New Mexico Board of Pharmacy Regular Board Meeting
January 9 & 10, 2006

Monday, January 9, 2006

PLACE AND TIME: The meeting was held at the Pharmacy Board Conference Room at 5200 Oakland Ave., Albuquerque, NM.

CALL TO ORDER: The meeting was called to order by the Chairman, Woodrow Storey, R.Ph., at 9:00am

MEMBERS PRESENT:
Woodrow Storey, R.Ph., Chairman
Danny Cross, R.Ph., Secretary (Monday Only)
Amy Buesing, R.Ph., Vice-Chairman
Tom Ortega, R.Ph., Member (Monday Only)
Howard Shaver, Public Member
Brenda Padilla, R.Ph., Member
Rudy Nolasco, R.Ph., Member
Allen Carrier, Public Member

MEMBERS ABSENT:
Buffie Saavedra, Public Member
(9:00am – 12:45pm Monday Only)
Tom Ortega, R.Ph., Member (Tuesday Only)
Brenda Padilla, R.Ph., Member

STAFF ATTENDING:
Kathy Kunkle, Assistant Attorney General
William Harvey, Executive Director
Debra Wilhite, Administrative Assistant
Larry Loring, Inspector
Mike Lyons, Inspector
Ben Kesner, Inspector
Bill Weast, Inspector

APPROVAL OF THE AGENDA:

Mr. Harvey stated that an updated agenda was handed out to all Board members and put on the table for the public. Mr. Storey asked if there were any changes or additions. Mr. Harvey stated the following changes; Compounding of Non-Sterile Pharmaceuticals was moved from Tuesday November 10, 2006 to Monday January 9, 2006 at 2:30pm and on Tuesday January 10, 2006 the Executive Directors Report was moved up to 10:30am from 1:00pm. Under the Executive Directors Report case numbers 2003-093, 2005-089, 2005-119, 2005-070, 2005-077, 2005-101, 2005-117, were added and letters "l" Schering Report 25th Anniversary, and "m" correspondence from HDMA.

Motion:

A motion was made by Mr. Storey, seconded by Ms. Buesing to accept the agenda as presented with additions. The Board voted unanimously to pass the motion.

APPROVAL OF THE NOVEMBER 14 & 15, 2005 MEETING MINUTES:

Mr. Storey asked if the Board members had any changes to the minutes. The board stated that there were no changes.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Nolasco to approve the minutes for the November 14 & 15, 2005 Board Meeting. The Board voted unanimously to pass the motion.

APPROVAL OF THE DECEMBER 8, 2005 MINUTES:

Mr. Story asked if the Board members had any changes to the minutes. The board stated that there were no changes.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the minutes for the December 8, 2005 Special Meeting. The Board voted unanimously to pass the motion.

EXECUTIVE DIRECTOR'S REPORT:

Mr. Harvey presented correspondence from the HDMA regarding the licensing of prescription drug distributors. Mr. Harvey briefly discussed the belief the HDMA has in providing the FDA with the authority to license prescription drug distributors and have an optional role for states to inspect facilities. FYI item, no action was taken.

Mr. Harvey suggested that case presentations be addressed at this time.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to go into closed session to hear case presentation. The Board voted unanimously to pass the motion.

Mr. Ortega was in attendance of the Board meeting at 9:30 a.m.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to go back into open session and all that was discussed were the case presentations. The Board voted unanimously to pass the motion.

Mr. Harvey introduced the current intern, Katie Gruchalla, to the Board. Mr. Harvey stated that there were a few other students in attendance at the Board meeting.

REGULATION HEARING – 16.19.28 NMAC - CONTACT LENS SELLERS:

The Chairman opened the hearing at approximately 9:35 a.m. Mr. Cross read the proposed changes aloud to the Board. The proposed changes are as follows:

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 28 SELLER OR DISPENSER OF CONTACT LENSES (EXCLUDING LICENSED OPTOMETRISTS AND PHYSICIANS)

16.19.28.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy. [~~Albuquerque, NM 87102, (505) 841-9102.~~]
[16.19.28.1 NMAC - N, 12-01-2003; A, 1/18/06]

16.19.28.2 SCOPE: All persons or entities selling or dispensing contact lenses pursuant to a valid prescription to patients in New Mexico.
[16.19.28.2 NMAC - N, 12-01-2003]

16.19.28.3 STATUTORY AUTHORITY: The board of pharmacy is authorized pursuant to the Optometry Act, Section 61-2-1 through Section 61-2-18 NMSA 1978 (1997 Repl. Pamp.) to register sellers or dispensers of contact lenses and collect a fee for registration.
[16.19.28.3 NMAC - N, 12-01-2003]

16.19.28.4 DURATION: Permanent
[16.19.28.4 NMAC - N, 12-01-2003]

16.19.28.5 EFFECTIVE DATE: December 1, 2003 unless a different date is cited at the end of a section.
[16.19.28.5 NMAC - N, 12-01-2003]

16.19.28.6 OBJECTIVE: The objective of Part 28 of Chapter 19 is to establish the registration of sellers or dispensers of contact lenses.
[16.19.28.6 NMAC - N, 12-01-2003]

16.19.28.7 DEFINITIONS:

A. "Board" means the New Mexico board of pharmacy, herein referred to as the board.

B. "Optometry Act" means NMSA 1978 Section 61-2-1 through 61-2-18 (1995 Repl. Pamp.), herein referred to as the Optometry Act or Section 61-2-1 et seq.

C. "Contact lens prescription" means a prescription that shall explicitly state that it is for contact lenses: specify the lens type: include all specifications for the ordering and fabrication of the lenses: include the date of issue, the name and address of the patient and the name and address of the prescriber: and indicate a specific date of expiration, which shall be twenty-four months from the date of the prescription, unless, in the professional opinion of the prescriber, a longer or shorter expiration date is in the best interest of the patient.

