that your business is or is not in compliance with all applicable statutes and regulation? (B&P 4198[e])

Does your business submit the most recent consultant pharmacist report with the annual application to renew the veterinary food-animal drug retailer license with this board? (B&P 4198[e])

Designated Representative in Charge/ Designated Representative

Yes No N/A

If a designated representative-in-charge terminates employment at this business, does the business notify the board within 30 days of the termination? (B&P 4101[b], 4305.5[c])

When a veterinary designated representative leaves the employ of a veterinary food-animal drug retailer, would the business owner immediately return the exemptee license to the Board of Pharmacy? (CCR 1780.1[I])

When a designated representative in charge terminates employment at this business, does the designated representative in charge notify the board within 30 days of the termination.? This requirement is in addition to the requirement for the owner to notify this board. (B&P 4101[c])

Discontinuation of Business

Yes No N/A

I understand if this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business? (CCR 1708.2).

I understand the owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs? (CCR 1705)

Controlled substances (if applicable)

Yes No N/A

Does the owner report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs? (CCR 1715.6)

Does the owner notify the DEA, on a DEA form 106, of any theft or significant loss of controlled substances upon discovery? (CFR 1301.74[c])

Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

Yes No N/A

If the business holds a DEA registration, does the owner understand the requirement to notify the DEA promptly of the discontinuation of the business and all unused DEA 222 order forms must be returned to the DEA? (CFR1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

20. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesaler licenses held in other states, permits or licenses required by foreign countries or other entities (B&P 4107, 4059[a], CFR 1305.11[a])

Designated Representative-in-Charge/Pharmacist Certification:

DESIGNATED REPRESENTATIVE-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this veterinary food-animal drug retailer of which I am the designated representative-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Designated Representative-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&P], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index*.

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index*.

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

Bureau of Narcotic Enforcement
Security Prescription and CURES Programs
1102 Q Street, 6th Fl.
Sacramento, CA 95817
(916) 319-9062
Fax: (916) 319-9448
<http://www.ag.ca.gov/bne>

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
www.lawtech-pub.com

CURES Patient Activity Report Request Forms:
<http://www.ag.ca.gov/bne/trips.php>

PRESCRIBER BOARDS:

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
Fax: (916) 263-2387
<http://www.mbc.ca.gov>

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
Phone: (888) 539-3370
Fax: 877-508-6704

Dental Board of California

1432 Howe Ave. #85
Sacramento, CA 95825
(916) 263-2300
fax: (916) 263-2140
<http://www.dbc.ca.gov>

Board of Registered Nursing

1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-8637
<http://www.rn.ca.gov/>

Board of Optometry

2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
<http://www.optometry.ca.gov/>

Osteopathic Medical Board of California

2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
<http://www.ombc.ca.gov>

Physician Assistant Committee

1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 561-8780
fax: (916) 263-2671
<http://www.physicianassistant.ca.gov>

Board of Podiatric Medicine

1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

1420 Howe Avenue, #6
Sacramento, CA 95825
(916) 263-2610
fax: (916) 263-2621
<http://www.vmb.ca.gov>

FEDERAL AGENCIES:**Food and Drug Administration
– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website:

<http://www.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>

**Online DEA 222 Controlled Substance
Ordering System (CSOS):**

<http://www.deaecom.gov/>

DEA - Fresno

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (510) 637-5600

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (909) 328-6000 or
(909) 328-6200

DEA - Sacramento

4328 Watt Avenue
Sacramento CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7100 or
(916) 480-7250

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

**Title 16. Board of Pharmacy
Proposed Language**

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.~~

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

- (a) "Reasonable quantity" means that quantity of an unapproved drug which:
 - (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
 - (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1716.2. Record Requirements—Compounding for Future Furnishing.~~

- (a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:
 - (1) The date of preparation.
 - (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
 - (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
 - (4) The signature or initials of the pharmacist performing the compounding.
 - (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.
 - (6) The name(s) of the manufacturer(s) of the raw materials.

- (7) ~~The quantity in units of finished products or grams of raw materials.~~
- (8) ~~The package size and the number of units prepared.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

Article 4.5 Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies

- (a) “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
 - (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
- (b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- (c) “Compounding” does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

- (d) “Strength” means amount of active ingredient per unit of a compounded drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
- (c) Pursuant to Business and Professions Code section 4052(a)(1), a “reasonable quantity” of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where “reasonable quantity” is that amount of compounded drug product that:
- (1) is sufficient for administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber’s practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
- (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post-compounding process or procedures required, if any.
 - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products

- (a) For each compounded drug product, the pharmacy records shall include:
 - (1) The master formula record.
 - (2) The date the drug product was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug product.
 - (4) The identity of the pharmacist reviewing the final drug product.
 - (5) The quantity of each component used in compounding the drug product.

- (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
 - (7) The equipment used in compounding the drug product.
 - (8) A pharmacy assigned reference or lot number for the compounded drug product.
 - (9) The expiration date of the final compounded drug product.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
 - (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
 - (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
 - (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.
- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Attachment 4

*Proposed Amendment to 16 CCR §1751.8 –
Accreditation Agencies for Pharmacies that
Compound Injectable Sterile Drug Products*

Board of Pharmacy
Specific Language to Add Section 1751.8

Add Section 1751.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

- (a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:
 - (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.
 - (2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.
 - (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.
 - (4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).
 - (5) The accrediting agency is able to accredit California and non-resident pharmacies.
- (b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.
- (c) The board shall consider the length of time the agency has been operating as an accrediting agency.
- (d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.
- (e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.
- (f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.
- (g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an

approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Attachment 5

*Proposed Amendment to 16 CCR §§1721 and
1723.1 – Dishonest Conduct on a Pharmacist
Licensure Examination/Confidentiality*

**Board of Pharmacy
Specific Language**

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

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

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.