New Mexico Board of Pharmacy Regular Board Meeting
November 14 & 15, 2005

Monday, November 14, 2005

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

MEMBERS ABSENT: Howard Shaver, Public Member (9:00am – 1:30pm Tuesday Only)

STAFF ATTENDING:
Kathy Kunkel, Assistant Attorney General
William Harvey, Executive Director
Debra Wilhite, Administrative Assistant
Larry Loring, Inspector
Bill Harvey, Inspector
Mike Lyons, Inspector
Ben Kesner, Inspector
Paul Therkildsen, 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; under Applications to include letter "c" Miners Colfax- Extension Request, under the Executive Director's Report, two additional cases for Inspector William Harvey 2005-109 and 2005-110, letter "f" to read Flu Vaccination. Mr. Shaver asked to add letter "k" Perpetual inventory requirements discussion. Mr. Cross asked to add letter "l" Schedule dates for November 2006 Board Meeting and letter "m" Informal discussion about minutes posted to the website. Ms. Buesing asked to add letter "n" Update of any correspondence for Ms. Jakiche's request for waiver from last meeting. Mr. Ortega stated that he needs to leave Tuesday November 15, 2005 at 4:00 p.m. Ms. Saavedra stated that she would be absent November 15, 2005.

Motion:

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

APPROVAL OF THE JUNE 20, 2005 EMERGENCY MEETING MINUTES:

Mr. Storey asked if the Board members had any changes to the minutes. Mr. Harvey stated that the minutes for this meeting were brief. There were no changes.

Motion:

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

APPROVAL OF THE AUGUST 29 & 30, 2005 MINUTES:

Mr. Story asked if the Board members had any changes to the minutes. Mr. Cross stated that on page 7, line 5, that the wording was unclear about Mr. Pitcher and it should read, "Mr. Storey instructed Mr. Pitcher that the Board would considered the revised stipulated agreement later today and to please return tomorrow to pick up the order". Ms. Buesing stated that it appeared as though a vote was not made regarding Mr. Pitcher R.Ph. A motion was made on page 12, under stipulated agreements, so it was deleted from page 12, and moved to page 7, under the revised stipulated agreement regarding Mr. Pitcher R.Ph. Mr. Cross stated that on page 13, row 11, the minutes referred to are for June 2005, not August 2005. Mr. Cross also stated that on page 15, line 26, that Alicia's last name should be spelled "Segal" and that line 38, that Joseph's name should be spelled "Hargues".

Motion:

A motion was made by Ms. Buesing, seconded by Ms. Padilla to approve the minutes as amended for the August 29 & 30, 2005 Board Meeting. The Board voted unanimously to pass the motion.

Mr. Harvey introduced the current intern, Joe Meza to the Board. Mr. Harvey stated that the College of Pharmacy is considering the March 2006 Board meeting to honor the Board of Pharmacy. Mr. Harvey briefly discussed NABP District meeting in Jackson Hole, WY. A few issues surrounding counterfeiting and adulteration of drugs, holographic imaging on tablets and containers, and purchasing over the internet were discussed by Mr. Harvey.

Mr. Nolasco and Ms. Buesing briefly discussed their attendance in Jackson Hole, WY at the NABP District meeting. Mr. Storey stated that he was on a task force dealing with remote pharmacies and the licensing issues.

REGULATION HEARING – 16.19.6.22 NMAC & 16.19.6.23 NMAC - PHARMACIES:

The Chairman opened the hearing at approximately 9:32 a.m. Mr. Cross read the proposed changes aloud to the Board, the proposed changes are as follows:

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 writing be retained as permanent record. Computers shall be maintained as required by the

Pharmacy Act; the Drug, Device, and Cosmetic Act; the Controlled Substances 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) if 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 writing 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 .

(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 reproduced in a manner consistent with state and federal laws within a 72 hour period.

(2) the identity of the pharmacist approving the scanned imaging and of the pharmacist responsible for destroying the original document 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

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 HIPAA and Board of Pharmacy Patient Privacy requirements are met.

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

16.19.6.23 PRESCRIPTIONS:

A. A valid prescription is an order for a dangerous drug given individually for the person for whom prescribed, either directly from the prescribing practitioner to the pharmacist, or indirectly by means of a written order signed by the practitioner. Signed by the practitioner includes handwritten signature, stamped or printed images of the practitioners handwritten signature or electronic signature as defined in section 16.19.6.23.F.(2). Every prescription shall contain on its' face the name and address of the prescriber, the name and address of the patient, the name and strength of the drug, the quantity prescribed, directions for use ~~and~~ ,the date of issue, and preferably the diagnosis.

B. A prescription may be prepared by a secretary or agent, i.e., office nurse under supervision, for the signature of the practitioner and where applicable; a prescription may be communicated to the pharmacist by an employee or agent of the registered practitioner. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

C. Prescription information received from a patient, other than a signed written prescription from a practitioner, has no legal status as a valid prescription. A pharmacist receiving such prescription information must contact the prescribing physician for a new prescription.

D. Exchange of prescription information between pharmacies for the purpose of refilling is authorized under the following conditions only:

(1) The original prescription entry shall be marked in the pharmacy computer system. Pharmacies not using a computer shall mark the hard copy.

(2) The prescription shall indicate that it has been transferred and pharmacy location and file number of the original prescription.

(3) In addition to all information required to appear on a prescription, the prescription shall show the date of original filling as well as the number of valid refills remaining.

(4) Transfer of controlled substances Schedules III, IV, and V shall not be allowed electronically except as permitted by federal law. Any manual transfer must be within any rule adopted by the federal DEA under Title 21 CFR 1306.26.

E. Fax ~~esimile~~ Machines: Fax ~~esimile~~ prescription means a valid prescription which is transmitted by an electronic device which sends an exact image of a written prescription signed by the practitioner to a pharmacy. The prescribing of controlled substances ~~listed in Schedule II, III, or IV~~ by fax ~~esimile~~ ~~machine must comply with 16.19.6.23.E.(1) through 16.19.6.23.E.(5). and 16.19.20.42.A through 16.19.20.42.F.~~ must comply with all state and federal laws. No pharmacist may dispense a drug solely on the basis of a prescription received by fax ~~esimile~~ except under the following circumstances:

(1) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the prescription consistent with existing federal and state statutes and regulations.

(2) The original fax ~~esimile~~ prescription ~~(or a legible copy) must be maintained by the pharmacy in numerical order for a period of three years from the date the prescription was originally filled~~. shall be printed and stored in the pharmacy as required by state and federal law and board rules, and may serve as the record of the prescription.

(3) The fax ~~esimile~~ prescription shall include name and fax ~~esimile~~ number of the pharmacy, the prescriber's phone number, for verbal confirmation, time and date of transmission, as well as any other information required by federal and state statute or regulation.

(4) In institutional practice, the fax ~~esimile~~ machine operator must be identified by a statement in the facility policy and procedures manual.

(5) The receiving fax ~~esimile~~ machine must be physically located in a restricted area to protect patient confidentiality.

(6) Electronically generated prescriptions may be transmitted directly to the pharmacy via telephone or thru approved secure electronic prescribing networks directly to a pharmacies fax machine.

(7) Electronically generated prescriptions faxed from a practitioner’s office computer shall include the prescriber's name, phone and fax number, time and date of transmission as well as any other information required by federal and state statute or regulation.