D. "Replacement contact lens prescription" means a prescription prepared by a licensed optometrist containing the information specified in this section and written expressly for the purpose of providing lenses that have already been properly fitted.

E. "Contact Lens" means any contact lens for which state law requires a prescription.

F. "Dispensing Facility" means the building or structure from which contact lens are stored, shipped or distributed.

G. "Seller/Dispenser" means one who is in the business of the sale or distribution of contact lenses.
[16.19.28.7 NMAC - N, 12-01-2003; A, 1/18/06]

16.19.28.8 REGISTRATION:

A. A person who is not a licensed optometrist or a licensed physician shall not sell or dispense a contact lens to a resident of this state unless he is registered with the board of pharmacy.

B. Pharmacies, hospitals and clinics licensed by the board are exempt from this regulation.

C. Registration will be submitted in forms provided by the board with the appropriate fee attached as a check or money Order.

D. Fees for registration are listed in 16.19.12 NMAC.

E. Period of registration is for two years with renewals due by the last day of the expiration month listed on the registration.

F. Refer to NMSA 1978, Section 61-11-14F for application requirements.
[16.19.28.8 NMAC - N, 12-01-2003; A, 1/18/06]

16.19.28.9 POLICY MANUAL: A policy manual containing at a minimum the information listed below shall be submitted with the registration application. **The initial manual must be approved by the board or its' agent. Subsequent changes or modifications require approval of the board or its' agent.**

A. A contact lens may not be sold, dispensed, or distributed to a patient in this state by a seller of contact lenses unless one of the following has occurred:

(1) the patient has given or mailed the seller an original, valid, unexpired written contact lens prescription:

(2) the prescribing licensed optometrist has given, mailed or transmitted by facsimile transmission a copy of a valid, unexpired written contact lens prescription to a seller designated in writing by the patient to act on the patient's behalf; or

(3) the prescribing licensed optometrist has orally or in writing verified the valid, unexpired prescription to a seller designated by the patient to act on his behalf.

B. The prescription contains all the information necessary for the replacement contact lens prescription to be properly dispensed, including the;

(1) lens manufacturer:
(2) type of lens:
(3) power of the lens:
(4) base curve:
(5) lens size:
(6) name of the patient:
(7) date the prescription was given to the patient:
(8) name and office location of the licensed optometrist who writes the replacement contact lens prescription; and
(9) expiration date of the replacement contact lens prescription.

C. A person other than a licensed optometrist or physician who fills a contact lens prescription shall maintain a record of that prescription for [~~five~~]**three** years.

D. Security Requirements: Restricting access, to all lenses and patient health records, to authorized personnel only.

E. Storage Requirements: The registrant must have policies and procedures for maintaining the proper storage conditions for contact lenses. The lenses must be stored at the licensed location.
[16.19.28.9 NMAC - N, 12-01-2003; A, 1/18/06]

16.19.28.10 REGISTRATION LIST: The board shall maintain a current list of all registered sellers and dispensers of contact lenses.
[16.19.28.10 NMAC - N, 12-01-2003]

The Chairman called for a five-minute recess to address technical difficulties with the overhead projector.

RECESS:

RECONVENE:

The Chairman reconvened at 9:45 a.m.

Discussion was held regarding the language and amendments to 16.19.28 NMAC. Under 16.19.28.1, the address and phone number have been deleted. Under 16.19.28.7, letters "E", "F", and "G" have been added. The language under 16.19.28.7, letter "F" should read, "Dispensing Facility means the building or structure from which contact lens are stored, shipped or distributed." Under 16.19.28.8, letter "F" has been added. Under 16.19.28.9, "Policy Manual"

language has been added and should read, "The initial manual must be approved by the Board or its' agent. Subsequent changes or modifications require approval of the board or its' agent." Under 16.19.28.9, letter "C", the word "five" has been deleted and replaced with the word "three", letters "D" and "E" have been added. "Violation Penalties" 16.19.28.11, has been deleted.

Motion:

A motion was made by Mr. Shaver, seconded by Ms. Buesing to approve the rule as amended. The board voted unanimously to pass the motion.

PROPOSED REGULATION HEARING - 16.19.6.25 - CENTRALIZED PRESCRIPTION DISPENSING:

Mr. Cross read the proposed rule to the Board, the proposed rule reads as follows:

16.19.25 Centralized Prescription Dispensing

Purpose: The purpose of these regulations is to provide mandatory standards for centralized prescription dispensing by a retail or nonresident pharmacy.

Definitions as used in this section:

A. "Centralized Prescription Dispensing" means the dispensing or refilling of a prescription drug order by a retail or nonresident pharmacy.
B. "Dispensing" as defined in the NMSA, section 61-11-2 (I), and pursuant to 61-11-21(C) dispensing is limited to a registered pharmacist.

Operational Standards

A. Minimum requirements:
    1) A retail pharmacy may outsource prescription drug order dispensing to another retail or nonresident pharmacy provided the pharmacies:
        a) have the same owner; or
        b) have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and
        c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or process a prescription drug order.

    2) The pharmacist-in-charge of the dispensing pharmacy shall ensure that:
        a) the pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and
        b) the dispensed prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.
    3) A retail or nonresidential dispensing pharmacy shall comply with the provisions of 16.19.6 and this section. .

