# New Mexico Board of Pharmacy Regular Board Meeting October 19th, 2009

# Monday October 19th, 2009

**PLACE AND TIME:** The meeting was held at the Board of Pharmacy conference room at

5200 Oakland NE, Albuquerque, NM 87113.

**CALL TO ORDER:** The meeting was called to order by the Chairman Danny Cross, R.Ph.,

at 9:05 a.m.

MEMBERS PRESENT: Danny Cross, R.Ph., Chairman

Buffie Saavedra, Public Member Amy Buesing R.Ph., Member Howard Shaver, Public Member Joe Anderson R.Ph., Member Ray Nunley R.Ph., Member Richard Mazzoni R.Ph., Member

MEMBERS ABSENT: Allen Carrier, Secretary, Public Member

Thomas Ortega, R.Ph., Member

**STAFF ATTENDING:** William Harvey, Executive Director

Debra Wilhite, Administrative Secretary Mary Smith, Assistant Attorney General

Adela Padilla, Inspector Larry Loring, Inspector Ben Kesner, Inspector

# **ROLL CALL:**

Mr. Cross took roll call at 9:07 a.m. Present were Mr. Shaver, Mr. Nunley, Ms. Buesing, Mr. Anderson, and Ms. Saavedra and Mr. Mazzoni were present. The Chairman stated that Mr. Ortega and Mr. Carrier would be absent.

# **APPROVAL OF THE AGENDA:**

The Chairman asked if there were any changes to the agenda. Mr. Loring stated that he will add case #2009-062 and #2009-109 to the agenda.

#### **Motion:**

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

# APPROVAL OF THE AUGUST 25<sup>TH</sup> & 26<sup>TH</sup> 2008 MEETING MINUTES:

The Chairman asked if there were any changes to the minutes. Ms. Buesing stated that she could not find the chiropractic board committee response and that there were a few typing errors. Ms. Wilhite stated that she recalled the response from the chiropractic committee and would address it on the final version of the minutes and take care of the typo's. Mr. Harvey stated that the clinic application for "Apex" needed to be deleted from the list that is attached to the minutes.

# **Motion:**

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

Mr. Harvey introduced the current board intern, Angelina to the board.

# MTP REPORT:

The Chairman asked if the presentation of the applications could be done after the MTP report since Mr. Thayer was present from the MTP. Mr. Harvey and Mr. Thayer agreed to present the report.

#### **Motion:**

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

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

The Chairman asked for a 10-minute recess at 10:23 a.m.

Superintendent Ms. Kelly O'Donnell was present to discuss the possible effects the budget cuts will have on the boards and commissions and directly impact the employees within the executive branch. The board asked questions regarding the sweeping of budgets, pooling of the money being swept, furloughs and wage decreases.

The board thanked the Superintendent for attending the board meeting and answering questions that were presented.

# **RECESS:**

# **RECONVENE:**

The board reconvened at 10:35 a.m.

# RULE HEARING 16.19.20.8 D NMAC AND 16.19.20 NMAC SCHEDULES 1-5:

The Chairman asked that the notice for the hearing be listed as exhibit #1, proposed amendments be listed as exhibit #2 and that the federal requirements be listed as exhibit #3. A roll call was taken. Present were Mr. Shaver, Mr. Nunley, Ms. Buesing, Mr. Anderson, Ms. Saavedra and Mr. Mazzoni. The Chairman stated that there is a quorum present. Mr. Ortega and Mr. Carrier were absent.

Mr. Harvey presented the proposed language for 16.19.20.8 D inclusion of types of practitioners and the addition of controlled substances under schedules 1 through 5. Ms. Buesing read the proposed language. The board approved the amendment to the rule.

# **Motion:**

A motion was made by Mr. Anderson, seconded by Mr. Nunley to approve the amendments to 16.19.20.8 D NMAC and 16.19.20 NMAC schedules 1 through 5 as presented. The board voted unanimously to pass the motion.

# **16.19.20.8 REGISTRATION REQUIREMENTS:** Persons required to register:

- **A.** manufacture term includes repackagers;
- **B.** distributors term includes wholesale drug distributors;
- **C.** dispensers pharmacies, hospital pharmacies, clinics (both health and veterinarian);
- **D.** practitioners includes a physician, doctor of oriental medicine, dentist, physician assistant, certified nurse practitioner, clinical nurse specialist, certified nurse-midwife, veterinarian, pharmacist, pharmacist

clinician, certified registered nurse anesthetists, psychologists, chiropractic examiner, euthanasia technicians or other person licensed or certified to prescribe and administer drugs that are subject to the Controlled Substances Act;