(8.) Electronically generated prescriptions faxed from a practitioner's contracted "Point of Care Vendor" directly to the pharmacy must include the name and phone number of the "Point of Care Vendor".

(9.) Electronically generated prescriptions faxed from a practitioner's contracted "Point of Care Vendor" thru "Network Vendors" or other electronic prescription transmission intermediaries are invalid unless the "Point of Care Vendor" , "Network Vendors" or other intermediaries are contracted with appropriate parties in the chain of trust with business associate agreements to assure the integrity and security of the prescription content. The receiving pharmacy, or their contracted pharmacy software vendor, must have a business associate agreement with the "Network Vendor" or other electronic prescription transmission intermediaries.

F. Electronic Transmission of Prescriptions

(1) electronic transmission of prescriptions and "electronically transmitted prescriptions" means the ~~electronic transmission of prescriptions for dangerous drugs, excluding controlled substances, via computer modem or other similar electronic devices.~~ communication of original prescriptions, refill authorizations, or drug orders, including controlled substances to the extent permitted by federal law, from an authorized licensed prescribing practitioner or his or her authorized agent directly to the pharmacy of the patient's choice by electronic means including, but not limited to, telephone, fax machine, routers, computer, computer modem or any other electronic device or authorized means.

(2) electronic signature" means ~~a unique security code or other identifier which specifically identifies and authenticates the signature for the purposes of secure electronic data transmission~~ an electronic sound, symbol or process attached to or logically associated with a prescription record and executed or adopted by a practitioner with the intent to sign or authenticate said prescription record.

(3) "Prescriber" means a licensed practitioner who generates a prescription order and assumes responsibility for the content of the prescription.

(4) "Point of Care Vendor" means an entity contracted with a prescriber to generate or transmit electronic prescriptions inputted and authorized by a practitioner directly to a pharmacy or to a contracted intermediary, or "Network Vendor", who will ultimately transmit the prescription order to a patient's pharmacy of choice. Vendor must provide an unbiased listing of provider pharmacies and not use advertisements, pop-ups or other mechanisms to influence the prescriber's choice of therapy or to interfere with patient's freedom of choice of pharmacy.

(5) "Network Vendor" means prescription transmission intermediary contracted by business associate agreements with appropriate parties involved, including point of care vendors, pharmacy computer vendors, pharmacies, to transmit the prescription information only having access to the prescription content to make format modifications to facilitate secure and accurate data transmission in a format that can be received and deciphered by the pharmacy.

6) "Contracted" or having "Business Associate Agreement" means having a written agreement between parties to ensure the authenticity and prescribing authority of each prescriber transmitting prescriptions, sufficient security to prevent the fraudulent creation or alteration of prescriptions by unauthorized parties, and assurance that "Network Vendors" or electronic prescription transmission intermediaries involved in the transmission and formatting of the prescription can provide documentation of chain of trust of who has had access to prescription content

~~(3).~~ (7) requirements for electronically transmitted prescriptions or drug orders, ~~excluding~~ including controlled substances as permitted by Federal law.

(a) The receiving computer or other similar electronic device used to view the prescription shall be located within the pharmacy or pharmacy department with only authorized personnel having access.

(b) The electronically transmitted prescription or drug order shall contain all information required by state and federal law including the prescriber's name, address and phone number, time and date of transmission.

(c) The prescribing practitioner's electronic signature ~~,or other secure method of validation~~ shall be provided with the electronically transmitted prescription or drug order.

(d) ~~A written or printed copy of the prescription or drug order shall be prepared~~ ////////~~,and maintained as required by state laws and regulations.~~ The electronically transmitted prescription

may serve as the hard copy record of the prescription so long as the electronically transmitted prescription information can be stored in the original format as when received and is readily retrievable so as to comply with federal and state recordkeeping requirements.

(e)) ~~The electronically transmitted prescription or drug order shall be marked "Electronically Transmitted Prescription" or "ETP".~~ electronically transmitted prescriptions from a practitioners contracted "Point of Care Vendor" thru "Network Vendors" or other electronic prescription transmission intermediaries are invalid unless the "Point of Care Vendor" , "Network Vendors" or other intermediaries are contracted with appropriate parties in the chain of trust with business associate agreements to assure the integrity and security of the prescription content. The receiving pharmacy, or their contracted pharmacy software vendor, must have a business associate agreement with the "Network Vendor" or other electronic prescription transmission intermediaries.

(f) The electronic transmission of a prescription or drug order shall maintain patient confidentiality with no ~~unauthorized~~ intervening person or other entity ~~controlling, screening, or otherwise having access to it.~~ accessing or altering the prescription content. The accessing or altering prohibition does not include format modifications for transmission purposes by approved secure electronic prescribing networks.

(g) ~~ETP~~ Electronically transmitted prescriptions or drug orders shall be sent only to the pharmacy of the patient's choice.

~~(h) The ETP shall identify the transmitter's telephone number. The time and date of transmission, and the pharmacy intended to receive the transmission.~~

~~(i) ETP's shall be transmitted only by authorized prescriber or the prescribers agent and shall include the prescribers electronic signature.~~

~~(j) Electronic transmission of Schedule II controlled substances for emergency dispensing shall conform to 16.19.20.47.~~

(8) "Point of Care Vendors", "Network Vendors" or other prescription transmission intermediaries not compliant with the requirements of this section will be considered an invalid source and listed on the Board of Pharmacy website and considered as an unacceptable source of prescription information and electronic prescriptions from these entities will be considered invalid.

(9) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from a "Point of Care Vendor" or "Network Vendor" which has not been prohibited by the board.

G. Transmission of prescriptions to answering machines and electronic voice recording devices.

(1) prescription information retrieved by a pharmacist from an answering machine or voice recording device from an authorized practitioner or approved agent is considered to be a direct transmission of a prescription order.

H. Confidentiality of patient records and prescription drug orders.

(1) Confidential information. As provided in 61-11-2.D, confidential information in the patient record, including the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber, may be released only as follows :

(a). Pursuant to the express written consent or release of the patient or the order of direction of a court.

(b) To the patient or the patient's authorized representative.

(c) To the prescriber or other licensed practitioner then for the patient.

(d) To another licensed pharmacist where the best interest of the patient require such release.

(e) To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information, A pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

(f) In compliance with HIPAA regulations regarding PHI.

(2) Exceptions. Nothing in this rule shall prohibit pharmacists from releasing confidential patient information as follows:

(a) Transferring a prescription to another pharmacy as required by the provision of patient counseling.

(b) Providing a copy of a non-refillable prescription to the person for whom the prescription was issued which is marked "For Information Purposed Only."

(c) Providing drug therapy information to physicians or other authorized prescribers for their patients.

(d) As required by the provision of patient counseling regulations.

[16.19.6.23 NMAC - Rp 16 NMAC 19.6.23, 03-30-02]

FINAL LANGUAGE AFTER CHANGES AND DELETIONS AFTER DISCUSION:

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 Substances 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) if 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 reproduced in a manner consistent with state and federal laws within a 72 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

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

16.19.6.23 PRESCRIPTIONS:

A. A valid prescription is an order for a dangerous drug given individually for the person for whom prescribed, either directly from the prescribing practitioner to the pharmacist, or indirectly by means of a written order signed by the practitioner. Signed by the practitioner includes handwritten signature, stamped or printed images of the practitioners handwritten signature or electronic signature as defined in section 16.19.6.23.F.(2). Every prescription record shall contain the name and address of the prescriber, the name and address of the patient, the name and strength of the drug, the quantity prescribed, directions for use, the date of issue, and preferably the diagnosis or indication.