B. Notifications to patients:
   1) A pharmacy that out-sources prescription dispensing to another pharmacy shall:
      a) Prior to outsourcing the prescription, notify patients that their prescription may be outsourced to another pharmacy; and
      b) Prior to outsourcing the prescription, give the name of that pharmacy or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may dispense the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through the use of a sign in the pharmacy; and
      c) If the prescription is delivered directly to the patient by the dispensing pharmacy upon request by the patient and not returned to the requesting pharmacy, the pharmacist employed by the dispensing pharmacy shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, and: (1) of his or her right to request counseling; and (2) a toll-free telephone number from which the patient or patient's agent may obtain oral counseling from a pharmacist who has ready access to the patient's record. For pharmacies delivering more than 50% of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than 6 days per week. The facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

C. Prescription Labeling. The dispensing pharmacy shall:
   1) place on the prescription label, the name and address or name and pharmacy license number of the pharmacy dispensing the prescription and the name and address of the pharmacy which receives the dispensed prescription;
   2) indicate in some manner which pharmacy dispensed the prescription (e.g.,"Filled by ABC Pharmacy for XYZ Pharmacy"); and
   3) comply with all other prescription labeling requirements.

D. Policies and Procedures. A policy and procedure manual as it relates to centralized dispensing shall be maintained at both pharmacies and be approved by the board or its' agent and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

   1) outline the responsibilities of each of the pharmacies;

   2) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription dispensing; and

   3) include policies and procedures for:
      a) notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription dispensing and providing the name of that pharmacy;
      b) protecting the confidentiality and integrity of patient information;
      c) dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

d) complying with federal and state laws and regulations;
e) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;
f) procedure identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications to the prescription record or patient profile, and the final check of the completed prescription;
g) identify the pharmacist responsible for counseling the patient pursuant to the requirements of 16 NMAC 19.4.16; and
h) annually reviewing the written policies and procedures and documenting such review

Records

A. Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:
   1) the records maintained in the alternative system contain all of the information required on the manual record; and
   2) the data processing system is capable of producing a hard copy of the record upon request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies within 48 hrs.

B. Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy and each pharmacist's or technician's involvement.

C. The requesting pharmacy shall maintain records which indicate the date:
   1) the request for dispensing was transmitted to the dispensing pharmacy; and
   2) the dispensed prescription was received by the requesting pharmacy, including the method of delivery (e.g., private, common, or contract carrier) and the name of the person accepting delivery.

D. The dispensing pharmacy shall maintain records which indicate:
   1) the date the prescription was shipped to the requesting pharmacy;
   2) the name and address where the prescription was shipped; and
   3) the method of delivery (e.g., private, common, or contract carrier).

Discussion was held regarding the language and changes to 16.19.6.25 NMAC. The changes are as follows:

Under 16.19.6.25, "Purpose" the word theses should be spelled "these" and no comma after retail. The wording in 16.19.6.25(A)(c) has an "a" after the word or and before the word process that will be deleted. The entire sentence under 16.19.6.25(A)(4) will be deleted. Under 16.19.6.25(B)(1)(c) sentence (2) the word "of" after number and before which will be replaced by the word "from". Under 16.19.6.25(D) the wording "and be available for" after pharmacies and before inspection will be replaced with "and be approved by the board or its' agent and be available for". The regulation will be formatted which will entail re-lettering and re-numbering to meet the requirements of the state.

Changes were made during the Board meeting on the overhead projector.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Cross to approve the changes and deletions made on 16.19.6.25 NMAC. The Board voted unanimously to pass the motion.

Dale Tinker was in the audience and stated that he and his organization are in support of the proposed rule, 16.19.6.25 NMAC.

After brief discussion the Board recommended to form a committee to draft language separate from this rule that would cover hospitals. The committee will include Ms. Amy Buesing and Mr. Phil Saucedo.

The Chairman called for a brief recess.

RECESS:

RECONVENE:

The Chairman reconvened at 11:00 a.m.

The Chairman called to go into closed session at 11:05 a.m. to complete the case presentations.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Shaver to go into Executive Session to hear case presentations. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Buesing to go back into open session and all that was discussed were the case presentations. The Board voted unanimously to pass the motion.

RECESS FOR LUNCH:

RECONVENE, MONDAY JANUARY 9, 2006:

The Chairman took role call at 12:45 p.m. and stated that Mr. Carrier was present but stepped out of the room briefly, that Ms. Saavedra was on her way down from Santa Fe, and that Ms. Padilla was absent and excused.

DANIEL HALL - SETTLEMENT AGREEMENT:

The Chairman stated that a settlement agreement for Daniel Hall was next for review by the Board. Ms. Francine Cordova presented the settlement agreement to the Board.

Mr. Storey asked Mr. Hall if he would like to address the Board. Mr. Hall stated that he was not too clear on the request. Mr. Storey asked Assistant Attorney General, Kathy Kunkel to clarify the request for Mr. Hall. Ms. Kathy Kunkel explained to Mr. Hall his rights in regards to the settlement agreement. Mr. Hall stated that the settlement agreement would give him the opportunity to walk the straight and narrow.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to accept the settlement agreement in the matter of Daniel Hall, R.Ph. case #2004-047. The Board voted unanimously to pass the motion.

REGULATION HEARING 16.19.20.68 - ADDITION OF TRAMADOL SCHEDULE IV - POSTPONED UNTIL MARCH BOARD MEETING:

Mr. Harvey stated that Johnson & Johnson had asked the Board for more time to prepare, therefore being postponed until March 2006 Board Meeting.

***CASE #2005-109 RECONSIDERATION OF ORDER TO SHOW CAUSE:**

The Chairman asked Mr. Harvey if case #2005-109 was an open or closed session item. Mr. Harvey stated that he would present case #2005-109 in public and Ms. Kunkel conferred to do so, as long as the individual is not identified.

Mr. Harvey asked the Board, to reconsider the order to show cause for case #2005-109 because he has been in communication with this practitioner and the practitioner is in agreement to modify the doctor's order with the Osteopathic Board. Mr. Harvey stated that the Osteopathic Board attorney and the Pharmacy Board attorney were the same, and that the order to show cause could be rescinded and a new modified stipulated order could be presented that would reflect the requests of both the Osteopathic and Pharmacy Board.

Ms. Kunkle stated that she felt that once the order was amended that this could be workable for both boards.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Buesing to rescind the order to show cause in the matter of case #2005-109. The Board voted unanimously to pass the motion.

