New Mexico Board of Pharmacy Regular Board Meeting
January 11th & 12th, 2010

Monday January 11th, 2010

PLACE AND TIME: The meeting was held at the board conference room located at 5200 Oakland Ave NE, Albuquerque, NM 87113.

CALL TO ORDER: The meeting was called to order by the Chairman Danny Cross, R.Ph., at 9:24 a.m.

MEMBERS PRESENT:
Danny Cross, R.Ph., Chairman
Amy Buesing R.Ph., Member
Thomas Ortega R.Ph., Member (Monday January 11th, 2010)
Richard Mazzoni, R.Ph., Member
Joe Anderson, R.Ph.,Member
Buffie Saavedra, Public Member

MEMBERS ABSENT:
Allen Carrier, Secretary
Howard Shaver, Public Member
Ray Nunley. Member
Thomas Ortega R.Ph., Member (Tuesday January 12th, 2010)

STAFF ATTENDING:
Mary Smith, Assistant Attorney General
William Harvey, Executive Director
Debra Wilhite, Administrative Secretary

ROLL CALL:

Mr. Cross took roll call at 9:24 a.m. Present were Ms. Buesing, Mr. Mazzoni, and Mr. Anderson. The Chairman stated that Mr. Carrier, Mr. Shaver and Mr. Nunley are absent and Ms. Saavedra and Mr. Ortega will be late.

Mr. Harvey introduced the new intern Ana and mentioned that another intern Eleanor was present in the audience from the college of pharmacy.

APPROVAL OF THE AGENDA:

The Chairman asked if there were any changes to the agenda. Mr. Harvey stated that there were no changes to the agenda.

Ms. Saavedra was present at 9:28 a.m.

Motion:

A motion was made by Mr. Mazzoni, seconded by Ms. Saavedra to approve the agenda as presented. The board voted unanimously to pass the motion.

APPROVAL OF THE OCTOBER 19th & 20th, 2009 MEETING MINUTES:

The Chairman asked if there were any changes to the minutes. There were no changes to the minutes.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve the minutes as presented. The Board voted unanimously to pass the motion.

MTP REPORT:

Representatives Jon Thayer and Kate Woods were present to discuss the MTP report.

The Chairman called for a motion to go into closed session to present the MTP report at 9:35 a.m.

Motion:

A motion was made by Mr. Mazzoni, seconded by Ms. Saavedra to go into closed session to discuss the MTP report. The Chairman took a roll call vote. Mr. Mazzoni, Ms. Saavedra, Mr. Anderson, Ms. Buesing and Mr. Cross voted unanimously to pass the motion.

The Chairman went back into open session and the only issue discussed was the MTP report.

APPLICATIONS:

Application List:

Clinic:

Ms.Buesing stated that there are 15 applications in this category and all are in order.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve all 15 applications in this category as presented. The board voted unanimously to pass the motion.

Animal Control:

Ms.Buesing stated that there are 2 applications in this category and is in order.

Motion:

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

Limited Drug Research:

Ms. Buesing stated that there is one application in this category and it is in order.

Motion:

A motion was made by Ms. Buesing, seconded by Ms. Saavedra to approve one application in this category as presented. The board voted unanimously to pass the motion.

Emergency Medical Services:

Ms. Buesing stated that there are 3 applications in this category and it is in order.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve the 3 applications in this category as presented. The board voted unanimously to pass the motion.

Custodial/Nursing Home:

Ms. Buesing stated that there were 25 applications in this category and all is in order.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Mazzoni to approve the 25 applications in this category as presented. The board voted unanimously to pass the motion.

Pharmacy:

Ms. Buesing stated that there are 4 applications in this category and all are in order.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve the 4 applications in this category as presented. The board voted unanimously to pass the motion.

Non-Resident Pharmacy:

Ms. Buesing stated that there are 18 applications in this category and all are in order.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Mazzoni to approve the 18 applications in this category as presented. The board voted unanimously to pass the motion.

Wholesale/Broker:

Ms. Buesing stated that there are 36 applications in this category and all are in order.

Motion:

A motion was made by Ms. Buesing, seconded by Ms. Saavedra to approve the 36 applications in this category as presented. The board voted unanimously to pass the motion.

Pharmacist Credentialing Committee:

Ms. Buesing presented 2 applications that were discussed by the committee. The applications presented are for Carol Bailar and Catherine Cone.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve the pharmacist clinician recommendations by the credentialing committee for Carol Bailar and Catherine Cone. The board voted unanimously to pass the motion.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to attach the lists to the minutes. The board voted unanimously to pass the motion.

The Chairman asked for a 10-minute recess.

RECESS:

RECONVENE:

The board reconvened at 10:33 a.m.

NOTICE OF RULE HEARING – 16.19.6 NMAC:

The Chairman opened the hearing at 10:30 a.m. He asked that the notice of hearing be listed as exhibit 1 and the proposed language for 16.19.6.22 NMAC be listed as exhibit 2.

After a brief discussion the board agreed to the proposed amendments.

This is an amendment to 16.19.6 NMAC, Sections 10, 11, 15, and 22, effective 04-15-10.