B. A prescription may be prepared by a secretary or agent, i.e., office nurse under supervision, for the signature of the practitioner and where applicable; a prescription may be communicated to the pharmacist by an employee or agent of the registered practitioner. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulation

C. Prescription information received from a patient, other than a signed written prescription from a practitioner, has no legal status as a valid prescription. A pharmacist receiving such prescription information must contact the prescribing physician for a new prescription.

D. Exchange of prescription information between pharmacies for the purpose of refilling is authorized under the following conditions only:

(1) The original prescription entry shall be marked in the pharmacy computer system. Pharmacies not using a computer shall mark the hard copy.

(2) The prescription shall indicate that it has been transferred and pharmacy location and file number of the original prescription.

(3) In addition to all information required to appear on a prescription, the prescription shall show the date of original filling as well as the number of valid refills remaining.

(4) Transfer of controlled substances Schedules III, IV, and V shall not be allowed electronically except as permitted by federal law. Any manual transfer must be within any rule adopted by the federal DEA under Title 21 CFR 1306.26.

E. Fax Machines: Fax prescription means a valid prescription which is transmitted by an electronic device which sends an exact image of a written prescription signed by the practitioner to a pharmacy. The prescribing of controlled substances by fax must comply with all state and federal laws. No pharmacist may

dispense a drug solely on the basis of a prescription received by fax except under the following circumstances:

(1) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the prescription consistent with existing federal and state statutes and regulations.

(2) The original fax prescription shall be printed and stored in the pharmacy as required by state and federal law and board rules, and may serve as the record of the prescription.

(3) The fax prescription shall include name and fax number of the pharmacy, the prescriber's phone number, for verbal confirmation, time and date of transmission, as well as any other information required by federal and state statute or regulation.

(4) In institutional practice, the fax machine operator must be identified by a statement in the facility policy and procedures manual.

(5) The receiving fax machine must be physically located in a restricted area to protect patient confidentiality.

(6) Electronically generated prescriptions may be transmitted directly to the pharmacy via telephone lines or indirectly thru one or more "Contracted" parties via valid "Network Vendors" directly to a pharmacy's fax machine.

(7) Electronically generated prescriptions faxed from a practitioner's office computer shall include the prescriber's name, phone and fax number, time and date of transmission as well as any other information required by federal and state statute or regulation.

(8.) Electronically generated prescriptions faxed from a practitioner's "Contracted" "Point of Care Vendor" directly to the pharmacy must include the name and phone number of the "Point of Care Vendor".

(9.) "Point of Care Vendors", "Network Vendors" or other prescription transmission intermediaries not compliant with the requirements of this section will be considered an invalid source.

(10.) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from a "Point of Care Vendor" or "Network Vendor" which has not been prohibited by the board.

F. Electronic Transmission of Prescriptions

(1) electronic transmission of prescriptions and "electronically transmitted prescriptions" means the communication of original prescriptions, refill authorizations, or drug orders, including controlled substances to the extent permitted by federal law, from an authorized licensed prescribing practitioner or his or her authorized agent directly or indirectly thru one or more "Contracted" parties to the pharmacy of the patient's choice by electronic means including, but not limited to, telephone, fax machine, routers, computer, computer modem or any other electronic device or authorized means.

(2) "Electronic signature" means an electronic sound, symbol or process attached to or logically associated with a prescription record and executed or adopted by a practitioner with the intent to sign or authenticate said prescription record.

(3) "Prescriber" means a licensed practitioner who generates a prescription order and assumes responsibility for the content of the prescription.

(4) "Point of Care Vendor" means an entity contracted with a prescriber to generate or transmit electronic prescriptions authorized by a practitioner directly to a pharmacy or to a "Contracted" intermediary, or "Network Vendor", who will ultimately transmit the prescription order to a patient's pharmacy of choice. Vendor must provide an unbiased listing of provider pharmacies and not use pop-ups or other paid advertisements to influence the prescriber's choice of therapy or to interfere with patient's freedom of choice of pharmacy. Presentation of drug formulary information, including preferred and non-preferred drugs and copay information if available, is allowed.

(5) "Network Vendor" means prescription transmission intermediary "Contracted" by business associate agreements with appropriate parties involved, including point of care vendors, pharmacy computer vendors, pharmacies, to transmit the prescription information only having access to the prescription content to make format modifications to facilitate secure and accurate data transmission in a format that can be received and deciphered by the pharmacy.

(6) "Contracted" means having a written agreement (to include "Business Associate Agreements" as required by federal law) between parties to ensure the authenticity and prescribing authority of each prescriber transmitting prescriptions, sufficient security to prevent the fraudulent creation or alteration of prescriptions by unauthorized parties, and assurance that "Network Vendors" or electronic prescription transmission intermediaries involved in the transmission and formatting of the prescription can provide documentation of chain of trust of who has had access to prescription content. Electronic prescription transmissions by non "Contracted" parties will be invalid.

(7) requirements for electronically transmitted prescriptions or drug orders including controlled substances as permitted by Federal law;

(a) The receiving computer or other similar electronic device used to view the prescription shall be located within the pharmacy or pharmacy department with only authorized personnel having access.

(b) The electronically transmitted prescription or drug order shall contain all information required by state and federal law including the prescriber's name, address and phone number, time and date of transmission.

(c) The prescribing practitioner's electronic signature shall be provided with the electronically transmitted prescription or drug order.

(d) The electronically transmitted prescription may serve as the hard copy record of the prescription so long as the electronically transmitted prescription information can be stored in the original format as when received and is readily retrievable so as to comply with federal and state recordkeeping requirements.

(e) The electronic transmission of a prescription or drug order shall maintain patient confidentiality with no intervening person or other entity accessing or altering the prescription content. The accessing or altering prohibition does not include format modifications for transmission purposes by approved secure electronic prescribing networks.

(f) Electronically transmitted prescriptions or drug orders shall be sent only to the pharmacy of the patient's choice.

(8) "Point of Care Vendors", "Network Vendors" or other prescription transmission intermediaries not compliant with the requirements of this section will be considered an invalid source.

(9) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from a "Point of Care Vendor" or "Network Vendor" which has not been prohibited by the board.

G. Transmission of prescriptions to answering machines and electronic voice recording devices.

(1) prescription information retrieved by a pharmacist from an answering machine or voice recording device from an authorized practitioner or approved agent is considered to be a direct transmission of a prescription order.

H. Confidentiality of patient records and prescription drug orders.

(1) Confidential information. As provided in 61-11-2.D, confidential information in the patient record, including the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber, may be released only as follows :

(a). Pursuant to the express written consent or release of the patient or the order of direction of a court.

(b) To the patient or the patient's authorized representative.

(c) To the prescriber or other licensed practitioner then for the patient.

(d) To another licensed pharmacist where the best interest of the patient require such release.

(e) To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information, A pharmacist shall utilize the resources

available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

(f) In compliance with Health Insurance Portability and Accountability Act regulations regarding protected health information..