PROPOSED REGULATION DISCUSSION– 16.19.30 NMAC – COMPOUNDING OF NON-STERILE PHARMACEUTICALS;

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 30 COMPOUNDING OF NON-STERILE PHARMACEUTICALS

16.19.30.6 OBJECTIVE: The objective of part 30 of chapter 19 is to provide standards for the compounding of non-sterile pharmaceuticals. Pharmacies compounding non-sterile pharmaceuticals shall comply with the requirements of this section in addition to all provisions for their specific license classification. **(61.11.2.BB, 61.11.2.C, 26.1.16.B)**

16.19.30.7 DEFINITIONS: In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

A. "Beyond-use date" the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

B. "Component" any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product

C. "Compounding" the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(1) as the result of a practitioner's prescription drug or medication order, or an initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(2) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(3) for the purpose of or as an incident to research, teaching, providing samples to practitioners, or chemical analysis and not for sale or dispensing.

(4) reconstitution of commercial products is not considered compounding for purposes of this article.

D. "Manufacturing" the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of the container and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners, or other persons. The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing

E "SOPs" standard operating procedures.

F. F. "USP/NF" the current edition of the United States Pharmacopeia/National Formulary

16.19.30.8 PERSONNEL:

A. Pharmacist-in-charge. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning non-sterile compounding:

(1) determining that all personnel involved in non-sterile compounding possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised;

(2) determining that all personnel involved in non-sterile compounding obtain continuing education appropriate for the type of compounding done by the personnel;

(3) assuring that the equipment used in compounding is properly maintained;

(4) maintaining an appropriate environment in areas where non-sterile compounding occurs; and

(5) assuring that effective quality control procedures are developed and followed.

B. Pharmacists. Special requirements for non-sterile compounding.

(1) All pharmacists engaged in compounding shall:

(a) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(b) obtain continuing education for the type of compounding done by the pharmacist.

(2) A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.

(3) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to assure that errors have not occurred in the compounding process.

(4) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

C. Pharmacy technicians. All technicians engaged in compounding shall:

(1) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken;

(2) obtain continuing education for the type of compounding done by the pharmacy technician: and

(3) perform compounding duties under the direct supervision of and responsible to a pharmacist.

D. Training.

(1) All personnel involved in non-sterile compounding shall be trained and must participate in continuing relevant training programs.

16.19.30.9 OPERATIONAL STANDARDS:

A. General requirements.

(1) Non-sterile drug products may be compounded in licensed pharmacies:

(a) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship; or

(b) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns.

(c) for physician or veterinary office use provided the requirements of this section are met.

~~(d) prepare compounds containing amounts of ingredients approved for over the counter use and properly labeled for OTC sale.~~

(2) Non-sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established patient/prescriber relationship.

(a) The beyond-use date should be based on the criteria outlined USP Chapter <795>

(b) Any product compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(i) name and strength of the compounded medication or list of the active ingredients and strengths;

(ii) facility's lot number;

(iii) beyond-use date

(iv) quantity or amount in the container.

(3) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

(a) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs; and

(b) the prescribing practitioner has requested that the drug be compounded.

(c) if the compounded product is changed to produce for that patient a significant difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if use of the compounded product is in the best interest of the patient. "Significant difference" would include the removal of a dye for a medical reason such as an allergic reaction. When a compounded product is to be dispensed in place of a commercially available product, the prescriber and patient shall be informed that the product will be compounded.

(4) Compounding for a prescriber's office use:

(a) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.

(b) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.

(c) The product is to be administered in the office or if dispensed to the patient, the product shall be labeled "For Office/Sample Use Only—Not for Resale".

(d) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer.

(e) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.

(f) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(5) Compounding veterinarian products:

(a) Prescriptions for animals may be compounded based on an order or prescription from a duly authorized veterinarian.

(b) These prescriptions are to be handled and filled the same as the human prescriptions.

(c) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(6) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide non-sterile prescription compounding services, which may include specific drug products and classes of drugs.

B. Environment.

(1) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of drug products, including the placement of equipment and materials. Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity which is adequate for safe and orderly compounding.

(2) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(3) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition.

(4) If drug products that require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products, must be used in order to prevent cross-contamination.

C. Equipment and Supplies. The pharmacy shall:

(1) have a Class A prescription balance, or analytical balance and weights when necessary which shall be properly maintained and subject to inspection by the New Mexico State Board of Pharmacy; and

(2) have equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(a) of appropriate design and capacity, and be operated within designed operational limits;

(b) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, 7identity, strength, quality, or purity of the drug product beyond the desired result;

(c) cleaned and sanitized appropriately prior to each use; and

(d) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

D. Labeling. In addition to the labeling requirements of the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(1) The generic name(s) or the designated name and the strength of the compounded preparation.

(2) The quantity dispensed.

(3) The date on which the product was compounded.

(4) A lot or batch number.

(5) The beyond-use date after which the compounded preparation should not be used.

(a) In the absence of stability information applicable for a specific drug the preparation shall adhere to the following maximum beyond-use date guidelines:

(i) Non-aqueous liquids and solid formulations (Where the manufactured drug product is the source of active ingredient): 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.

(ii) Water-containing formulations (Prepared from ingredients in solid form): Not later than 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit)

(iii) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.

(b) Beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

E. Drugs, components, and materials used in non-sterile compounding.

(1) Drugs used in non-sterile compounding shall preferably be a USP/NF grade substances manufactured in an FDA-registered facility.

(2) If USP/NF grade substances are not available, documentation of stability and purity must be established and documented

(3) A pharmacy may not compound a drug product which appears on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

F. Compounding process.

(1) The safety, quality, and performance of compounded prescriptions depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. Each pharmacy shall develop and follow written SOPs based on established compounding procedures as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding of Non-Sterile Preparations designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process.

