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

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: September 22, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621

Workgroup Members: Ken Schell, Pharm.D., Chair
John Tilley, R.Ph.

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General

Call to Order/Introductions

Chair of the workgroup, Dr. Schell, called the meeting to order at 1:30 p.m. Individuals attending the meeting were all invited to participate and were asked to introduce themselves.

Dr. Schell stated that this is the third meeting of the workgroup. He acknowledged and thanked the participants for their commitment and involvement. While the workgroup was initially formed in part to respond to a request from the Department of Health Services to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer, it is the board's goal to work with the compounding profession in trying to respond to the request from DHS as well as to identify "gaps" in pharmacy law related to pharmacy compounding, and to address them.

General Compounding Proposal

Board Supervising Inspector Dennis Ming and Chief of Legislation and Regulation Paul Riches presented a concept proposal on general compounding. Dr. Ming explained that the concept draft was developed by he and Mr. Riches using documents prepared by the law subcommittee formed from this workgroup, compounding guidelines from the National Association of Boards

of Pharmacy (NABP), compounding requirements developed by the Texas State Board of Pharmacy, and California pharmacy law(s).

The workgroup discussed the concept draft and provided suggestions to clarify various provisions. Mr. Riches requested that any additional comments be provided by November 1st.

Subcommittee on Law - *Compounding versus Manufacturing*

The subcommittee on law presented their draft revisions of compounding guidelines that the Board of Pharmacy adopted in 1995. These guidelines were developed using the FDA Compliance Policy Guides in effect at the time and their original purpose was to provide the factors to be considered by board inspectors that may suggest that a pharmacy that claims to be compounding may actually be engaged in manufacturing.

The workgroup reviewed the subcommittee's revisions to the factors. It was noted that the general concept draft developed by Dr. Ming and Mr. Riches includes a definition of compounding, which currently is not defined in pharmacy law. The concept draft also requires that the pharmacist have a professional relationship with both the prescriber and the patient. Moreover, the general compounding draft addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), recordkeeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug, and requirements for facilities and equipment. The concept draft also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications. There also was discussion regarding the compounding of OTC products and whether a prescription is required. It is the board's position that a prescription would be required whenever a pharmacy compounds a drug product. A drug product is defined broadly enough to include OTC compounding.

In response to questions about the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s), it was explained to the workgroup that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer. It was noted that compounding is included in the definition of manufacturing but a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner). Because the FDA is concerned with public safety, it is reassessing pharmacy compounding.

The board is seeking to establish guidelines that provide uniformity in compounding in California. Better definition and regulation of the practice of compounding is primarily for the purpose of public safety. It may also solidify the role of compounding in pharmacy practice, and thereby diminish the likelihood that pharmacies compounding within their practice of pharmacy will be required to register as manufacturers. However, the board can offer no such guarantee.

Moreover, counsel advised that the proposed "factors" for distinguishing compounding from manufacturing would at best be considered "guidelines," and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

It was reiterated during the meeting that the Board of Pharmacy's priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. It would appear that the general compounding draft provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.

Next Meeting Date

Dr. Schell stated that the next meeting date for the Workgroup on Compounding is December 1, 2004, in Burbank.

Adjournment

Dr. Schell thanked the participants for attending and adjourned the meeting at 4:00 p.m.