(2) Exceptions. Nothing in this rule shall prohibit pharmacists from releasing confidential patient information as follows:

(a) Transferring a prescription to another pharmacy as required by the provision of patient counseling.

(b) Providing a copy of a non-refillable prescription to the person for whom the prescription was issued which is marked "For Information Purposed Only."

(c) Providing drug therapy information to physicians or other authorized prescribers for their patients.

(d) As required by the provision of patient counseling regulations.

[16.19.6.23 NMAC - Rp 16 NMAC 19.6.23, 03-30-02]

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Padilla to approve the changes and deletions made on 16.19.6.22 NMAC and 16.19.6.23 NMAC. The Board voted unanimously to pass the motion.

Mr. Cross gave special thanks to Phil Rothermitch, Debra Herman, Dale Tinker, and Mike Lyons for their participation on the committee.

The Chairman closed the hearing.

The Chairman commended Mr. Cross for the leadership he provided for the committee.

RECESS FOR LUNCH:

RECONVENE MONDAY NOVEMBER 14, 2005:

PROPOSED REGULATION DISCUSSION– 16.19.30 NMAC – 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.

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 re-labeling of the container and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons but does not include compounding or practitioner samples.

E. "SOPs" standard operating procedures.

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 training activities shall be documented and covered by SOPs as outlined in subsection 16.19.30.9.G.1 of this section.

(2) 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.

(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 in paragraph D(6) of this subsection.

(b) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and available for inspection.

(c) 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 as determined by the pharmacist using appropriate documented criteria as outlined in clause (a) of this subparagraph; and

(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".

(g) A retail pharmacy is not precluded from making more that five percent (5%) of its annual sales to licensed practitioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(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, identity, strength, quality, or purity of the drug product beyond the desired result;

(c) cleaned and sanitized immediately 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) A beyond-use date after which the compounded preparation should not be used. The beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations including the following.

(a) The pharmacist shall consider:

(i) physical and chemical properties of active ingredients;

(ii) use of preservatives and/or stabilizing agents;

(iii) dosage form;

(iv) storage containers and conditions; and

(v) scientific, laboratory, or reference data.

(b) In the absence of stability information applicable for a specific drug or preparation, the following maximum beyond-use dates are to be used when the compounded preparation is packaged in tight, light-resistant containers and stored at controlled room temperatures.

(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.

(c) 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, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(a) Chemically Pure (CP);

(b) Analytical Reagent (AR); or

(c) American Chemical Society (ACS); or

(d) Food Chemical Codex; or

(3) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier.

(4) A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a batch control number and a future expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products the pharmacist must consider all ingredients present in the drug product relative to the intended use of the compounded preparation.

(5) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

(6) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond the desired result.

(7) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.

(8) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(9) 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) All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:

(a) the facility;

(b) equipment;

(c) personnel;

(d) actual compounding;

(e) product evaluation;

(f) packaging; and

(g) storage of compounded preparations.

(2) Any compounded preparation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(3) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.

(4) Personnel engaged in the compounding of drug products shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hairnets, gowns, hand or arm coverings, or masks shall be worn as

necessary to protect personnel from chemical exposure and drug products from contamination.

(5) At each step of the compounding process, the pharmacist shall assure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

G. Quality Control.

(1) The pharmacy shall follow established quality control procedures 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) Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(a) the date of preparation;

(b) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of the manufacturer(s) of the raw materials and the quantities of each;

(c) signature or initials of the pharmacist or pharmacy technician performing the compounding;

(d) signature or initials of the pharmacist responsible for supervising pharmacy technicians and other supportive personnel and conducting in-process and final checks of compounded preparations if pharmacy technicians perform the compounding function;

(e) the quantity in units of finished products or amount of raw materials;

(f) the container used and the number of units prepared;

(g) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(i) the criteria used to determine the beyond-use date; and

(ii) documentation of performance of quality control procedures. Documentation of the performance of quality control procedures is not required if the compounding process is done pursuant to a patient specific order and involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.

(2) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.

(a) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for formulations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:

(i) the formula;
(ii) the components;
(iii) the compounding directions;
(iv) a sample label;
(v) evaluation and testing requirements;
(vi) specific equipment used during preparation; and
(vii) storage requirements.

(b) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:

(i) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;
(ii) lot number or each component;
(iii) component manufacturer/distributor or suitable identifying number;
(iv) container specifications (e.g., syringe, pump cassette);
(v) unique lot or control number assigned to batch;
(vi) beyond use date of batch-prepared products;
(vii) date of preparation;
(viii) name, initials, or electronic signature of the person(s) involved in the preparation;
(ix) name, initials, or electronic signature of the responsible pharmacist;
(x) end-product evaluation and testing specifications, if applicable; and
(xi) comparison of actual yield to anticipated yield, when appropriate.

Mr. Nolasco stated that he had received numerous phone calls from around the state regarding the posted proposed language. The general consensus was that this was too much language for what is needed. A brief discussion was held by the Board regarding acceptance of the use of the United States Pharmacopeia National Formulary Chapter (795) be incorporated by reference as the proposed language.

Motion:

A motion was made by Mr. Nolasco, seconded by Mr. Cross to approve the acceptance of Chapter (795) of the United States Pharmacopeia National Formulary to be incorporated by reference as the proposed language on 16.19.30 NMAC.

After further discussion of 16.19.30 NMAC, the Board decided that more information was needed regarding the need to "incorporate by reference".

The Chairman stated that there was a motion on the table.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Padilla to withdraw the previous motion and amend to table 16.19.30 NMAC until the January 2006 Board Meeting. The Board voted unanimously to pass the motion.

TECHNICIAN COMMITTEE PROPOSED REGULATION CHANGE - 16.19.22 NMAC AND 16.19.4 NMAC:

Steve Mulryan and Sheri Schramm appeared before the Board to present proposed language changes from the Technician Committee incorporated from the last Board meeting. Mr. Mulryan read the proposed changes aloud to the Board, the proposed changes are as follows:

16.19.22.7 DEFINITIONS:

A. "Pharmacy Technician" means a person who, under the supervision of a licensed pharmacist, performs [~~repetitive~~] tasks not requiring the professional judgment of a pharmacist. [~~This includes assisting in various technical activities associated with the preparation and distribution of medications.~~]

(1) "Certified Pharmacy Technician" means a Pharmacy Technician who has completed the training and certification outlined in 16.19.22.9 NMAC and is registered by the Board of Pharmacy and maintains current certification.

(2) "[~~Non-certified~~] Pharmacy Technician in Training" means a Pharmacy Technician who is in process of completing the training and education **and PTCB certification** outlined in 16.19.22.9 NMAC and is registered by the Board of Pharmacy. **Registration by the Board is not required of students currently enrolled in Board approved technician training programs while completing their required experiential training.**

B. "Support Personnel" means [~~pharmacy personnel other than pharmacy technicians, which may include clerks, typists, secretaries and delivery personnel, who under the supervision of a pharmacist, may perform clerical duties associated with the practice of pharmacy, but no including the duties restricted to only a pharmacist, pharmacist intern, or pharmacy technician~~]**any non-registered or non-certified individual who performs various tasks in the pharmacy not to include procuring, data entry, preparing, or dispensing medications**.

C. "Supervision" means that the pharmacist shall observe and direct to a sufficient degree to assure the accurate completion of the activities of the pharmacy technicians and must provide a final check of all aspects of the prepared product and document the final check before dispensing.