16.19.6.10 MINIMUM STANDARDS:

A. The restricted area to be occupied by the prescription department shall be an undivided area of not less than 240 square feet. The floor area shall extend the full length of the prescription compounding counter. This area shall provide for the compounding and dispensing and storage of all dangerous or restricted drugs, pharmaceuticals, or chemicals under proper condition of sanitation, temperature, light, ventilation, segregation and security. No space in this area shall provide for an office, auxiliary store room or public restroom(s).

(1) A private restroom, for exclusive use by the pharmacy staff, may be attached to the restricted area. This restroom does not count as square footage for the restricted area.

(2) An office for the exclusive use by the pharmacy may be attached to the restricted area. No general store accounting functions may be performed in this office. This area will not be considered as square footage for the restricted area.

(3) An auxiliary storage area for the exclusive use of the pharmacy may be attached to the restricted area. No items may be stored in this area that are not directly related to the operations performed in the restricted area. This area will not be considered as square footage for the restricted area.

(4) Each pharmacy shall provide facilities whereby a pharmacist may professionally counsel a patient or a patients' agent and protect the right to privacy and confidentiality.

B. An exception to the minimum space footage requirement may be considered by the Board on an individual basis. The Board may consider such factors as:

(1) Rural area location with small population.

(2) No pharmacy within the same geographical area.

(3) No prescription area of less than 120 square feet will be acceptable.

(4) All special waivers will be subject to review annually for reconsideration.

C. The prescription compounding counter must provide a minimum of 16 square feet of unobstructed compounding and dispensing space for one pharmacist and a minimum of 24 square feet for two or more pharmacists when on duty concurrently. **The counter shall be of adequate height of at least 36 inches, if necessary, five-percent (5%) or at least one work station will comply with the American with Disabilities Act.**

D. The restricted floor area shall be unobstructed for a minimum width of thirty inches from the prescription compounding center.

E. The pharmacy restricted area shall be separated from the merchandising area by a barrier of sufficient height and depth to render the dangerous drugs within the pharmacy inaccessible to the reach of any unauthorized person. All windows, doors, and gates to the restricted area shall be equipped with secure locks. The restricted area shall be locked in the absence of a pharmacist on the premises.

F. The restricted area shall contain an adequate sink with hot and cold water.

G. The restricted area shall contain a refrigerator capable of maintaining the adequate temperature.

H. The restricted area of a retail pharmacy established in conjunction with any other business other than a retail drug store, shall be separated from the merchandising area of the other business by a permanent barrier or partition from floor to roof with entry doors that may be securely locked when a pharmacist is not on duty.

[16.19.6.10 NMAC - Rp, 16 NMAC 19.6.10, 03-30-02; A, 04-15-10]

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS:

A. The pharmacy shall have the necessary equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparations of drugs and parenteral products appropriate to the scope of pharmaceutical services provided. The following items shall be in the pharmacy:

(1) An updated reference source, appropriate to each practice site, either electronic or paper version;

(2) One copy of the most recently published New Mexico pharmacy laws, rules and regulations and available revisions, either electronic or paper version

B. PARENTERAL PHARMACEUTICALS

(1) Purpose: To ensure that the citizens of New Mexico receive routine safe and competent delivery of parenteral products and nutritional support throughout the state. To establish guidelines for licensure and inspection of such facilities by the state board of pharmacy.

(2) Definitions

(a) "Parenteral products pharmacy" is a retail pharmacy which prepares and distributes prescriptions for sterile products intended for parenteral administration to patients either at home or in or out of an institution licensed by the state.

(b) "Parenteral product" means any preparation administered by injection through one or more layers of skin tissue.

(c) "Sterile" means a preparation that has undergone a valid sterilization process and is devoid of all living microorganisms, packaged in such a way to ensure the retention of this characteristic.

(d) "Preparation" means a sterile product which has been subjected to manipulation by a pharmacist under aseptic conditions to render the product suitable for administration.

(e) "Aseptic conditions" means a cabinet or facility capable of obtaining ISO class 5 clean air as defined by the federal standards 209E and which is certified by a testing agency at least every six months.

(f) "Aseptic technique" means proper manipulation of articles within a ISO class 5 clean air room or station to maintain sterility.

(g) "Disinfectant" means a chemical compound used to kill and or control microbial growth within a ISO class 5 area or its surroundings and is approved for such use by the environmental protection agency.

(h) "Antimicrobial soap" means soap containing an active ingredient that is active both in vitro and vivo against skin microorganisms.

(i) "Surgical hand scrub" means an antimicrobial containing preparation which significantly decreases the number of microorganisms on intact skin.

(j) "SOP" means standard operating procedures. These are written standards for performance for tasks and operations within a facility.

(k) "Quality control" means procedures performed on preparations to assess their sterility and/or freedom from other contamination.

(l) "Quality assurance" means the procedures involved to maintain standards of goods and services.

(m) "ISO class 5 environment" means having less than 100 particles 0.5 microns or larger per cubic foot.