G. Quality Control.

(1) to monitor the output of compounded drug products for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795 concerning Pharmacy Compounding Non-Sterile Preparations, Chapter 1075 concerning Good Compounding Practices, and Chapter 1160 concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

(2) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a compounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.

(3) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.

16.19.30.10 RECORDS:

A. Maintenance of records. Every record required by this section shall be kept by the pharmacy for at least three years.

B. Compounding records.

(1) Formulation records:

(a) provides a consistent source document for preparing the preparation (recipe) is a file of individually compounded preparations

(b) must list the name, strength, and dosage form of the preparation compounded

(c) must list all ingredients and their quantities

(d) must list equipment needed to prepare the preparation, when appropriate, and mixing instructions

(e) other environmental controls, such as the duration of mixing, and other factors pertinent to the replication of the preparation as compounded.

(f) must contain beyond-use date and methodology, the container used in dispensing, the storage requirements, and any quality control procedures.

(2) Compounding records:

(a) documents the actual ingredients in the preparation and the person responsible for the compounding activity

(b) contains the name and strength of the compounded preparation, the formulation record reference for the preparation, and the sources and lot numbers of the ingredients
(c) contains information on the total number of dosage units compounded, the name of the person who prepared the preparation and the name of the pharmacist who approved the preparation
(d) contains the date of the preparation, the assigned internal identification number or the prescription number and an assigned beyond use date.
(e) For all compounded preparations, results of quality control procedures are to be recorded.

Mr. Nolasco briefly discussed the language proposed for 16.19.30 NMAC regarding problematic areas and included references to USP 795 that have been added. Mr. Nolasco stated that under 16.19.30.9(A)(1) he wanted to remove letter "d". Mr. Nolasco stated that he felt everything else was in order and wanted to notice 16.19.30 NMAC for the Board meeting in March, 2006.

Mr. Storey asked Mr. Nolasco if safe practices were addressed by USP 795 in the language and Mr. Nolasco stated that they were addressed on page 4 under "Operational Standards", number (4), (5), and (6).

Mr. Harvey stated that the FDA would be sending comments about this regulation.

Ms. Buesing asked for clarification of 16.19.30.9(A)(4)(d). A brief discussion was held by Mr. Cross and Mr. Storey regarding the clarification of these issues.

Mr. Storey stated that all the regulations would by typed and in the format needed by the state.

Changes were made during the Board meeting on the overhead projector.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to notice for hearing 16.19.30 NMAC at the March 2006 Board meeting. The Board voted unanimously to pass the motion.

Executive Director's Report Cont'd:

Mr. Harvey discussed the three million dollars in funds that had been received through wholesale licensing for the senior prescription drug program and proposed legislation.

Mr. Harvey discussed his meeting with the Lt. Governor, Diane Denish, regarding the proposed legislation for a bill to make pseudoephedrine a Schedule V exempt narcotic. The Board discussed numerous issues surrounding the monitoring, and distribution of pseudoephedrine. Mr. Cross stated he would like to see Representative John Heaton support the language being changed so that technicians would be able to sign out pseudoephedrine instead of requiring pharmacists to do so. Mr. Storey supported Mr. Cross's recommendation.

Mr. Harvey presented documentation from the NABP Annual Meeting in New Orleans regarding bylaw changes that effect reciprocity from other states such as California and Florida. Mr. Harvey discussed the changes he would like to see regarding active and inactive status fees.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Buesing to approve the policy changes as presented below by the Executive Director, William Harvey. The Board voted unanimously to pass the motion.

1. Original state licensure is required by the New Mexico Board of Pharmacy.
2. A one-time activation fee of $100 and the inactive status fees of $70 for every two years.
3. Allow California and Florida to reciprocate into New Mexico as long as they have taken the NAPLEX and can be certified.

APPLICATION APPROVAL:

Mr. Harvey stated that he would like to start with Mr. Korsunsky who was in the audience from Secure Pharmacy. Mr. Harvey stated he has been corresponding with Mr. Korsunsky about his concerns regarding importation from Canada through Arizona and Mr. Korsunsky's business plan whether it involved compounded pharmaceuticals or a selected group of providers. Mr. Korsunsky correspondence stated that he was no longer in that business and would not do business with anyone that was not licensed in New Mexico that was a drug wholesaler. Mr. Harvey gave Mr. Korsusky a temporary license until further discussion was held at this current Board meeting. Mr. Harvey informed the Board that Inspector Mike Lyons went to the "closed door mail-order pharmacy" and performed an inspection. Mr. Korsunsky stated that an alarm system and firewalls had been completed and there were not any controlled substances on the premises. Mr. Cross asked if a valid practitioner/patient relationship would exist for each of the patients' that a prescription is being filled for and Mr. Korsunsky stated that there would be. Mr. Storey asked if the drug list was reviewed by Inspector Mike Lyons for controlled substances, and Mr. Harvey stated that he had agreed to remove the controlled substances from the list and that he had passed inspection.

The Chairman called for a 10-minute recess.

RECESS:

RECONVENE:

The Chairman reconvened at 2:19 p.m.

Application List:

Clinic Applications:

Mr. Cross stated that there are 10 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to approve all 10 applications in this category as presented. The Board voted unanimously to pass the motion.

Custodial Homes:

Mr. Cross stated that there are 37 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to approve the 37 applications in this category as presented. The Board voted unanimously to pass the motion.

Home Healthcare:

Mr. Cross stated that there are 2 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 2 applications in this category as presented. The Board voted unanimously to pass the motion.

Non-Resident Pharmacy:

A discussion was held regarding **Smart Choice Pharmacy** in Austin, TX and the relationship between Smart Choice Drug Store. Inspector Mike Lyons was able to attend to discuss the inspection for Smart Choice Pharmacy and indicated that they had split up and that the same owner is acting as a mediator to direct people to Canadian pharmacies but Smart Choice Pharmacy is not one. Smart Choice Pharmacy passed the inspection.