#### 16.19.20.65 SCHEDULE I:

A. NMSA 1978 Section 30-31-6 schedule I shall consist of the following drugs and other substances, by whatever name, common or usual name, chemical name or brand name designated, listed in this section; **OPIATES**, unless specifically exempt or unless listed in another schedule, any of the following opiates, including its' isomers, esters, ethers, salts and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

- (1) Acetylmethadol
- (2) Allyl prodine
- (3) Alphacetylmethadol
- (4) Alphameprodine
- (5) Alphamethadol
- (6) Alpha-methyl fentanyl
- (7) Benzethidine
- (8) Betacetylmethadol
- (9) Betameprodine
- (10) Betamethadol
- (11) Betaprodine
- (12) Clonitazene
- (13) Dextromoramide
- (14) Diampromide
- (15) Diethylthiambutene
- (16) Dimethylthiambutene
- (17) Difenoxin
- (18) Dimenoxadol
- (19) Dimepheptanol
- (20) Dimethylthiambutene
- (21) Dioxaphetyl Butyrate
- (22) Dipipanone
- (23) Ethylmethylthiambutene
- (24) Etonitazene
- (25) Etoxeridine
- (26) Furethidine
- (27) Hydroxypethidine
- (28) Ketobemidone
- (29) Levomoramide
- (30) Levophenacylmorphan
- (31) Morpheridine
- (32) Noracymethadol
- (33) Norlevorphanol
- (34) Normethadone
- (35) Norpipanone
- (36) Phenadoxone
- (37) Phenampromide
- (38) Phenomorphan
- (39) Phenoperidine
- (40) Piritramide
- (41) Proheptazine
- (42) Properidine
- (43) Propiram
- (44) Racemoramide
- (45) Tilidine
- (46) Trimeperidine
- **B. OPIUM DERIVATIVES:** Unless specifically exempt or unless listed in another schedule, any of

the following opium derivatives, its' salts, isomers, and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

- (1) Acetorphine
- (2) Acetyl dihydrocodeine
- (3) Benzyl morphine
- (4) Codeine methylbromide
- (5) Codeine-N-Oxide
- (6) Cyprenorphine
- (7) Desomorphine
- (8) Dehydro morphine
- (9) Etorphine
- (10) Heroin
- (11) Hydromorphinol
- (12) Methyldesorphine
- (13) Methyldihydromorphine
- (14) Morphine methylbromide
- (15) Morphine methylsulfonate
- (16) Morphine-N-Oxide
- (17) Myrophine
- (18) Nicocodeine
- (19) Nicomorphine
- (20) Normorphine
- (21) Pholcodine
- (22) Thebacon
- (23) Drotebanol
- (24) Beta-Hydroxy-3-Methylfentanyl
- (25) 3-Methylthiofentanyl
- (26) Acetyl-Alpha-Methyl fentanyl
- (27) Alpha-Methylthiofentanyl
- (28) Beta-hydroxfentanyl
- (29) Para-Fluoro fentanyl
- (30) Thiofentanyl
- C. HALLUCINOGENIC SUBSTANCES: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its' salts, isomers, and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation (for purpose of this sub-section only, the term "isomers" includes the optical position, and geometric isomers).
  - (1) 3,4 -methylenedioxy amphetamine
  - (2) 5 methoxy 3,4-methylenedioxy amphetamine
  - (3) 3,4,5 -trimethoxy amphetamine
  - (4) Bufotenine
  - (5) Diethyltryptamine; DET
  - (6) Dimethyltryptamine; DMT
  - (7) 4-methyl-2,5-dimethoxy-amphetamine; DOM or STP
  - (8) Lysergic acid diethylamide
  - (9) Lysergic acid diethylamide
  - (10) Marijuana
  - (11) Mescaline
  - (12) Peyote
  - (13) N-ethyl-3-piperidyl benzilate
  - (14) N-methyl-3-piperidyl benzilate
  - (15) Psilocybin
  - (16) Psilocyn
  - (17) Tetrahydrocannabinols
- (18) Parahexyl (synthetic analog of delta-9-tetrahydrocannabinol (THC) an active ingredient of cannabis)