(n) "ISO class 8 environment" means having less than 100,000 particles 0.5 microns or larger per cubic foot.

(o) "Critical area" means any area in the controlled area where products or containers are exposed to the environment.

(p) "Process validation" means documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

(q) "Positive pressure controlled area" means the clean room is to have a positive pressure differential relative to the adjacent pharmacy.

(r) "Barrier isolator" is an enclosed containment device which provides a controlled ISO class 5 environment. The device has four components; the stainless steel shell, HEPA filtration of entering and exiting air flows, glove ports for people interaction and an air lock for moving products into and out of the controlled environment.

(s) "Plan of care" means an individualized care plan for each patient receiving parenteral products in a home setting to include the following:

(i) a description of actual or potential drug therapy problems and their proposed solutions;

(ii) a description of desired outcomes of drug therapy provided;

(iii) a proposal for patient education and counseling; and

(iv) a plan specifying proactive objective and subjective monitoring (e.g. vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and non compliance) and the frequency with which monitoring is to occur.

(t) USP/NF standards means USP/NF Chapter 797 titled "pharmacy compounding - sterile products".

(u) "Cytotoxic drugs" shall be defined in the most current American hospital formulary service (AHFS).

(3) Pharmacist-in-Charge: In order to obtain a license, all parenteral product pharmacies must designate a pharmacist in charge of operations who is:

(a) licensed to practice pharmacy in the state of New Mexico;

(b) responsible for the development, implementation and continuing review of written SOP's consistent with USP/NF standards which are used by the operation in their daily operation;

(c) pharmacist on staff who is available for twenty-four hour seven-day-a-week services;

(d) responsible for establishing a system to assure that the products prepared by the establishment are administered by licensed personnel or properly trained and instructed patients;

(e) responsible for developing an appropriate and individualized plan of care in collaboration with patient or caregiver and other healthcare providers for each patient receiving parenteral products in a home setting.

(4) Physical Requirements:

(a) The parenteral products pharmacy must have sufficient floor space to assure that the products are properly prepared and stored to prevent contamination or deterioration prior to administration to the patient and meet the following:

(i) be separated physically from other pharmacy activities and enclosed on all sides except for doors and/or windows for the passage of materials;

(ii) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet; the stand alone parenteral product pharmacy must have a minimum of 240 square feet;

(iii) addition of a parenteral area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure;

(iv) a new parenteral pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.

(b) Equipment and materials. The parenteral products pharmacy has sufficient equipment and physical facilities to safely compound and store such products and includes the following:

(i) either a ISO class 5 clean air work station or a room which meets ISO class 5 conditions;

(ii) refrigeration capacity for proper storage of prepared parenterals at 2C to 8C after preparation and until prescriptions are received by the patient or their agent;

(iii) if bulk reconstitution of antibiotics is performed the facility has a freezer capable of freezing and storing the product at -20C for periods not to exceed the manufacturer's recommendations;

(c) References. Parenteral products pharmacies maintain in their library at least one current edition reference book from each category listed below in addition to other required references:

(i) drug monograph reference, i.e., USP-DI, AHFS: drug information service, martindale's extra pharmacopoeia, or other suitable reference;

(ii) stability and incompatibility reference; i.e., trissell's handbook of parenteral medications, king/cutter IV incompatibilities, or other suitable reference;

(iii) reference on pharmaceutical technology and compounding; i.e., remington's pharmaceutical sciences, block's disinfection sterilization and preservation, or other suitable reference;

(iv) periodicals, i.e., American journal of hospital pharmacy, ASHP's clinical pharmacy, American journal of parenteral and enteral nutrition, or other suitable periodical.

(5) Documentation Requirements for Parenteral Product Pharmacies: Written policies and procedures must be available for inspection and review by authorized agents of the board of pharmacy. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These records must include but are not limited to:

(a) cleaning, disinfection, evaluation and maintenance of the preparation area;
(b) regular recertification of the clean air unit or units by independent testing agencies;
(c) surveillance of parenteral solutions for microbiological contamination;
(d) surveillance of parenteral solutions for particulate contamination;
(e) personnel qualifications, training and performance guidelines;
(f) facility and equipment guidelines and standards;
(g) SOP's for dispensing all solutions and medications;
(h) SOP's for disposal of physical, chemical and infectious waste;
(i) quality control guidelines and standards;
(j) quality assurance guidelines and standards;
(k) SOP's for determination of stability, incompatibilities or drug interactions.

(6) Record keeping and Patient Profile: The parenteral products pharmacy is required to maintain complete records of each patient's medications which include but are not limited to the following:

(a) prescription records including the original Rx, refill authorization, alterations in the original Rx, and interruptions in therapy due to hospitalization;

(b) patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patients;

(c) patients receiving parenteral products in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;

(d) documentation that the patient receiving parenteral products in a home setting or their agent has received a written copy of their plan of care and training in the safe administration of their medication.