[16.19.22.7 NMAC - Rp, 16 NMAC 19.22.7, 06-27-2001]

16.19.22.8 PERMISSIBLE ACTIVITIES: permissible activities of appropriately trained pharmacy technicians, under the supervision of a pharmacist, **are duties and tasks not requiring the use of professional judgment.** [~~include, but are not limited to the following:.~~ Duties and tasks not requiring the use of professional judgment. [~~as defined in 16.19.4.7 NMAC~~]

[~~A.~~ ~~The preparation, mixing, assembling, packaging and labeling of medications and sterile products: and~~]

[~~B.~~ ~~Filling of a prescription or medication order including counting, pouring, labeling or reconstituting medications; and~~]

[~~C~~]. . [~~Duties and tasks not requiring the use of professional judgment as defined in 16.19.4.7 NMAC~~]

[16.19.22.8 NMAC - Rp, 16 NMAC 19.22.8, 06-27-2001]

16.19.22.9 TRAINING AND EDUCATION

A. [~~The pharmacist-in-charge shall ensure that the pharmacy technician has completed initial training which includes~~]**Appropriate on-the-job training or Board approved training and education of pharmacy technicians is required within the first year of registration in the following areas**:

(1) Federal and State laws and regulations that affect pharmacy practice. Specific regulations which address the use of supportive personnel and technicians;

(2) Ethical and professional standards of practice;

[~~B.~~ ~~A total of 220 hours of on-the-job or board approved training and education is required within the first year of registration in the following areas~~].

([~~1~~]3) Medical and pharmaceutical terminology, symbols and abbreviations used in the practice of
pharmacy and components of a prescription;

([~~2~~]4) Pharmaceutical calculations necessary for the preparation and dispensing of drug products;

([~~3~~]5) Manufacturing, preparation, packaging, labeling and proper storage of drug products;

([~~4~~]6) Dosage forms and routes of administration; and

([~~5~~]7) Trade and generic names for medications frequently dispensed by the pharmacy.

([~~6~~]8) [~~Applicants failing to complete training and education within one year may petition the Board for a one time extention~~] Basic pharmacology**

[~~C~~]B. If the duties of the technician will include the preparation of sterile products then, in addition to the training and education requirements listed in 16.19.22.9.3 NMAC, the technician will complete training outlined in [~~12 NMAC 19.6.11 (2)~~]**16.19.6.11.C(2) NMAC**.

C. If the duties of the technician will include the preparation of chemotherapeutic agents, then, in addition to the training and education requirements listed in 16.19.22.9.3 NMAC, the technician will complete training outlined in 16.19.6.11.C(2) NMAC.

D. A written record of training and education will be maintained by the pharmacy **technician** and contain the following:

(1) Name of person receiving the training;

(2) Date(s) of the training;

(3) Description of the topics covered;

(4) Names of the person(s) who provided the training; and

(5) Signature of the technician and the pharmacist[~~-in-charge~~] **providing the training**. [~~Education and training records will be maintained by the pharmacy for a minimum of three years after resignation or termination of the technician~~].

E. Upon successful completion of the PTCB and one year of practice as a pharmacy technician, the retention of training records of a pharmacy technician shall not be required

[~~E~~]D. All Technicians are required to obtain [~~Board approved~~] **PTCB** certification within [~~one year~~]**12 months** of registration with the Board as a Technician.
[16.19.22.9 NMAC - Rp, 16 NMAC 19.22.9, 06-27-2001]

16.19.22.10 RATIO OF TECHNICIANS TO PHARMACISTS: The ratio of pharmacy technicians to pharmacists should be sufficient to provide adequate patient care and safety in the respective workplace and is subject to the professional judgment of the pharmacist.

[~~A. The permissible ratio of pharmacy technicians to pharmacists on duty is 4-1. Support personnel are not included in this ratio~~].

[~~B. The ratio may be increased if the pharmacy submits to the Board of Pharmacy a protocol for increased ratios and the Board approves the protocol~~].
[16.19.22.10 NMAC - Rp, 16 NMAC 19.22.10, 06-27-2001]

16.19.22.14 REGISTRATION OF PHARMACY TECHNICIANS

A. Application (and required registration fee) shall be submitted to the Board within 10 days.

B. Registration for pharmacy technicians will expire annually on the last day of their birth month and must be renewed prior to expiration. **The initial registration will expire on the last day of the month of registration one year later. During the first year of registration the technician must submit proof of PTCB certification and proof of appropriate training whether from and educational institution or on-the-job. The renewal registration will be for a period of 24 months, plus the partial year remaining so that the expiration date will be the last day of the birth month.**

C. There will be no extensions to certification within one year. Pharmacy technicians may not practice for failure to maintain current Board approved certification and registration.
[16.19.22.14 NMAC - Rp, 16 NMAC 19.22.14, 06-27-2001]

16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

A. The following responsibilities require the use of professional judgment and shall therefore only be performed by a pharmacist or pharmacist intern:

(1) receipt of all new verbal prescription orders and reduction to writing;

(2) [~~initial~~] identification, evaluation and interpretation of the prescription order and any necessary clarification prior to dispensing;]

(3) professional consultation with a patient or his agent regarding a prescription;

(**4**) evaluation of available clinical data in patient medication record system.

(5) oral communication to the patient or patient's agent of information, as defined in this section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

[~~(6) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription.~~]

B. Only a Pharmacist Shall Perform The Following Duties:

(1) final check on all aspects of the completed prescription including sterile products and cytotoxic preparations, and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container.

(2) evaluation of pharmaceuticals for formulary selection within the facility.

(3) supervision of all supportive personnel activities including preparation, mixing, assembling, packaging, labeling and storage of medications.

(4) ensure that supportive personnel have been properly trained for the duties they may perform.

(5) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories). This does not apply to substitution of generic equivalents.

(6) any other duty required of a pharmacist by any federal or state law.

C. Patient Records:

(1) A reasonable effort must be made to obtain, record and maintain at least the following information:

(a) name, address, telephone number, date of birth (or age) and gender of the patient;

(b) individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; and

(c) pharmacists comments relevant to the individuals drug therapy.

(2) Such information contained in the patient record should be considered by the pharmacist or pharmacist intern in the exercise of their professional judgment concerning both the offer to counsel and the content of counseling.

D. Prospective Drug Review:

(1) A pharmacist or pharmacist intern shall review the patient record for:

(a) clinical abuse/misuse;
(b) therapeutic duplication;
(c) drug-disease contraindications;
(d) drug-drug interactions;
(e) incorrect drug dosage;
(f) incorrect duration of drug treatment;
(g) drug-allergy interactions;
(h) appropriate medication indication.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

E. Counseling:

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent. Upon receipt of a refill prescription drug order a pharmacy technician may query the patient or patient's agent regarding counseling by the pharmacist or pharmacist intern concerning drug therapy. Such counseling shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling which may include, in their professional judgment, one or more of the following:

(a) the name and description of the drug;

(b) the dosage form, dosage, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;
(h) prescriptions refill information;
(i) action to be taken in the event of a missed dose;
(j) the need to check with the pharmacist or practitioner before taking other medication; and
(k) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) [REPEALED]

(3) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

(4) Patient counseling, as described above and defined in this regulation shall not be required for in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(5) A pharmacist shall in no way attempt to circumvent or willfully discourage a patient or patient's agent from receiving counseling. However, a pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(6) When the patient or agent is not present when the prescription is dispensed, including but not limited to a prescription that was shipped by the mail, the pharmacist 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 in 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.