- (19) Hashish
- (20) 2, 5 -dimethoxyamphetamine; 2, 5-DMA
- (21) 4-bromo-2, 5-dimethoxy-amphetamine; 2,5-DMA
- (22) 4-methoxyamphetamine; PMA
- (23) Ethylamine N-ethyl-1-phenylcyclohexylamine (PCE)
- (24) Pyrrolidine 1-(1-phenylcyclohexyl)-pyrrolidine (PCPy), (PHP) analog of the drug phencyclidine
- (25) Thiophene (analog of phencyclidine) TCP or TPCP
- (26) Alpha-ethyltryptamine
- (27) 2, 5-dimethoxy-4-ethylamphet-amine
- (29) Ibogaine
- (30) 2,5 dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)
- (31) Alpha-methyltryptamine (AMT)
- (32) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT)
- **D. DEPRESSANTS:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its' salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:
  - (1) Mecloqualone
  - (2) Methaqualone
  - (3) Benzodiazepines
    - (a) bromazepam
    - (b) camazepam
    - (c) clobazam
    - (d) cloxazolam
    - (e) delorazepam
    - (f) ethyl loflazepate
    - (g) fludiazepam
    - (h) flunitrazepam
    - (i) haloxazolam
    - (j) ketazolam
    - (k) loprazolam
    - (l) lormetazepam
    - (**m**) medazepam
    - $(n) \quad \text{nimetazepam} \\$
    - (o) nitrazepam
    - (p) nordiazepam
    - (q) oxazolam
    - (r) pinazepam
    - (s) tetrazepam
  - (4) Gamma hydroxybutyric acid and any chemical compound that is metabolically converted to
  - (5) Gamma butyrolactone and any chemical compound that is metabolically converted to GHB.
  - (6) 1-4 butane diol and any chemical compound that is metabolically converted to GHB.
- **E. STIMULANTS:** Unless specifically exempted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its' salts, isomers, and salts of isomers.
  - (1) Fenethylline

GHB.

- (2) N-ethylamphetamine
- (3) cis-4-methylaminorex
- (4) N, N-dimethylamphetamine
- (5) N-benzylpiperazine (BZP, 1-benzylpiperazine)
- **F.** Any material, compound, mixture of preparation which contains any quantity of the following substances.
- (1) 3-Methylfentanyl(N-3-methyl-1-(2-phenyl-ethyl)-4-Piperidyl)-N-phenylpropanamide, its' optical and geometric isomers, salts and salts of isomers.
  - (2) 3, 4-methylenedioxymethamphetamine (MDMA), its' optical, positional and geometric isomers,

salts and salts of isomers.

isomers.

- (3) 1-methyl-4-phenyl-4-proprionoxypiperidine (MPPP), its' optical isomers, salts, and salts of isomers.
  - (4) 1-(-2-phenylethyl)-4-phenyl-4-acetoxy piperidine (PEPAP), its' optical isomers, salts and salts of
    - (5) Cathinone.
    - **(6)** Methcathinone.

[16.19.20.65 NMAC - Rp 16 NMAC 19.20.28, 07-15-02; A, 06-30-05; A, 01-15-08]

# **16.19.20.66** SCHEDULE II:

- A. Shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Substance, vegetable origin or chemical synthesis. Unless specifically exempt or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.
- (1) Opium and opiate, and any salts, compound, derivative, or preparation of opium or opiate excluding naloxone, dextrorphan, nalbuphine, naltrexone and apomorphine but including the following:
  - (a) raw opium
  - (b) opium extracts
  - (c) opium fluid extracts
  - (d) powdered opium
  - (e) granulated opium
  - (f) tincture of opium
  - (g) codeine
  - (h) ethylmorphine
  - (i) etorphine hydrochloride
  - (j) hydrocodone
  - (k) hydromorphone
  - (l) metopon
  - (m) morphine
  - (n) oxycodone
  - (o) oxymorphone
  - (**p**) thebaine
  - (q) alfentanil
  - (r) oripavine
- (2) Any salt, compound derivative, or preparation thereof, which is chemically equivalent or identical with any of the substances referred to in 16.19.20.66.A.(1) NMAC, except that these substances shall not include the isoquinoline alkaloids of opium.
  - (3) Opium poppy and poppy straw.
- (4) Coca leaves and any salt, compound, derivative or preparation of coca leaves and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include de-cocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
- **B. OPIATES:** Unless specifically excepted or unless in another schedule any of the following opiates, including its' isomers, esters, ethers, salts and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation except dextrose and levopropoxyphene.
  - (1) Alphaprodine
  - (2) Anileridine
  - (3) Bezitramide
  - (4) Diphenoxylate
  - (5) Dihydrocodeine
  - **(6)** Dextropropoxyphene (bulk) non-dosage form
  - (7) Fentanyl
  - (8) Isomethadone
  - (9) Levomethorphan