C. STERILE PHARMACEUTICAL PREPARATION

(1) Pharmacies compounding sterile pharmaceuticals shall prepare products in an appropriate aseptic environment which meets ISO class 5 requirements. Devices used to maintain a ISO class 5 environment will:

(a) be certified in the course of normal operation by an independent contractor according to Federal Standard 209E et seq. for operational efficiency at least every 6 months and when moved, certification records will be maintained for 3 years;

(b) have pre-filters which are inspected periodically and inspection/replacement date documented according to written policy; and

(c) have a positive pressure controlled area that is certified as at least a ISO class 8 which is functionally separate from other areas of the pharmacy and which minimizes the opportunity for particulate and microbial contamination; this area shall:

(i) have a controlled aseptic environment or contain a device which maintains an aseptic environment;

(ii) be clean, lighted, and at an average of 80-150 foot candles;

(iii) be a minimum of 100 sq. ft to support sterile compounding activities;

(iv) be used only for the compounding of sterile pharmaceuticals using appropriate aseptic technique including gowning and gloving;

(v) be designed to avoid outside traffic and airflow;

(vi) be ventilated in a manner which does not interfere with aseptic environment control conditions;

(vii) have non-porous, washable floor coverings, hard cleanable walls and ceilings (which may include acoustical ceiling tiles coated with an acrylic paint) to enable regular disinfection; (contain only compounding medication and supplies and not be used for bulk storage;

(viii) a self contained, ISO class 5 barrier isolator not located in the clean room is acceptable; the barrier isolator may only be located in an area which is maintained under sanitary conditions and traveled only by persons engaged in sterile product preparation. Such barrier isolators must

be certified by an independent certification contractor according to ISO class 5 conditions, as defined by federal standard 209E et seq. prior to use and at six-month intervals; certification records will be maintained for 3 years;

(d) store medications and supplies on shelves above the floor;

(e) develop and implement a disposal process for packaging materials, used supplies, containers, syringes, and needles; this process shall be performed to enhance sanitation and avoid accumulation in the controlled area;

(f) prohibit particle generating activities in the controlled area:

(i) removal of medications or supplies from cardboard boxes shall not be done in the controlled area;

(ii) cardboard boxes or other packaging/ shipping material which generate an unacceptable amount of particles shall not be permitted. The removal of immediate packaging designed to retain sterility or stability will be allowed;

(g) cytotoxic drugs shall:

(i) be prepared in a vertical flow biological safety cabinet, micro-biological isolation chamber or equivalent containment device;

(ii) be prepared in a cabinet thoroughly cleaned prior to use for preparation of other products; said cleaning will be documented;

(iii) be prepared in a cabinet located in a controlled area as described in 11.C.(1).(c);

(iv) be disposed of according to written policies and procedures maintained at the facility;

(h) maintain a library of specialty references appropriate for the scope of services provided; reference material may be hard copy or computerized.

(2) Requirements for training.

(a) All pharmacists prior to compounding sterile pharmaceuticals, or supervising pharmacy personnel compounding sterile pharmaceuticals, all shall have completed[~~a minimum of 20 contact hours of~~] didactic, experiential training and competency evaluation through demonstration and testing (written or practical) as outlined by the pharmacist-in-charge and described in the policy and procedures or training manual. Such training shall be evidenced by completion of a recognized course in [~~an~~] **a board approved** accredited college of pharmacy or[~~an ACPE approved~~] course which shall include instruction and hands-on experience in the following areas:

(i) aseptic technique;
(ii) critical area contamination factors;
(iii) environmental monitoring;
(iv) facilities;
(v) equipment and supplies;
(vi) sterile pharmaceutical calculations and terminology;
(vii) sterile pharmaceutical compounding documentation;
(viii) quality assurance procedures;
(ix) proper gowning and gloving technique;
(x) the handling of cytotoxic and hazardous drugs; and
(xi) general conduct in the controlled area.

(b) All pharmacist interns prior to compounding sterile pharmaceuticals shall have completed[~~a minimum of 40 hours of~~] instruction and experience in the areas listed in paragraph [~~1~~]**2**. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy); or

(ii) completion of a[~~course sponsored by an ACPE~~] **board** approved **course** [~~provider~~].

(iii) certification by University of New Mexico College of Pharmacy.

(c) All pharmacy technicians who compound sterile pharmaceuticals shall[~~have a high school or equivalent education and~~] be a certified pharmacy technician, and complete[~~a minimum of 40 hours of~~] instruction and experience in the areas listed in paragraph [~~1~~]**2**. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy) which provides[~~40 hours of~~] instruction and experience in the areas listed in paragraph [~~1~~]**2**; or

(ii) completion of[~~a course sponsored by an~~] **a board approved course[**~~ACPE approved provider~~] which provides [~~40 hours of~~] instructions and experience in the areas listed in paragraph [~~1~~]**2**.

(d) All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs shall[~~,effective December 31, 2008,~~] have completed a board approved[~~training program~~] **course** in chemotherapy drug preparation. All pharmacy interns and technicians must complete this training prior to preparing sterile chemotherapy drug products.

