California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: December 1, 2004

TIME: 10:00 a.m. – 12:30 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019

Workgroup Members: Ken Schell, Pharm.D., Chair

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

The meeting was called to order at 10:00 a.m. Meeting participants introduced themselves.

It was reported that this was the final meeting of the workgroup. A draft proposal on general compounding was provided. It contained proposed statutory and regulatory language to define general compounding, which currently is not defined in pharmacy law. It also establishes the requirements for all pharmacies that compound drug products. It requires that the pharmacist have a professional relationship with both the prescriber and the patient. The proposal also addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug product, and requirements for facilities and equipment. The proposal also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications. One section that will be added to the proposal will be a recall process should the compounded drug product be misbranded, adulterated, or potential to harm a patient.

Dr. Schell acknowledged the participants and thanked them for their commitment and involvement. While the workgroup was initially formed in part to respond to a request from the Department of Health Services (DHS) to identify the criteria used by the board to determine

when a compounding pharmacy should be considered a manufacturer, it was 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.

Dr. Schell stated that the purpose of this final meeting was to review the proposed draft, discuss questions and comments, and to revise the draft accordingly. In the afternoon, Dr. Schell would present the proposal to the Licensing Committee with the request that the committee recommend to the Board of Pharmacy that it support the general compounding proposal. The board will review this request at its January meeting. If the board approves the recommendation, then the intent is to sponsor legislation in 2005. Dr. Schell explained that throughout this process, interested parties have the opportunity to comment on the proposal.

General Compounding Proposal

Board Supervising Inspector Dennis Ming and Deputy Attorney General Joshua Room reviewed the general compounding proposal. The workgroup discussed the proposal and comments were noted. It was suggested that the definition be clarified regarding the reconstitution of a drug product according to the manufacturers' directions, the use of flavoring and whether the compounding of over-the-counter (OTC) products requires a prescription. (It is the board's position that any compounding by a pharmacy requires a prescription.)

Another concern raised was the proposed amendment to Business and Professions Code section 4123 regarding the authority for a pharmacy to contract with another pharmacy to a compound a drug. The language would allow for a pharmacy to contract with another pharmacy for the purpose of delivering a compounded drug product to another pharmacy pursuant to a prescription, provided that the drug is not compounded prior to the receipt of the prescription.

Many of the workgroup participants recommended that the proposed language allow for the contract pharmacy to compound drug products in anticipation of receiving a prescription. It was argued especially in the hospital setting. It was stated that since the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) adopted the newly revised USP 797 on sterile compounding, many pharmacies plan to centralize their compounding facilities and for good patient care; pharmacies must have the ability to compound in anticipation of some prescriptions in order to furnish the need medication timely.

The workgroup reviewed the proposal and provided comments.

Adjournment

Dr. Schell thanked the participants for attending. He stated that a copy of the revised proposal will be provided to the workgroup members in early January. Dr. Schell adjourned the meeting at 12:30 p.m.