

**New Mexico Board of Pharmacy Regular Board Meeting
August 27th & 28th, 2007**

Monday August 27th, 2007

PLACE AND TIME:

The meeting was held at the Ruidoso Convention Center - Rms. 1 & 2 at 111 Sierra Blanca Dr. Ruidoso, NM 88345

CALL TO ORDER:

The meeting was called to order by the Chairman Woodrow Storey, R.Ph., at 9:00a.m.

MEMBERS PRESENT:

Woodrow Storey, R.Ph., Chairman
Danny Cross, R.Ph., Vice-Chairman
Amy Buesing, R.Ph., Secretary
Rudy Nolasco, R.Ph., Member
Thomas Ortega, R.Ph., Member
Brenda Padilla, R.Ph., Member
Howard Shaver, Public Member
Allen Carrier, Public Member

MEMBERS ABSENT:

Buffie Saavedra, Public Member

STAFF ATTENDING:

Mary Smith, Assistant Attorney General
William Harvey, Executive Director
Debra Wilhite, Administrative Secretary
Larry Loring, Inspector
Bill Weast, Inspector

ROLL CALL:

Mr. Storey took roll call at 9:00 a.m. Present were Mr. Cross, Ms. Buesing, Mr. Nolasco, Mr. Carrier, Mr. Ortega, Mr. Shaver, Ms. Padilla and Woodrow Storey. The Chairman stated that there was a quorum. The Chairman stated that Ms. Saavedra would be absent for this board meeting.

GREETINGS FROM RUIDOSO MAYOR RAY NUNLEY:

Mayor Ray Nunley greeted and met with all the board members and extended his hospitality. He thanked the board for choosing Ruidoso to hold a regularly scheduled board meeting and extended the offer for future board meetings.

APPROVAL OF THE AGENDA:

The Chairman asked if there were any changes to the agenda.

Mr. Harvey stated that there were no further changes to the agenda.

Motion:

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

APPROVAL OF THE JUNE 11TH & 12TH, 2007 MEETING MINUTES:

The Chairman asked if there were any changes to the minutes for June 11th & 12th, 2007.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Nolasco to approve the minutes for June 11th & 12th, 2007. The Board voted unanimously to pass the motion.

MTP REPORT:

The Chairman called for a motion to go into closed session to present the MTP Report at 9:30 a.m.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Padilla to go into closed session to discuss the MTP report. The Chairman took a roll call vote. Mr. Ortega, Ms. Padilla, Mr. Carrier, Mr. Nolasco, Mr. Cross, Mr. Storey, Ms. Buesing and Mr. Shaver 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 33 applications in this category and all are in order.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Ortega to approve all 33 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 all are in order.

Motion:

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

Emergency Medical Services:

Ms. Buesing stated that there were 13 applications in this category and all are in order.

Motion:

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

Custodial Home:

Ms. Buesing stated that there were 35 applications in this category and all are in order.

Motion:

A motion was made by Mr. Storey, seconded by Ms. Buesing to approve all 35 applications in this category as presented. The Board voted unanimously to pass the motion. Mr. Storey abstained from voting on Journey's-Minaret, Yahtahey Men's Home and Yahtahey Women's Home

Pharmacy:

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

Motion:

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

Hospital:

Ms. Buesing stated that there is 1 application in this category and all is in order.

Motion:

A motion was made by Mr. Storey, seconded by Mr. Nolasco to approve the 1 applications in this category as presented. The Board voted unanimously to pass the motion. Ms. Buseing abstained from voting on Advanced Care Hospital of Southern NM.

Non-Resident Pharmacy:

Ms. Buesing stated that there are 17 applications in this category and all are in order.

Motion:

A motion was made by Mr. Storey, seconded by Mr. Shaver to approve all 17 applications in this category as presented. The Board voted unanimously to pass the motion.

Wholesale/Broker:

Ms. Buesing stated that there are 28 applications in this category and all are in order.

Motion:

A motion was made by Mr. Storey, seconded by Ms. Buesing to approve all 28 applications in this category as presented. The Board voted unanimously to pass the motion.

Pharmacist Credentialing Committee:

Ms. Buesing presented 3 applications that were discussed by the committee in August 2007. The applicants are Randy Burden, Mary Jo Zunica and Sandra J. Sanchez.

Motion:

A motion was made by Mr. Storey, seconded by Ms. Buesing to approve the recommendations by the credentialing committee for Randy Burden and table the applications for Mary Jo Zunic and Sandra J. Sanchez until the next board meeting in October 2007. The Board voted unanimously to pass the motion.