(e) Documentation of Training. A written record of initial and in-service training and the results of written or practical testing and process validation of pharmacy personnel shall be maintained and contain the following information:

(i) name of person receiving the training or completing the testing or process validation;

(ii) date(s) of the training, testing, or process validation;

(iii) general description of the topics covered in the training or testing or of the process validated;

(iv) name of person supervising the training, testing, or process validation;

(v) signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

(f) No product intended for patient uses shall be compounded by an individual until the process validation test indicates that the individual can competently perform aseptic procedures.

(g) On an annual basis the pharmacist-in-charge shall assure continuing competency of pharmacy personnel through in-service education, training, and process validation to supplement initial training. A written record of such training will be maintained for 3 years.

(3) Patient or Caregiver Training for Home Sterile Products.

(a) The pharmacist shall maintain documentation that the patient has received training consistent with regulation 16.19.4.17.5 NMAC.

(b) The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy.

(c) There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:

(i) routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(ii) patient monitoring plans that include written outcome measures and systems for routine patient assessment;

(iii) documentation of patient training; and

(4) Quality Assurance/compounding and preparation of sterile pharmaceuticals.

(a) There shall be a documented, ongoing performance improvement control program that monitors personnel performance, equipment, and facilities:

(i) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;

(ii) if bulk compounding of parenteral solutions is performed using non-sterile chemicals, appropriate end product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;

(iii) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits; a plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken; a periodic evaluation as stated in the policy and procedures of the effectiveness of the quality assurance activities shall be completed and documented;

(iv) the label of each sterile compounded product shall contain: patient name; if batch filling, lot or control number; solution, ingredient names, amounts; expiration date and time, when

applicable; directions for use (only if the patient is the end user; not in a hospital setting), including infusion rates, specific times scheduled when appropriate; name or initials of person preparing the product and , if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check; when appropriate, ancillary instructions such as storage instructions or cautionary systems, including cytotoxic warning labels and containment bags; 8 device instructions when needed.

(b) There shall be a mechanism for tracking and retrieving products which have been recalled.

(c) Automated compounding devices shall:

(i) have accuracy verified on a routine basis at least every thirty days per manufacturer's specifications;

(ii) be observed every thirty days by the operator during the mixing process to ensure the device is working properly;

(iii) have data entry verified by a pharmacist prior to compounding; and

(iv) have accuracy of delivery of the end product verified according to written policies and procedures.

(d) If batch preparation of sterile products is being performed, a worksheet (log) must be maintained for each batch. This worksheet shall consist of formula, components, compounding directions or procedures, a sample label and evaluation and testing requirements, if applicable, and shall be used to document the following:

(i) all solutions and ingredients and their corresponding amounts, concentrations and volumes;

(ii) component manufacturer and lot number;

(iii) lot or control number assigned to batch;

(iv) date of preparation;

(v) expiration date of batch prepared products;

(vi) identity of personnel in preparation and pharmacist responsible for final check;

(vii) comparison of actual yield to anticipated yield, when appropriate.

(5) Application of Regulation: Pharmacies licensed by the board prior to adoption of this regulation shall comply with the controlled area standards defined in section 11.C.(1).(c). by December 31, 2002. When these pharmacies change ownership, remodel the pharmacy, or relocate the pharmacy after the effective date of this regulation, Section 11(2)A.3. shall apply. All other portions of this regulation apply on the effective date.

[16.19.6.11 NMAC - Rp, 16 NMAC 19.6.11, 03-30-02; A, 01-15-2005; A, 01-15-08; A, 04-15-10]

16.19.6.15 DISPOSITION OF DANGEROUS DRUGS OR CONTROLLED SUBSTANCES: Permission shall be obtained, in writing, from the Board, after inspection, before any inventory of dangerous drugs or controlled substances may be sold, transferred, disposed of, or otherwise removed from the current premises. All sales shall be subject to the laws of the state.

A. DISPENSED PHARMACEUTICALS, COLLECTION AND DISPOSAL; Patient dispensed legend and OTC medications that are unwanted or expired may be returned to an authorized pharmacy for destruction. The pharmacy must submit a protocol or subsequent changes to the board or the boards agent, for approval. Once approved the pharmacy is authorized to collect pharmaceuticals for destruction. A protocol is to be submitted to the board of pharmacy for staff approval. Such protocol must include:

(1) Secure and enclosed collection unit that does not allow for unauthorized access.

(2) A description of the dedicated area for collection unit inside the pharmacy within site of the authorized pharmacy staff.

(3) Direction of collection that allows for safe and secure disposition.

(4) Name of contracted disposal company that is licensed for pharmaceutical destruction.

(5) Frequency of collection and destruction by disposal company.

(6) Records of collection and destruction supplied by the disposal company.

B. Items accepted at a take back site may include:

(1) Dangerous drugs (prescription drugs);

(2) Controlled substances if authorized under federal law or rule;
(3) Over-the-counter medications;
(4) Veterinary medications;
(5) medicated ointments and lotions;
(6) liquid medication in glass or leak-proof containers.

C. Items NOT accepted at a take back site may include:
(1) Needles;
(2) Thermometers;
(3) Bloody or infectious waste;
(4) Personal care products;
(5) Controlled substances (unless authorized by federal law);
(6) Hydrogen Peroxide;
(7) Empty containers;
(8) Business waste.