(7) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice concerning available counseling.

F. [REPEALED]

G. Regulatory Assessment: Profiles, either electronic or hard copy, shall be available for inspection, and shall provide the capability of storing the described historical information. The profiles must demonstrate that an effort is being made to fulfill the requirements by the completion of the detail required. A patient record shall be maintained for a period of not less than three (3) years from the date of the last entry in the profile record.
[08-27-90; 16.19.4.16 NMAC - Rn, 16 NMAC 19.4.16, 03-30-02; 16.19.4.16 NMAC - Rn, 16.19.4.17 NMAC, 12-15-02; A, 02-01-04; A, 11-30-04; A, 01-15-2005]

Mr. Cross had several questions regarding the language regarding the requirements of training and education and the registration process. Mr. Cross stated that the language was not very clear on the differences for technicians in training and "certified" technicians in training. Mr. Cross had a question about maintaining records of certification and training and what entity would be responsible for keeping those records. He felt they should be filed at the Board.

Ms. Schramm stated that a few changes had been made from the last meeting. Ms. Schramm also stated that what the Technician Committee was trying to accomplish was once a Pharmacist finished school and passes the NAPLEX, they would not have to carry their transcripts with them and she believed they were not on file with the Board. Ms. Schramm stated that they wanted to allow the PTCE to be the "gold standard" for technicians.

Mr. Storey stated that they are filed with the NABP and that the NABP will certify any license transfer. Mr. Storey stated that Mr. Cross brought up a very good point about the standards for technicians because they vary so much from state to state.

Ms. Padilla made a recommendation that the retention of training records of the pharmacy technician shall not be required and will be kept by the Board.

A brief discussion of 16.19.22 Mr. Mulryan stated anywhere PTCB appears should now read "PTCE", the wording in 16.19.22.9.B should read "during the first year of registration the technician must submit proof of PTCE certification and proof of appropriate training which will be maintained by the Board". The Board recommended deleting the language in 16.19.22.9.E and the second "D" will now be a new "E". The wording in 16.19.22.9 D number (5) should read "Signature of the technician and the pharmacist or program director providing the training." The wording in 16.19.22.10 Ratio of Technicians to Pharmacists: should read "The ratio of pharmacy technicians to pharmacists should be sufficient to provide adequate patient care and safety in the workplace and as determined by the professional judgment of the pharmacist."

After further discussion Mr. Cross recommended that on page 4, the new letter "E" should read "All Pharmacy Technicians in training are required to obtain PTCE certification within 12 months of registration with the Board as a Technician and no extension will be granted", therefore on page 6, in 16.19.22.14.D will be deleted.

Further lengthy discussion was held regarding ratios of Technicians to Pharmacists between the public and the Board.

Mr. Cross asked Ms. Schramm what the objective of the Technician Committee was, and she stated that it was to look outside of the box to advance the duties of the Pharmacy Technician and increase the levels of education and training. Mr. Cross asked for clarification of the duties of Pharmacy Technicians, Administrative Staff and what is understood as the Pharmacists professional discretion.

Mr. Mulryan asked the Board for further direction.

Mr. Storey suggested that one of two options be provided; give the wide open option of allowing the Pharmacist professional discretion or assign specific duties for the Pharmacist Technician. Secondly, to come back with language that puts the old ratio back.

Mr. Cross asked the Technician Committee to reconsider 16.19.4.16.A. (6.) as well as the technician ratios. Mr. Cross stated that he would help progress empowering the duties in a way that the technicians would be able to perform more "professional duties".

The Chairman called for a 10-minute recess.

RECESS:

RECONVENE:

The Chairman reconvened at 2:15 p.m. and opened with Citizens Petition To Ban Aspartame.

DR. KENNETH STOLLER AND COLLEAGUES – CITIZENS PETITION TO BAN ASPARTAME AND MERCURY IN CHILDREN'S MEDICATIONS AND VITAMINS:

The Chairman stated that the Board had received a number of comments and documentation regarding this subject. He stated that a one hour period of time would be allotted to receive comments and that any items that had already been submitted to the Board, he asked not be re-submitted again. He also stated that this is an issue presented by the public to the Board and would not need a regulatory hearing.

Presentations were made by Dr. Kenneth Stoller, Rich Murray and Stephen Fox opposing the use of Aspartame in products listed; diet, children's vitamins, and aspirin. Presentations were also made on the vaccines that contain Thimerisal.

A lengthy discussion was held with the presenters, audience and the Board.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Ortega to table the issues regarding Aspartame and Thimerisal until the January 2006 Board meeting. The Board voted unanimously to pass the motion.

RECESS:

RECONVENE:

APPLICATION APPROVAL:

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. Mr. Cross abstained from voting on #2.

Emergency Medical Services:

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

Motion:

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

Home Healthcare:

Mr. Cross stated that there is one application 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 pass the motion.

Animal Control:

Mr. Cross stated that there is one application 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 pass the motion.

Custodial Homes:

Mr. Cross stated that there are 21 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 21 applications in this category as presented. The Board voted unanimously to pass the motion.

Hospital Pharmacy:

Mr. Cross stated that there are 2 applications in this category. A correction was made to the pharmacist in charge at the Gila Regional Medical Center as listed. Mr. Larry Rivkin, R.Ph. was replaced by Mr. Wayne S. Mosteller R.Ph.

Motion:

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

Non-Resident Pharmacy:

Mr. Cross stated that there are 19 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Shaver to approve the 19 applications in this category as presented. The Board voted unanimously to pass the motion.

After brief discussion, the Board decided to table the application for Smart Choice Drug Store Inc. in Austin, TX, until more information was obtained on November 15, 2005. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Carrier to withdraw the approval of Smart Choice Drug Store Inc. until November 15, 2005. The Board voted unanimously to pass the motion.

Pharmacy:

Mr. Cross stated that there are 4 applications in this category. A discussion was held regarding Secure Pharmacy in Las Cruces, NM.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to table the application for Secure Pharmacy until further information is obtained regarding the patient-physician relationship. The Board voted unanimously to pass the motion.

Inspector Ben Kesner for the Board of Pharmacy was able to attend to discuss the inspection done at Secure Pharmacy in Las Cruces, NM. The security requirements and the licensing for controlled substances were discussed by the Board.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to not grant a license until a re-inspection is done and the security requirements are met by Secure Pharmacy, once that has been established the Board will grant a temporary license to Secure Pharmacy until the next Board meeting. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve applications #1, #3, and #4 in this category as presented. The Board voted unanimously to accept the motion.

Wholesaler/Broker:

Mr. Cross stated that there are 16 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 16 applications in this category as presented. The Board voted unanimously to pass the motion.

Drug Precursor Wholesaler:

Mr. Cross stated that there are 3 applications in this category. A correction was made to #3 listed as Excel Inc. The spelling of the city Mechanisdburg should be Mechanicsburg.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to approve the 3 applications with the change made as presented. 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.