Ms. Buesing requested that the application lists be attached to the minutes.

The Chairman asked to take a 10-minute recess at 9:40 a.m.

RECESS:

RECONVENE:

The Board reconvened at 9:50 a.m.

EXECUTIVE DIRECTOR'S REPORT:

Mr. Harvey presented the proposed board meeting dates for 2008.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Buesing to accept the meeting dates as presented: January 14th and 15th, March 17th and 18th, June 16th and 17th, August 25th and 26th in Ruidoso, October 20th and 21st. The Board voted unanimously to pass the motion.

The board briefly discussed the "Findings of Civil Division" for Hossein Afshari. FYI, no action taken.

After a lengthy discussion the board presented many issues that an "Emergency Provisions Committee" would address regarding regulations, protocols and types of emergencies. An appointment of committee members is in order.

The board discussed the proposed language with Mr. Bill Weast regarding identification requirements of patient and/or patient representatives for 16.19.20.42 NMAC as follows;

16.19.20.42 PRESCRIPTION REQUIREMENTS:

A. Prescriptions for controlled substances shall be dated and signed as of the date of issue, and shall contain the full name and address of the patient, the name, address and federal registration number of the prescribing practitioner. Prescriptions for controlled substances listed in Schedule II shall be written in ink, indelible pencil, or typewritten and manually signed by the practitioner.

B. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in 16.19.20.41.C NMAC, 16.19.20.41.D NMAC, and 16.19.20.42.E NMAC. The original prescription shall be maintained in accordance with 16.19.20.31 NMAC.

C. A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, or subcutaneous infusion may be transmitted by the practitioner or the practitioner's agent to the Parenteral Products Pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with 16.19.20.31 NMAC.

D. A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this sub-section and it shall be maintained in accordance with 16.19.20.31 NMAC.

E. A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II narcotic substance for a patient enrolled in a hospice program certified by Medicare under Title XVIII or licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this sub-section and it shall be maintained in accordance with 16.19.20.31 NMAC.

F. A pharmacist may dispense directly a controlled substance listed in Schedule III or IV, which is a prescription drug as determined under the New Mexico Drugs and Cosmetics Act, only pursuant

to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist containing all information required for a prescription except the signature of the practitioner.

G. A pharmacist, pharmacist intern, or pharmacy technician, must verify the identity of the patient or the patient's representative before a new prescription for a controlled substance listed in Schedule II, III, or IV, is delivered. Acceptable identification means a state issued driver's license, including photo, or other government issued photo identification. The identification number of the government issued identification and the name imprinted on that identification must be recorded in a manner to be determined by a written policy developed by the pharmacist-in-charge. Exceptions are, a new controlled substance prescription filled for a patient known to the pharmacist or pharmacist intern, whose identification has already been documented in a manner determined by a written policy developed by the pharmacist-in-charge; a controlled substance prescription filled by a mail order pharmacy that does not have a "pickup" service; or a controlled substance prescription filled for and delivered to a patient residing in a licensed nursing home.

[16.19.20.42 NMAC - Rp 16 NMAC 19.20(1), 07-15-02]

(161920BW03-20-07)

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to notice 16.19.20.42 NMAC for hearing at the October 2007 board meeting. The Board voted unanimously to pass the motion.

Mr. Harvey discussed the proposed amendments to 16.19.20 NMAC Controlled Substances that will be noticed at the October 2007 board meeting.

Amendment of Schedules I, II, III:	Schedule I Stimulants: 16.19.20.65 Add Cathinone and Methcathinone to paragraph E.
	Schedule II Stimulants: 16.19.20.66 C (5) Precursors and (6) Phenylacetone
	Schedule III: 16 NMAC 19.20.67F Add to anabolics and re-letter. Mestanolone Methyltrienolone Norbolethone

(161920BH06-11-07)

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to notice 16.19.20.65 -67 NMAC at the October 2007 board meeting. The Board voted unanimously to pass the motion.

16.19.4.9 DEFINING UNPROFESSIONAL OR DISHONORABLE CONDUCT:

- A.** Preamble: In defining "unprofessional conduct" the definitions of professional conduct and a pharmacist's duty should be considered.
- B.** Professional conduct may be defined as complying with all the laws and regulations that apply to a given professional activity.
- C.** Definition: Unprofessional or dishonorable conduct by a pharmacist shall mean, among other things, but not be limited to:
 - (1) Violation of any provision of the Pharmacy Act as determined by the Board.
 - (2) Violation of the Board of Pharmacy Regulations as determined by the Board.