D. Collected medications are not for re-dispensing.

E. Directions for take back for patients and list od accepted and non-accepted products must be posted on the collection unit.

F. Suspension of the pharmacy's authority to collect and dispose of dispensed pharmaceutical shall occur upon violation of the approved protocol. The pharmacy may petition the board for removal of that suspension.

[16.19.6.15 NMAC - Rp, 16 NMAC 19.6.15, 03-30-02; A, 04-15-10]

16.19.6.22 COMPUTERIZED PRESCRIPTION INFORMATION:

A. Computers for the storage and retrieval of prescription information do not replace the requirement that a prescription written by a practitioner or telephoned to the pharmacist by a practitioner and reduced to hardcopy be retained as permanent record. Computers shall be maintained as required by the Pharmacy Act; the Drug, Device, and Cosmetic Act; the Controlled Substance Act; and the board of pharmacy regulations.

B. The computer shall be capable of producing a printout of prescription information within a 72 hour period on demand, with certification by the practitioner stating it is a true and accurate record. Requested printouts include: patient specific; practitioner specific; drug specific; or date specific reports. The printout shall include:

(1) the original prescription number;
(2) the practitioner's name;
(3) full name and address of patient;
(4) date of issuance of original prescription order by the practitioner and the date filled;
(5) name, strength, dosage form, quantity of drug prescribed;
(6) total number of refills authorized by the practitioner;
(7) the quantity dispensed is different than the quantity prescribed, then record of the quantity dispensed;
(8) in the case of a controlled substance, the name, address and DEA registration number of the practitioner and the schedule of the drug;
(9) identification of the dispensing pharmacist; computer-generated pharmacist initials are considered to be the pharmacist of record unless overridden manually by a different pharmacist who will be the pharmacist of record.

C. Permanent records of electronic prescriptions, transmitted directly over approved secure electronic prescribing networks or other board approved transmissions standards, do not have to be reduced to hardcopy provided the following requirements are met.

(1) Electronic prescription information or data must be maintained in the original format received for ten years.
(2) Documentation of business associate agreements with "network vendors", electronic prescription transmission intermediaries and pharmacy software vendors involved in the transmission and formatting of the prescription who can provide documentation of chain of trust of who has had access to prescription content is available.
(3) Reliable backup copies of the information are available and stored in a secure manner as approved by the board.

(4) All elements required on a prescription and record keeping requirements are fulfilled including identification of the dispensing pharmacist of record.

D. Electronically archived prescription records of scanned images of indirect written or faxed prescriptions are permitted provided the following requirements are met:

(1) images of scanned prescriptions are readily retrievable and can be reproduces in a manner consistent with state and federal laws within a seventy-two hour period;

(2) the identity of the pharmacist approving the scanned imaging and of the pharmacist responsible for destroying the original document after three years is clearly documented;

(3) the electronic form shows the exact and legible image of the original prescription;

(4) the original paper prescription document must be maintained for a minimum of three years and the electronic image of the prescription for ten years;

(5) the prescription is not for a controlled substance except as allowed by federal law;

(6) reliable backup copies of the information are available and stored in a secure manner as approved by the board;

(7) all elements required on a prescription and record keeping requirements are fulfilled including identification of the dispensing pharmacist of record.

(8) the original paper prescription document for a non-controlled substance must be maintained on the licensed premises for a period of 120 days from the initial date of dispensing.

(9) the original paper prescription document for a controlled substance must be maintained on the licensed premises for a period of two years from the initial date of dispensing.

E. Electronic records of prescriptions and patient prescription records may be stored offsite on secure electronic servers provided the following requirements are met:

(1) records are readily retrievable;

(2) all Health Insurance Portability and Accountability Act and board of pharmacy patient privacy requirements are met;

(3) reliable backup copies of the information are available and stored in a secure manner as approved by the board.

F. Original paper prescription documents may be stored offsite after the minimum period of storage on the licensed premises has been reached, provided that the following requirements are met:

(1) the storage area is maintained so that records are secure and prevented from unauthorized access;

(2) the storage area is maintained with appropriate fire suppression safeguards and climate control capabilities;

(3) all Health Insurance Portability and Accountability Act and board of pharmacy patient privacy requirements are met;

(4) the pharmacist-in charge maintains a record-keeping system that records storage location(s) and documents an inventory of original paper prescription documents that are maintained offsite;

(5) original paper prescription records must be able to be produced within three business days upon the request of the board or an authorized officer of the law.

[16.19.6.22 NMAC - Rp, 16 NMAC 19.6.22, 03-30-02; A, 06-30-06; A, 04-15-10]

Motion:

A motion was made Ms. Buesing, seconded by Mr. Mazzoni to approve the proposed amendment to 16.19.6.22 NMAC. The Chairman took a roll call vote. Mr. Mazzoni, Ms. Saavedra, Mr. Anderson, Ms. Buesing and Mr. Cross voted unanimously to pass the motion.