Pharmacist Credentialing Committee:

Mr. Greg D'Amour presented 2 applications that were discussed by the committee on November 3, 2005. A discussion was held regarding the recommendations and follow up for the following applicants, Stephanie Sue Koewler and Tera Liddil.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to approve the application for Tera Liddil as presented. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to leave the application open for further requirements by the committee for Stefanie Sue Koewler. The Board voted unanimously to pass the motion.

Motion:

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

Miners Colfax – Extension Request:

Mr. Ken Volpato**,** Mr. Mark Wade and Ms. Kathy Wade attended the Board meeting to request an extension on the hospital pharmacy license for Miner's Colfax Medical Center. Mr. Mark Wade stated to the Board that due to the completion period of the new hospital they would like an extension of eighteen months.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Cross to approve the 18-month extension requested by Miner's Colfax Medical Center. The Board voted unanimously to pass the motion.

After a brief discussion the Board decided that circumstances might prevent the hospital from completion in eighteen months, therefore a 24-month extension would be a better option.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Cross to amend the motion of an 18-month extension to a 24-month extension. The Board voted unanimously to pass the motion.

RECESS:

RECONVENE TUESDAY NOVEMBER 15, 2005:

The Chairman reconvened at 9:00 a.m. at which time he took roll call. The Chairman stated that Ms. Saavedra was absent and that Mr. Shaver would be absent until 1:30 p.m.

TONY HAL MC DONALD – REQUEST FOR REINSTATEMENT OF LICENSE:

Mr. Harvey discussed feedback from the last Board meeting regarding Mr. Mc Donald's case. The Board felt that Mr. Mc Donald needed to provide more information on his progress. The Board felt that a mentor be involved in his rehabilitation and evidence of the steps being taken during his rehabilitation be presented to the Board.

Mr. Storey stated that the need for a reputable person mentor Mr. Mc Donald and adequate monitoring of his progress by the Board based on the unique nature of this case. Mr. Storey asked Mr. Mc Donald if he had any leads on employment. Mr. Mc Donald stated that he would be interested in working in a hospital environment but he would take any job that became available. Mr. Storey addressed the need for Mr. Mc Donald to divulge the circumstances of his revocation of licensure in order for the employer to properly mentor him. Mr. Story asked if Mr. Mc Donald had an acquaintance that is a Pharmacist here in Albuquerque that could vouch for him. Mr. Mc Donald stated that he had not been in Albuquerque for a long period of time therefore he did not know anyone.

Mr. Cross asked Mr. Mc Donald if he was maintaining his CE's and was he on probation. Mr. Mc Donald stated that he had CE's and that he met with his U.S. probation officer once a month.

Mr. Ortega asked Mr. Mc Donald if he had a preacher, reverend, priest or counselor and if he complies with all the requirements set forth. Mr. Mc Donald stated that he had a counselor that he sees every two weeks and that he has complied with everything.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to go into closed session to discuss the matter of Tony Hall Mc Donald R.Ph. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Storey, seconded by Mr. Cross to go back into open session and all that was discussed was the case of Tony Hal Mc Donald R.Ph. The Board voted unanimously to pass the motion.

Mr. Cross stated that the Board would consider offering a stipulated agreement to Mr. Mc Donald for licensure in New Mexico and going back to work. He outlined the order as follows: For the period of one year he may not work alone and must have another pharmacist present, for a period of one year he must have a worksite mentor, for a period of one year the pharmacist in charge must report back quarterly on the status of your progress to the Board, you must sign a five year contract with the MTP, he may not be a pharmacist in charge during this probationary period, you must disclose the reasons why your license was revoked to potential employers or employers, any violation of your federal probation will violate this agreement, he must provide documentation that you have completed 60 hours of CE, which can include anything back from when your revocation occurred, the Board must receive the 60 hours of CE before the order will be signed, he must take the MPJE within six months, non-compliance of providing 60 hours of CE within six months will automatically revoke this agreement, he must notify the Board within ten days of any change of residence or employment in or out of the State of New Mexico and each employer must have a signed agreement in that state to comply with the stipulated agreement as set forth, the employer must notify the Board that they have received a copy of this agreement. The payment of fees are as follows: all previous fees must be paid in full as set forth in the existing order by January 2006 by Mr. Mc Donald, he must pay the current Pharmacist registration fee of

$200 for this two-year period when he turns in his 60 hours of CE's. An extension of 12 months will be granted to Mr. Mc Donald to pay "back fees" for Pharmacist registration and the cost of the previous hearing.

Mr. Storey clarified to Mr. Mc Donald that the probationary period is five years which coincides with the MTP of five years probation and any violation of this stipulated agreement will result in immediate revocation.

Mr. Harvey suggested that Mr. Mc Donald attend one of our live programs for two hours of law, the next one is on November 18, 2005.

The Board discussed that an "Emergency Meeting" would be set up if Mr. Mc Donald turned in his CE's within one week. After further discussion, the Board stated that if Mr. Mc Donald did not turn in the CE's within one week, that the stipulated agreement would be presented at the next Board Meeting in January 2006.

EMERGENCY RULE HEARING 16.19.31 NMAC – EMERGENCY PROVISIONS:

Mr. Harvey gave a brief update to the Board regarding the progress of the first phase of the draft that Mr. Loring has been writing. He stated that a draft would be ready for review at the upcoming Board meeting scheduled for January 2006. Mr. Harvey also stated that Mr. Loring had gone to Louisiana several times and is going to Atlanta, GA in January 2006 primarily as the lead pharmacist in the country writing these rules.

CHAPTER 19 PHARMACIST
TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
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. Sections 61-11-6(A) NMSA 1978authorizes 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:

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 PROVISIONS FOR PHARMACIST LICENSURE DURING A DECLARED EMERGENCY:

A. Emergency provisions for licensure by endorsement: Pharmacists 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 issued under 16.19.2 NMAC shall expire six months after issue date.

16.19.31.9 PROVISIONS FOR PRACTITIONER CONTROLLED SUBSTANCE 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 driver's 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: Practitioner registrations issued under 16.19.20 NMAC shall expire six months after issue date.

After lengthy discussion was held regarding the proposed language and changes Ms. Kunkle stated that she would re-write the proposed rule and present it at the next Board meeting.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Cross to table this proposal until after lunch. The Board voted unanimously to pass the motion.

RECESS:

RECONVENE:

COLIN BAYLISS – ADOPTION OF BOARD ORDER:

Mr. Storey stated that the adoption of the order as presented would allow Mr. Bayliss to practice as an intern. The Board did not make any changes to the order as presented.

Motion:

A motion was made by Ms.Padilla, seconded by Mr. Nolasco to adopt the order for Colin Bayliss as presented. The Board voted unanimously to pass the motion. Mr. Shaver was absent for voting. Mr. Cross voted, no. Mr. Chairman stated that the motion still passes.

CAROL BAILAR – REQUEST TO MODIFY BOARD ORDER:

Ms. Bailar appeared before the Board to request modification of her Board order. Ms. Bailar stated that she has complied with the stipulations as set for the by the Board and MTP. Mr. Harvey stated that the Board received a response from the MTP that they supported Ms. Bailar to return to the Board and ask for modification to her order.

Mr. Harvey stated that council would draft the modified agreement as follows: Eliminate #2, #3, and #4. Re-number #5 to #2. Add a #3 to read as follows; Agrees to any other workplace restrictions required by MTP.