- (3) Violation of the Drug and Cosmetic Act as determined by the Board.
- (4) Violation of the Controlled Substances Act as determined by the Board.
- (5) Failure of the pharmacist to conduct himself professionally in conformity with all applicable federal, state and municipal laws and regulations to his relationship with the public, other health professions and fellow pharmacists.
- (6) Failure to keep his pharmacy and/or area of professional practice clean, orderly, maintained and secured for the proper performance of his professional duties.
- (7) Acquiring prescription stock from unlicensed sources.
- (8) Failure to hold on the strictest confidence all knowledge concerning patrons, their prescriptions, and other confidence entrusted or acquired of by him; divulging in the interest of the patron only by proper forms, or where required for proper compliance with legal authorities.
- (9) Participation in a plan or agreement which compromises the quality or extent of professional services, or facilities at the expense of public health or welfare.
- (10) The solicitation of prescription business by providing prescribers with prescription blanks with the name of any licensed pharmacy or pharmacist printed thereon.
- (11) Failure to report a theft or loss of controlled substances in accordance with 16.19.20.36 NMAC.
- (12) Failure to report an impaired licensee in compliance with Subparagraph a of Paragraph 1 of Subsection C of 16.19.4.12 NMAC.
- (13) Failure to train or supervise adequately supportive personnel or the use of supportive personnel in activities outside the scope of their permitted activities.
- (14) Conviction, plea of nolo contendere, or entering into any other legal agreements for any violation of the Pharmacy Act, Controlled Substances Act, Drug Device and Cosmetic Act or any similar act of another state or territory of the United States.
- (15) Suspension, revocation, denial, or forfeiture of license to practice or similar disciplinary action by a licensing agency of another state or territory of the United States.
- (16) Dispensing a prescription for a dangerous drug to a patient without an established practitioner-patient relationship:
 - (a) except for the provision of treatment of partners of patients with sexually transmitted diseases when this treatment is conducted in accordance with the expedited partner therapy guidelines and protocol published by the New Mexico department of health;
 - (b) except for on-call practitioners providing services for a patient's established practitioner;
 - (c) except for delivery of dangerous drug therapies to patients ordered by a New Mexico department of health physician as part of a declared public health emergency;
 - (d) except for dispensing a prescription for the dangerous drug naloxone to a person for administration to another as authorized in public health law 24-23 administration of opioid antagonist.

(16194LL08-27/07)

Motion:

Mr. Cross, seconded by Ms. Padilla to notice 16.19.4.9 NMAC with the added language for letter "e" to be submitted at the October 2007 board meeting, made a motion. The Board voted unanimously to pass the motion

Regulation concerning Public Notice of Closure of a Pharmacy:

Pharmacies permanently closing shall notify the public of the closure at least 14 days prior to the final day of service. The notice shall include the last date of service and the name, address, and phone number of the location where patient records will be transferred or stored. Notice must occur via newspaper notice, radio broadcast, or other method as approved by the Board of Pharmacy.

After a brief discussion the board asked the Executive Director, Mr. Harvey to prepare language to amend the regulation 16.19.6 NMAC for discussion at the October 2007 board meeting.

Larry W. Sperl - Food And Drug Administration:

Mr. Harvey presented a recognition letter addressing Inspectors Larry Loring, Ben Kesner, Mike Lyons and Bill Weast for their assistance in the execution of two federal search warrants for the FDA. The board was congratulated the inspectors for their efforts.

Medicaid Tamper-Resistant Prescription Requirements:

After a brief discussion Mr. Harvey indicated that the new requirements would be posted on the website for reference.

The Chairman asked for a recess for lunch @ 12:00 p.m.

RECESS FOR LUNCH:

RECONVENE MONDAY AUGUST 27TH, 2007:

The board reconvened at 1:35 p.m.

COMMITTEE REPORTS:

Technician Committee; Contact Bill Harvey for committee membership.

Remote Pharmacy Committee; Contact Bill Harvey for committee membership.

Wholesale Distribution Committee; Contact Bill Harvey for committee membership.

The Chairman asked for a recess at 2:40 p.m.

RECESS:

RECONVENE:

The board reconvened at 2:50 p.m.