STIPULATED OR SETTLEMENT AGREEMENTS/SURRENDERS/DEFAULT ORDERS:

2009-031 Stipulated Agreement: The course presented in the agreement is no longer available. Another course will be approved by the executive director and a handwritten change will be made to the agreement and the licensee will initial the change.

Motion:

A motion was made by Ms. Saavedra, seconded by Mr. Anderson to accept the stipulated agreement as amended. The board voted unanimously to pass the motion.

2009-072 Stipulated Agreement: The course presented in the agreement is no longer available. Another course will be approved by the executive director and a handwritten change will be made to the agreement and the licensee will initial the change.

Motion:

A motion was made by Mr. Mazzoni, seconded by Ms. Saavedra to accept the stipulated agreement as amended. The board voted unanimously to pass the motion.

2009-003 Stipulated Agreement: The course presented in the agreement is no longer available. Another course will be approved by the executive director and a handwritten change will be made to the agreement and the licensee will initial the change.

Motion:

A motion was made by Ms. Saavedra, seconded by Ms. Buesing to accept the stipulated agreement as amended. The board voted unanimously to pass the motion.

2009-145 Voluntary Surrender: After a brief discussion the board agreed to accept the voluntary surrender.

Motion:

A motion was made by Mr. Mazzoni, seconded by Ms. Saavedera to accept the voluntary surrender. The board voted unanimously to pass the motion.

2009-143 Voluntary Surrender: After a brief discussion the board agreed to accept the voluntary surrender.

Motion: A motion was made by Ms. Buesing, seconded by Mr. Anderson to accept the voluntary surrender. The board voted unanimously to pass the motion.

2009-111 Default Order: After a brief discussion the board agreed to accept the default order to revoke the license.

Motion: A motion was made by Ms. Saavedra, seconded by Mr. Mazzoni to accept the default order to revoke the license. The board voted unanimously to pass the motion.

The Chairman asked for a 10-minute recess.

RECESS:

RECONVENE:

The board reconvened at 11:20 a.m.

EXECUTIVE DIRECTORS REPORT:

Required fees, fines, investigational costs: Ms. Wilhite asked the board and Ms. Mary Smith to consider adding language to the voluntary surrenders to include any and all costs incurred by the board to be paid by the licensee. The board agreed to the request.

AAG Mary Smith – confidential memorandum*: Mary Smith discussed feedback from the EIB (Environmental Improvement Board) regarding changing language to allow the drug take-back program and how this would have a positive affect on the environment and good for the public.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Mazzoni to go into closed session to discuss case presentations and the confidential memorandum. The board voted unanimously to pass the motion.

The board went back into open session and the only issues discussed were case presentations and the confidential memorandum.

Motion:

A motion was made by Buesing, seconded by Mr. Mazzoni to close cases; 2009-136, 2009-104, 2009-128, 2009-106, 2009-116, 2009-091, 2009-117, 2009-126, 2009-148, 2009-147; leave open case 2009-062; recind case 2009-085; refer to medical board and send advisory letter for case 2009-101; send advisory letters to; 2009-122, 2009-129, 2009-132, PIC regarding reviewing process of filling and counseling for case 2009-087, technician and pharmacy regarding safe handling of medications for case 2009-120, PIC and pharmacy for case 2009-121, 2009-137 regarding error prevention mechanism; send NCA's to 2009-014, 2009-087, 2009-149, 2009-100, 2009-109, 2009-133. The board voted unanimously to pass the motion.

Executive Director's Report Cont'd:

NABP 106th Annual Meeting May 22-25, 2010 Anaheim, CA: After a brief discussion the board suggested that Ms. Saavedra should attend the NABP Annual Meeting.

NABP District 6, 7 and 8 Meeting September 28 – 30, 2010 in Albuquerque: The budget has been approved for one staff member and a voting member for the Anaheim and annual meeting.

The Chairman asked that the board recess for lunch at 12:00 noon.

RECESS:

RECONVENE:

The Board reconvened at 1:21 p.m.

Mr. Ortega arrived during the lunch recess.

PUBLIC AND PROFESSIONAL REQUESTS/WAIVER PETITIONS:

Waiver Request – David Oberstein, Authorized Agent, Memorial Ventures (Use of term Apothecary in a sign): After discussions of use of the term "Apothecary" the board agreed to accept the waiver to use the term "Apothecary" in a non-related pharmacy venture in the remodeling of the Memorial Hospital in downtown Albuquerque.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Anderson to accept the waiver for David Oberstein request to use the term "Apothecary" in a sign. The board voted unanimously to pass the motion.

Request to prevent pharmacists or technicians who smoke from working in clean rooms – Ray Goellner, PIC – Gila Regional Medical Center: FYI, no recommendation by board.

NMDOH Bobbie MacKenzie, Nmserves Member Service Coordinator _ Request for CEU approval for pharmacists volunteering there time to assist with Seasonal Flu and H1N1 vaccination clinics and PODS throughout our state: After discussion with the board it was agreed that 1 CEU for 3 hours worked volunteering. Mr. Loring will help Mr. MacKenzie write the waiver to be presented on January 12th, 2010.