Mr. Cross stated that there are 9 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 9 applications in this category as presented. The Board voted unanimously to pass the motion...

Pharmacy:

Mr. Cross stated that there are 5 applications in this category. Mr. Cross asked that a correction be made to the numbering of the Pharmacy applications as follows; number 3 should be number 4 and number 4 should be number 5.

Mr. Shaver stated that he would like to know the business nature of Secure Pharmacy and suggested to go into closed session with the applicant present to discuss his concerns.

Motion:

A motion was made by Mr. Shaver, ***(the second was not audible)*** to go into executive session in accordance with Section 10-15-1 of the Open Meeting Act to discuss Secure Pharmacy with the applicant present. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to go back into open session. The Board voted unanimously to pass the motion.

Mr. Cross stated that there are 5 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 5 applications in this category as presented. The Board voted unanimously to pass the motion.

Wholesaler/Broker:

Mr. Cross stated that there were 13 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 13 applications in this category as presented. The Board voted unanimously to pass the motion.

Drug Precursor:

Mr. Cross stated that one application is in this category and all is in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the one application in this category as presented. The Board voted unanimously to accept the motion.

Pharmacist Credentialing Committee:

Mr. Cross presented 2 applications that were discussed by the committee on December 29, 2005. A discussion was held regarding the recommendations and follow up for the following applicants, Allyson Burnett and Paulina Dziamka-Deming. Mr. Cross stated that the approval of both applicants would be pending receipt and successful review of the transcripts by the clinician committee.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Carrier to accept the application of Allyson Burnett and Paulina Dziamka-Deming pursuant to the stipulations stated. The Board voted unanimously to pass the motion.

Motion:

A motion by Mr. Cross, seconded by Ms. Buesing to approve the protocols of Keith Romero, Cheryl Burlett and Krista Dominguez-Salazar. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to attach the application list to the minutes. The Board voted unanimously to pass the motion.

Ms. Buesing gave an update on the pharmacist's credentialing committee. She stated that they meet once a month telephonically to review applications and stated that they would be meeting in February in Albuquerque to review regulation language. Ms. Buesing stated the committee's goal would be to create a written format that could be presented to the Board for recommending rule changes. Ms. Buesing

suggested that strategic planning take place to determine what other committees or goals might be met for 2006.

Executive Director's Report Cont'd:

The Chairman stated that he has made a decision to disband the current Technician Committee. Mr. Storey stated that another committee would be developed and the obstacles that prevented the committee from going further such as guidelines from the Board, boundaries and scope of the members would be addressed. He also stated that a written format for recommending rule changes would be developed. Mr. Harvey stated that he has received calls from volunteers to be on the committee and to please forward any future requests to him. Mr. Storey suggested sending out an e-alert for more volunteers for the technician committee. Mr. Storey will be selecting committee members upon his return on January 23, 2006.

Mr. Ortega stated that he would like to see technicians do more and not be restricted to perform more tasks to help the pharmacist. Mr. Ortega stated he would like to be on the technician committee.

The Board had a brief discussion on what issues could be addressed during the year regarding current policies, rule revisions, and archiving that would have a positive impact on the public's health safety and practice of pharmacy.

Mr. Harvey gave an update on case #2005-088. Mr. Harvey stated that he would like to see the Board ratify the surrender and when the individual is rehabilitated through MTP, and when he contacts us wishing to seek reinstatement that we can negotiate a stipulated agreement. Mr. Harvey would like to call the Board Chairman and hold a teleconference to ratify.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to accept the surrender and negotiate to prepare a stipulated agreement for case #2005-088. The Board voted unanimously to pass the motion.

Mr. Harvey discussed the proposed regulation for re-use of pharmaceuticals in correctional facilities. The Board discussed that under special conditions pharmaceuticals can be re-labeled. Many times the medications that are prescribed to the inmate do not leave with the inmate when discharged, therefore there are pharmaceuticals that the correctional facility can not re-use. Mr. Storey stated that there are other states that do allow the return of medications as long as they are put back into the correctional facility. Mr. Nolasco stated that he would not trust nurses re-labeling pharmaceuticals in a correctional facility and that the consultant pharmacist would have to return to the facility more often to do the re-labeling. Mr. Harvey agreed with his statement and commented that it would be in the states' best interest to pay the consultant pharmacist to re-label the medications for another inmate.

16.19.6.27 Limited Re-Use of Pharmaceuticals in Correctional Facilities

A. No drug that has been dispensed pursuant to a prescription and has left the physical premises of the facility licensed by the Board shall be dispensed or re-used again except the re-labeling and reuse of pharmaceuticals may be permitted in the following situations:

(1) In a correctional facility, licensed by the Board, under the following circumstances:

(a) The patients must reside in the same facility,

(b) The reused medication must have been discontinued from the original patient's drug regimen,
(c) The drug was never out of the possession of the licensee (keep on person pharmaceuticals may never be re-used),
(d) The drugs were originally dispensed in packaging that is unopened, single-dose or tamper-evident containers,
(e) The patient receiving the relabeled medication must have a valid prescription/order for the medication that is to be re-used,
(f) Repackaging and re-labeling may only be completed on site by the consultant pharmacist designated for that facility,
(g) The consultant pharmacist must maintain records at the facility for 3 years containing the following information:
1. Date when the re-labeling occurred,
2. The name and ID of the patient for whom the medication was originally intended for and the date in which it was discontinued from his or her drug regimen,
3. The name and ID of the patient who will receive the Re-used medication,
4. The name, strength and amount of the medication being reused,
5. The name of pharmacist re-labeling the medication,

6. Pursuant to 16 NMAC 19.10.11: the pharmacist must label the re-used pharmaceutical and maintain a dispensing log for all such the re-issued pharmaceuticals. The expiration date for such re-issued drugs shall be no greater than 50% of the time remaining from the time of repackaging until the expiration date indicated on the original dispensing label or container.