OPEN FORUM:

PUBLIC REQUESTS:

Mr. John E. Ellison - Pharmacy Law CE;

Discussion on Adding Live CE - Pharmacy Law Reviews:

Response from Lance D. Richards for Case# 2001-088;

Mr. Fleischer - Faxing Prescriptions;

Motion:

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

The board meeting was adjourned at 5:00 p.m.

RECONVENE TUESDAY AUGUST 28TH, 2007:

The Chairman reconvened at 9:09 a.m. and took roll call. Present were Mr. Ortega, Ms. Padilla, Mr. Carrier, Mr. Nolasco, Mr. Cross, Mr. Storey, Ms. Buesing, and Mr. Shaver. The Chairman stated that Ms. Saavedra would be absent.

ADOPTION OF THE “OPEN MEETINGS RESOLUTION”:

The Assistant Attorney General Mary Smith presented the language for the “Open Meetings Resolution”. After a brief discussion the board recommended that the “Open Meetings Resolution” be presented every year for modification if necessary at the August board meeting.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Buesing to approve the “Open Meetings Resolution”. The Board voted unanimously to pass the motion.

REGULATION HEARING - 16.19.6 NMAC - PHARMACIES:

Mr. Loring presented the language for 16.19.6 NMAC to the board. The board approved of the change.

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS:

16.19.6.11C(2d) NMAC

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 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. 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 approved provider.

(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. 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; or

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

(d) All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs shall, effective December 31, [2007]2008, have completed a board approved training program 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:
(16196LL06-11-07)

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to notice 16.19.6 NMAC at the October 2007 board meeting. The Chairman took a roll call vote. Mr. Ortega, Ms. Padilla, Mr. Carrier, Mr. Nolasco, Mr. Cross, Mr. Storey, Ms. Buesing and Mr. Shaver voted unanimously to pass the motion.

Public Requests Cont'd:

Mr. Dan Liebig - Mobile Pharmacy Trailers in Times of Disasters or Emergencies;

Designation of Nurses as "Agents" in Assisted Living (Boarding Homes);

Stephanie Raitt - 2007 Critical Care Collaborative;

NABP CORRESPONDENCE - MEETINGS - NEWS:

The Board discussed the temporary discontinuation of the NABP testing for the NAPLEX and MPJE in Georgia. The NABP Executive Committee is evaluating how actions noted in the findings of the federal court impact the NAPLEX and MPJE and what changes need to occur to ensure the integrity of the NAPLEX and MPJE. FYI, no action taken.

ELECTION OF OFFICERS:

Mr. Cross was nominated Chairman; Ms. Buesing was nominated Vice-Chairman and Mr. Allen Carrier was nominated Secretary. Ms. Buesing thanked Mr. Storey for his participation as board Chairman and Mr. Shaver asked that the board prepare a letter recognizing his participation to be sent to his employer.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Nolasco to approve the nominations presented. The Board voted unanimously to pass the motion.

The Chairman called for a 10-minute break @ 10:35 a.m.

RECESS:

RECONVENE:

The Board reconvened @10:45 a.m.

Executive Director's Report Cont'd:

The Chairman asked to go into closed session to discuss case presentations.

Case Presentations:

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Nolasco to go into closed session for case presentations. The Chairman took a roll call vote. Mr. Ortega, Mr. Carrier, Mr. Nolasco, Mr. Storey, Mr. Cross, Mr. Shaver, Ms. Buesing, and Ms. Padilla all voted unanimously to pass the motion.

The Chairman went back into open session at 11:50 a.m. and the only issues discussed were case presentations.

Motion:

A motion was made by Mr. Carrier, seconded by Mr. Storey to proceed as follows; 2007-081 issue NCA to deny, 2007-083 issue NCA's to all 5 applications lettered a, b, c, d, e, 2007-012 closed, 2007-013 closed, 2007-021 closed, 2007-026 closed, 2007-027 closed, 2007-057 closed, 2007-118 closed, 2007-043 advisory letter to pharmacist in charge, 2007-046 issue NCA to pharmacy technician, 2007-050 closed, 2007-059 advisory letter to pharmacy, 2007-060 closed, 2007-072 Pre-NCA to pharmacist and company/ advisory letter to pharmacist in charge, 2007-016 closed, 2007-041 closed, 2007-045 closed, 2007-053 closed, 2007-061 closed, 2007-064 closed, 2007-071 issue Pre-NCA Mr. Ortega abstained from voting on case 2007-046 and Ms. Padilla abstained from voting on case 2007-072. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Storey to adjourn the board meeting. The board meeting was adjourned at 11:55 a.m. The Board voted unanimously to pass the motion.