EXECUTIVE DIRECTOR'S REPORT:

Mr. Harvey gave an update on Methamphetamine and his participation in the task force headed by Herman Silva. He stated that reports of Meth-labs have decreased by approximately 40% in New Mexico, but the quantity available on the streets is still up. Foreign sources such as Mexico contribute to the availability. Mr. Harvey stated that there is an ongoing push on education for individuals not to use these substances. Mr. Harvey stated that on the national scene there are bills in congress, which will require Pseudoephedrine to be a schedule IV exempt drug to be sold to pharmacies. He also stated that representative Heaton wants to re-introduce at the next legislature Pseudoephedrine as a schedule IV exempt registry product. Mr. Cross stated that he would speak to representative Heaton about modifying the language on his bill to express the Boards concerns on restricting legitimate users from having access.

RECESS FOR LUNCH:

RECONVENE:

OPTOMETRY BOARD PROPOSED REGULATION AND APPLICATION CHANGE 16.19.28 NMAC:

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]

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 Sections 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 interests 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.
[16.19.28.7 NMAC - N, 12-01-2003]

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

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

G. "Seller/Dispenser" means one who is in the business of the sale or distribution of contact lenses.

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 on 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]

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 and any subsequent changes or modifications require prior 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]

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]

16.19.28.11 VIOLATION PENALTIES: Any person who violates any of the provisions of this chapter shall be subject to a fine of one thousand dollars ($1,000.00) and the fine is in addition to any other penalty imposed for violation of these provisions.

[16.19.28.11 NMAC – N, XX-XX-200X]

HISTORY OF 16.19.28 NMAC: [RESERVED]

Mr. Harvey gave a brief update to the Board from the last meeting regarding changes to the application for sellers or dispensers of contact lenses. The Board discussed the wording in 16.19.28.11 Violation Penalties: should read "Any person who violates any of the provisions of this part shall be subject to the provisions of the ULA."

Motion:

A motion was made by Ms. Padilla, seconded by Mr. Ortega to notice for hearing 16.19.28 NMAC, Seller or Dispenser of Contact Lenses with the changes as presented for the January 2006 Board meeting. The Board voted unanimously to pass the motion.

Mr. Storey asked that the minutes reflect that the Board approved the "Application For Sellers Or Dispensers Of Contact Lenses". Mr. Harvey stated that the Optometry Board will be asked to attach a copy of the policy and procedure manual.

DR. ZOBEL'S REQUEST FOR OPINION ON PRESCRIBING RELPAX:

Mr. Harvey gave a brief update on the correspondence from Dr. Zoble asking the Board for their opinion if prescribing of the drug "Relpax" is within an optometrist's scope of practice. Mr. Harvey stated that the Board does not have the authority to determine the Board of Optometry's scope of practice.

Mr. Harvey stated that he would respond to the Board of Optometry by writing a letter indicating the drug class of "Relpax".

Executive Director's Report Cont'd:

Mr. Harvey presented documentation on Tramadol regarding the use and abuse of this drug. After brief discussions the Board agreed that Tramadol should be classified as a Schedule IV drug.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Nolasco to notice for hearing16.19.20.68D & E NMAC, addition of Tramadol to the list of Schedule IV controlled substances for the January 2006 Board meeting. The Board voted unanimously to pass the motion.

Motion:

A was made by Mr. Ortega, seconded by Ms. Buesing to notice for hearing 16.19.6.25 NMAC, Fulfillment Pharmacies for the January 2006 Board meeting. The Board voted unanimously to pass the motion.

Mr. Harvey presented the additions under "Arrest Procedures" for the policy manual.

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Padilla to approve the additions as presented for the policy manual. The Board voted unanimously to pass the motion.

Emergency Rule Hearing 16.19.31 NMAC – Emergency Provisions Cont'd:

Discussion was held regarding the language and amendments to 16.19.31 NMAC. Section number 7 was added for **DEFINITIONS [RESERVED]**. Section number 1 was changed to section number 8. Section number 2 was changed to section number 9. Letter "C" in section 8 and 9 were changed to letter "B". Under letter "B" in section 8 and 9 the sentence ends at the word date, "unless a renewal application is approved by the board or an agent of the board" has been deleted.

Motion:

A motion was made by Ms. Padilla, seconded by Mr. Cross to adopt the rule as amended. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Cross to notice for hearing 16.19.31 NMAC, Emergency Provisions for the January 2006 Board meeting.

Executive Director's Report Cont'd:

Mr. Harvey gave a brief update regarding Stephanie Salas. Mr. Harvey stated that Ms. Salas contacted him, at which time she informed him that she would attend the next Board meeting January 2006.

Mr. Harvey gave a brief update on Mr. George Anderson. Mr. Harvey stated that Mr. Anderson had passed the MPJE and the MTP gave the Board their recommendation that he was cleared to practice.

Mr. Harvey presented correspondence from the Compressed Gas Association regarding gas packagers and re-packagers and stated that the Board had added these as licensed categories. FYI item, no action taken.

The Board discussed the issues Mr. Shaver had regarding perpetual inventories. Mr. Harvey stated that he would like to see policies and procedures in place that would verify that drugs are being accounted for.
Ms. Buesing asked Mr. Shaver if the topics of discussion were adequately addressing his questions and concerns. Mr. Shaver stated that he saw the problems and benefits of perpetual inventories.

Mr. Harvey discussed the steps that the Board was taking regarding the issues surrounding Flu Clinics and facilities that were operating that were not licensed. Mr. Harvey invited Carlene Brown, to discuss issues surrounding standing orders and the practitioner signing off as the physician authorizing the administration of the flu vaccines.

The Board discussed the dates for the November 2006 Board meeting. The Board agreed to the dates for the November 2006 Board meeting as the 2nd & 3rd.

Mr. Harvey and the Board discussed the issues regarding posting the approved minutes to the website and forwarding the current Board meeting minutes to the Board Secretary, Mr. Cross, for review within 7 to 10 days after the Board meeting. Mr. Harvey stated he was working with personnel to supply the minutes within a 7 to 10 day turn around time and that the website is

maintained by volunteers. He also stated that the website reflected the most recent approved minutes for June 2005.

Mr. Harvey gave an update on Ms. Jakiche's request for waiver from the last meeting.

Motion:

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

Motion:

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

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to issue an NCA in case 2005-110, an order to show cause in case 2005-109, close cases 2005-042, 2005-071, 2005-075, 2005-091, 2005-087, 2005-106, 2005-108, 2005-054, 2005-073, 2005-079, 2005-080, 2005-104, 2005-107. The Board voted unanimously to pass the motion.

EXECUTIVE SESSION – PERSONNEL ISSUES:

Mr. Harvey asked Mr. Therkildsen if he would like to go into closed session to discuss his resignation, Mr. Therkildsen stated that, that was not necessary and proceeded to discuss his departure as an inspector with the Board of Pharmacy. Mr. Therkildsen commended the staff at the Board of Pharmacy and stated that he enjoyed working with hard working staff that were always conscientious about patient and public safety. Mr. Harvey stated that Mr. Therkildsen was a great asset to the staff and had received positive feedback in regards to his presentations given at the Law updates. The Board thanked him for his services.

Motion:

A motion was made by Ms. Padilla, seconded by Mr. Carrier to adjourn. The Board voted unanimously to pass the motion.