After further discussion Mr. Harvey stated that the language should be entered into 16.19.4 NMAC instead of 16.19.6 NMAC. Mr. Cross suggested that the title should also be changed to read, "Limited Re-Use of Pharmaceuticals in Correctional Facilities".

Corrections were made during the Board meeting on the overhead projector. Formatting

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Saavedra to notice for hearing 16.19.4 NMAC at the March 2006 Board Meeting. The Board voted unanimously to pass the motion.

Mr. Harvey gave a brief update on correspondence received from Ms. Stephanie Salas as to why she was unable to attend the Board meeting. No action was taken. FYI item.

Mr. Harvey requested that any of the Board members that wish to attend the NMPhA Mid-Winter Meeting on January 28, 2006 please submit their applications with Ms. Cindy McCormick.

Mr. Harvey informed the Board of the NABP Annual Meeting in San Francisco on April 8th through April 11th. Mr. Storey asked that a grant application be sent to him and he would be the voting delegate. The Board briefly discussed the possible attendees: Mr. Cross, Mr. Shaver, Mr. Carrier and Ms. Padilla.

Mr. Harvey passed out the 25th Anniversary Schering Report to the Board members. No action was taken. FYI item.

Mr. Harvey and Ms. Saavedra discussed issuing a PSA for the new Medicare program. FYI item.

Mr. Harvey presented correspondence from Jill Sellers regarding "Exam for the Certification of Pharmacy Technicians". The Board discussed presenting the documentation to the new technician committee being developed.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Saavedra to go into closed session to finish case presentations. The Board voted unanimously to pass the motion

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to go back into open session and all that was discussed were the case presentation. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Shaver to issue an NCA in cases 2003-093, 2005-119, close cases 2005-089, 2005-101, 2005-117, issue a pre NCA to case 2005-070, issue an advisory letter to 2005-077. The Board voted unanimously to pass the motion.

The Chairman called for a recess at 4:15 p.m. until Tuesday January 10, 2006.

RECONVENE TUESDAY JANUARY 10, 2006:

The Chairman reconvened at 9:04 a.m. at which time he took roll call. The Chairman stated that Mr. Ortega and Ms. Padilla were absent and excused. Mr. Cross was also absent and excused but can be reached telephonically if needed.

EMERGENCY RULE HEARING 16.19.31 NMAC – EMERGENCY PROVISIONS:

The Chairman opened the hearing at approximately 9:10 a.m. Ms. Buesing read the proposed regulation aloud to the Board.

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 31 EMERGENCY PROVISIONS

16.19.31.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.

16.19.31.2 SCOPE: All pharmacies, resident and non-resident, as defined in 61-11-2(S), (Y) NMSA 1978, and all persons or entities that own or operate, or are employed by, a pharmacy for the purpose of providing pharmaceutical products or services.

16.19.31.3 STATUTORY AUTHORITY: Section 61-11-6.A.(1) authorizes the Board of Pharmacy to adopt, regularly review and revise rules and regulations necessary to carry out the provisions of the Pharmacy Act, Sections 61-11-1, 61-11-2, 61-11-4 to 61-11-28 NMSA 1978. Section 61-11-6.A.(3) provides for the issuance and renewal of licenses for pharmacists. Section 61-11-6.A. NMSA 1978 authorizes the Board of Pharmacy to register and regulate qualifications, training and permissible activities of pharmacy technicians. Section 61-11-6.A.(6) NMSA 1978 requires that the Board of Pharmacy provide for the licensing of retail pharmacies and nonresident pharmacies and for the inspection of their facilities and activities.

16.19.31.4 DURATION: Permanent

16.19.31.5 EFFECTIVE DATE: January 17, 2006, unless a different date is cited in the history note at the end of a Section.

16.19.31.6 OBJECTIVE: The objective of Part 31 of Chapter 19 is to ensure the safe and competent delivery of quality pharmaceutical products and services to the public by establishing standards for the operation of pharmacies, including but not limited to minimum space requirements and standards for equipment, accessories, personnel, dispensing, labeling and advertising during emergency situations.

16.19.31.7 DEFINITIONS: [RESERVED]

16.19.31.8 EMERGENCY TEMPORARY PHARMACIST LICENSE:

A. Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Emergency situation - an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services.

(2) Sponsoring pharmacy - a pharmacy licensed by the Board in which the emergency temporary pharmacist will practice.

(3) State - One of the 50 United States of America, the District of Columbia, and Puerto Rico.

B. Emergency Temporary Pharmacist license. In an emergency situation, the board may grant a pharmacist who holds a license to practice pharmacy in another state an emergency temporary pharmacist license to practice in New Mexico. The following is applicable for the emergency temporary pharmacist license.

(1) An applicant for an emergency temporary pharmacist license under this section must:

(a) hold a current pharmacist license in another state and that license and other licenses held by the applicant in any other state may not be suspended, revoked, canceled, surrendered, or otherwise restricted for any reason, and;

(b) be sponsored by a pharmacy with an active license in New Mexico.

(2) To qualify for an emergency temporary pharmacist license, the applicant must submit an application including the following information:

(a) name, address, and phone number of the applicant.

(b) name and license number of the pharmacist-in-charge of the sponsoring pharmacy.

(c) name and license number of the sponsoring pharmacy, and;

(d) any other information that is required by the board.

(3) An emergency temporary pharmacist license shall be valid for a period as determined by the executive director of the Board not to exceed six months. The executive director, in his/her discretion, may renew the license for an additional six months, if the emergency situation still exists.

(4) The board will notify the sponsoring pharmacy of the approval of an emergency temporary pharmacist license.