Request from Dale McClesky, PIC Best Buy Drugs to repackage previously dispensed pharmaceuticals – 16.19.11.8B(7)(f): Recommendation by the board was to take to the Pharmacy Practice Committee for review.

Board of Pharmacy /Chiropractor Formulary Committee: There are 35 advanced practice chiropractors in the state of New Mexico. The board looked over the updated formulary tables that were presented. Mr. Anderson requested that he have more time go over the updated tables and consult with another professional along with Inspector Ben Kesner and get back to the board at the March 2010 board meeting. Mr. Anderson stated that the Chiropractic board was having a rule hearing in March that would be attended by committee members so that formal testimony can be presented.

Board of Pharmacy/BAOM Education Committee: FYI, no report at this time.

Emergency Preparedness Committee: FYI, no report at this time.

Tele-Pharmacy Committee: FYI, no report at this time.

Pharmacist CE Committee: Mr. Anderson discussed the results of the meeting on December 15, 2009 with Sarah Trujillo, Bill Harvey, Dean Pieper, Greg D'Amour and Julie Watson. The committee is tasked with establishing a live CE component.

A power point presentation on "Continuous Professional Development" was given by Kristina Wittstrom from UNM College of Pharmacy. The board asked Ms. Wittstrom to proceed with the "CPD" project and have Mr. Anderson prepare a waiver for the March 2010 meeting to do a pilot project.

Milton Gordon petition for intern hours: After a brief discussion the board agreed to deny the waiver as presented.

~~Presentation Vacated – Express Scripts, Henna Griego PIC – Petition to increase technician /pharmacist ration:~~

The Chairman asked that the board meeting be adjourned at 5:00 p.m.

TUESDAY JANUARY 12TH, 2010

ROLL CALL:

The Chairman called the meeting to order at 9:05 a.m. Present were Mr. Mazzoni, Ms. Saavedra, Mr. Anderson, Ms. Buesing, and Mr. Cross.

Public and Professional Requests/Waiver Petitions Cont'd:

Pharmacist Clinician Committee: Mr. Anderson stated that there appeared to be an error in rule 16.19.4.17 NMAC regarding the word "initialed". Mr. Anderson stated that the word should be "initiated".

Motion:

A motion was made by Mr. Anderson, seconded by Ms. Buesing to notice 16.19.4 NMAC at the March 2010 board meeting. The board voted unanimously to pass the motion.

NMDOH Bobbie MacKenzie, NMserves Member Service Coordinator _ Request for CEU approval for pharmacists volunteering there time to assist with Seasonal Flu and H1N1 vaccination clinics and PODS throughout our state: Mr. Loring presented the waiver to the board for Mr. MacKenzie.

Motion:

A motion was made by Ms. Saavedra, seconded by Ms. Buesing to accept the waiver as presented. The board voted unanimously to pass the motion.

DISCIPLINARY HEARING CASE NO. 2009-006 (Bean & Associated will record hearing):

The Chairman Danny Cross opened the hearing and took roll call. Present were Mr. Mazzoni, Ms. Saavedra, Mr. Anderson, Ms. Buesing and prosecuting attorney David Tourek. Absent were Mr. Ortega, Mr. Carrier, Mr. Nunley, and Mr. Shaver.

The Chairman stated that Mr. Enrique Chacon was also present.

The Chairman asked to list the NCA as exhibit #1, the notice of hearing as exhibit #2 and the certified copies of the Texas order that was enclosed with the NCA as exhibit #3.

The prosecuting attorney David Tourek presented his findings to the board. The Chairman asked Mr. Chacon to present his case.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Anderson to go into closed session to discuss the hearing.

The board went back into open session and the only issue discussed was the hearing for case 2009-006.

After deliberation the board agreed that Enrique Chacon's license be suspended until probation is fulfilled with the Texas conviction of a felony, currently 10 years as of conviction date 2008. At which time Mr. Chacon can re-apply and based on the NMBOP requirements.

Public and Professional Requests/Waiver Petitions Cont'd:

Pharmacy Technician Committee - Proposed changes to 16.19.22 NMAC: The proposed language was presented to the board by Chairman Danny Cross. After a lengthy discussion the board agreed to continue after the lunch recess.

The Chairman asked for a lunch recess at 12:00 noon.

RECESS:

RECONVENE:

The board reconvened at 1:15 p.m.

Public and Professional Requests/Waiver Petitions Cont'd:

Pharmacy Technician Committee - Proposed changes to 16.19.22 NMAC: After lengthy discussion the board agreed to notice 16.19.22 NMAC at the March 2010 board meeting.

Motion:
A motion was made by Ms. Buesing, seconded by Ms. Saavedra to accept the amendments as presented for 16.19.22 NMAC and notice for hearing at the March 2010 board meeting. The board voted unanimously to pass the motion.

Pharmacist Practice Committee: Mr. Cross stated that he is now on this committee. FYI, no report at this time.

The Chairman asked to adjourn the board meeting at 3:45 p.m.

Motion:

A motion was made by Mr. Mazzoni, seconded by Mr. Anderson to adjourn the meeting. The board voted unanimously to pass the motion.