C. Limitations on practice. A holder of an emergency temporary pharmacist license;

(1) may only practice in the sponsoring pharmacy, and;

(2) must notify the board in writing, prior to beginning employment in another sponsoring pharmacy.

16.19.31.9 PROVISIONS FOR PHARMACIST LICENSURE DURING DECLARED DISASTER:

A. **Emergency provisions for license by endorsement.** Pharmacist currently licensed in a state in which a federal disaster has been declared may be licensed by endorsement in New Mexico during the four months following the declared disaster at no cost with the following requirements:

(1) receipt of a completed application which has been signed and notarized accompanied by proof of identity, which may include a copy of a drivers license, passport or other photo identification issued by a governmental entity;

(2) other required verification will be obtained online if possible by board staff to include: current licensure status, national pharmacists data bank, national association of boards of pharmacy disciplinary database, and;

(3) nothing in this provision shall constitute a waiver of the requirements for licensure contained in 16.19.2 NMAC.

B. License expiration. Pharmacist licenses under 16.19.2 NMAC shall expire six months after issue date.

16.19.31.10 PROVISIONS FOR PRACTITIONER CONTROLLED SUBSTANCES REGISTRATION DURING A DECLARED DISASTER:

A. Emergency provisions for registration by endorsement. Practitioners currently possessing a temporary license issued by a New Mexico regulatory agency and possessing a current Drug Enforcement Administration controlled substance registration in a state in which a federal disaster has been declared may be registered by endorsement in New Mexico during the four months following the declared disaster at no cost with the following requirements:

(1) receipt of a completed application which has been signed and accompanied by proof of identity, which may include a copy of a drivers license, passport or other photo identification issued by a governmental entity;

(2) other required verification will be obtained online if possible by board staff to include: current licensure status, national practitioners data banks, and;

(3) nothing in this provision shall constitute a waiver of the requirements for licensure contained in 16.19.20 NMAC.

B. Registration expiration. Practitioners registrations issued under 16.19.20 NMAC shall expire six months after issue date.

[16.19.31 NMAC - N, 12/30/2005]

Corrections were made during the Board meeting on the overhead projector.

Motion:

A motion was made by Mr. Shaver, seconded by Mr. Nolasco to approve the language with changes made during the Board meeting to 16.19.31 NMAC. The Board voted unanimously to pass the motion.

The Chairman called for a recess until 9:35 a.m.

RECESS:

RECONVENE:

The Chairman reconvened at 9:35 a.m.

***CITIZENS PETITION TO NEW MEXICO BOARD OF PHARMACY TO BAN ASPARTAME IN MEDICATIONS AND VITAMINS, AND THIMEROSAL USE IN IMMUNIZATIONS:**

Ms. Kunkle informed the Board on the parameters regarding discussions about the "citizens petition" in open and closed forums.

The Board had received a number of comments and documentation regarding this subject. Mr. Storey stated that a 2-3 minute period of time per person would be allotted to receive new information and that any items that had already been submitted to the Board, he asked not be re-submitted

After lengthy discussion with the Board and the presenters Mr. Fox and Mr. Stoller, it was decided that Aspartame and Thimerosal should be handled as two separate issues.

Motion:

A motion was made by Mr. Shaver, seconded by Ms. Buesing to separate Aspartame and Thimerosal and handle as two separate issues. The Board voted unanimously to pass the motion.

The Chairman asked that Mr. Stoller to withdraw the current petition and re-submit the petitions as two separate issues as banning Aspartame and banning Thimerosal. Mr. Stoller and Mr. Fox were in agreement to consider the request and present the petitions when completed.

Executive Director's Report Cont'd:

Mr. Harvey presented correspondence from Mr. Bruce Onefrey, OD, R.Ph. requesting reinstatement of his pharmacist license. Mr. Onofrey was present in the audience. Ms. Sarah Trujillo, licensing manager informed the Board of the requirements for reinstatement. After a lengthy discussion of the issues regarding Mr. Onofrey's reinstatement, the Board decided to go into closed session.

Motion:

A motion was made by Ms. Saavedra, seconded by Mr. Nolasco to go into executive session to discuss Mr. Onofrey's reinstatement. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Ms. Saavedra, seconded by Ms. Buesing to go back into open session and the only issue discussed was Mr. Onofrey's reinstatement. The Board voted unanimously to pass the motion.

Mr. Storey stated that there were two options available to Mr. Onofrey as follows:

1) Take the NABP self-assessment evaluation and report back to the Board with the results at which time the Board would decide what requirements could be waived if any, or;

2) Fulfill all the requirements as stated: Take and pass the NAPLEX and MPJE, pay the reinstatement fee of $100.00, pay inactive fees for years inactive as established by the Board at the rate of $70.00 per year, obtain eight-hundred-forty intern hours, and obtain two-hundred-ten CE'S eleven of which must be law.

Mr. Harvey stated that he would follow-up with Mr. Onofrey's status of reinstatement.

Ms. Buesing asked about the status of hiring another inspector for the Board of Pharmacy. Mr. Harvey stated that there were two potential candidates and that he was able to increase Ms. Jeane Johnson's rate of pay due to an in-band pay adjustment. Mr. Harvey also stated that he was submitting requests for in-band pay increases for all the Board of Pharmacy employees.

Mr. Harvey informed the Board that our Superintendent Art Jaramillo for RLD will be moving to GSD, and Secretary Ed Lopez will be switching to RLD. Mr. Storey suggested that a sort of transitional visit be set up so that the relationship that the Board had fostered with Mr. Jaramillo be done so with Mr. Lopez. Mr. Storey stated that he would send out an invitation after the legislative session was over to attend a visit with Mr. Ed Lopez.

The Chairman called to adjourn the Board meeting.

Motion:

A motion was made by Mr. Nolasco, seconded by Ms. Buesing to adjourn the Board meeting. The Board voted unanimously to pass the motion.

The Board meeting was adjourned at 11:12 a.m.