- (10) Levorphanol
- (11) Metazocine
- (12) Methadone
- (13) Methadone-Intermediate
- (14) Monamide-Intermediate
- (15) Pethidine
- (16) Pethidine-Intermediate A
- (17) Pethidine-Intermediate B
- (18) Pethidine-Intermediate C
- (19) Phenazocine
- (20) Piminodine
- (21) Racemethorphan
- (22) Racemorphan
- (23) Sufentanil
- (24) Carfentanil
- (25) Levo-alphacetylmethadol (LAAM)
- (26) Tapentadol
- C. STIMULANTS: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system. (See 16.19.21 NMAC- Drug Precursors)
  - (1) Amphetamine, its' salts, optical isomers and salts of its' optical isomers.
  - (2) Methamphetamine, its' salts, isomers and salts of isomers.
  - (3) Phenmetrazine and its' salts.
  - (4) Methylphenidate.
  - (5) Lisdexamfetamine.
- **D. DEPRESSANTS:** Unless specifically exempt or unless listed in another schedule any material, compound mixture or preparation which contains any quantity of the substance having a depressant effect on the central nervous system, including its' salts, isomers and salts of isomers is possible within the specific chemical designation.
  - (1) Amobarbital
  - (2) Secobarbital
  - (3) Pentobarbital
  - (4) Phencyclidine
- (5) Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a drug product approved by the U.S. Food and Drug Administration
  - (6) Glutethimide
  - (7) 1-phenylcyclohexylamine
  - (8) 1-piperidinocyclohexanecarbonitrile
- **E. HALLUCINOGENIC SUBSTANCES:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its' salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purpose of this paragraph only, the term "isomers" includes the optical position, and geometric isomers): Nabilone

# F. MISCELLANEOUS:

- (1) Dihydroetorphine
- (2) Bulk dextropropoxyphene
- (3) Remifentanil
- [16.19.20.66 NMAC Rp 16 NMAC 19.20.28(1), 07-15-02; A, 06-30-05; A, 01-15-08]
- **16.19.20.67 SCHEDULE III:** Shall Consist of Drugs and Other Substances, By Whatever Official Name, Common or Usual Name Designated Listed in This Section.
- **A. STIMULANTS:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system.
- (1) Those compounds, mixtures or preparations in dosage unit form containing any stimulant, amphetamine, phenmetrazine or methamphetamine previously exempt, for which the exemption was revoked by

FDA Regulation Title 21, Part 308.13, and any other drug of the quantitative composition shown in that regulation for those drugs or which is the same except that it contains a lesser quantity of controlled substances.

- (2) Benzphetamine.
- (3) Phendimetrazine.
- (4) Chlorphentermine.
- (5) Clortermine.
- **B. DEPRESSANTS:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system.
  - (1) Any compound, mixture or preparation containing:
    - (a) amobarbital;
    - (b) secobarbital;
    - (c) pentobarbital;
- (d) butalbital; or any salt thereof and one or more active medicinal ingredients which are not listed in any schedule.
  - (2) Any suppository dosage form containing:
    - (a) amobarbital;
    - (b) secobarbital;
- (c) pentobarbital; or any salt of any of these drugs approved by the FDA for marketing only as a suppository.
- (3) Any substance which contains any quantity of a derivative of barbituric acid or any salt of a derivative of barbituric acid.
  - (4) Chlorhexadol
  - (5) Lysergic Acid
  - (6) Lysergic Acid Amide
  - (7) Methyprylon
  - (8) Sulfondiethylmethane
  - (9) Sulfonethylmethane
  - (10) Sulfonmethane
  - (11) Tiletamine/zolazepam (Telazol)
  - (12) Ketamine Hydrochloride
- (13) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug and Cosmetic Act.
  - (14) Embutramide
  - **C. Nalorphine** (a narcotic drug).
  - D. Buprenorphine.
- **E. NARCOTIC DRUGS:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of the following narcotic drugs, or any salts thereof.
- (1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
- (2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage units, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.
- (3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.
- (4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
  - F. ANABOLIC STEROIDS: The term "anabolic steroid" means any drug or hormonal substance,

chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth. Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances listed in this section:

- (1) boldenone
- (2) chloro testosterone
- (3) clostebol
- (4) dehydrochlormethyltestosterone
- (5) dihydrotestosterone
- (6) drostanolone
- (7) ethylestrenol
- (8) fluoxymesterone
- (9) formebolone
- (10) mestanolone
- (11) mesterolone
- (12) methandienone
- (13) methandranone
- (14) methandriol
- (15) methandrostenolone
- (16) methenolone
- (17) methyltrienolone
- (18) methyltestosterone
- (19) mibolerone
- (20) nandrolone
- (21) norbolethone
- (22) norethandrolone
- (23) oxandrolone
- (24) oxymesterone
- (25) oxymetholone
- (26) stanolone
- (27) stanozolol
- (28) testolactone
- (29) testosterone
- (30) trenbolone; and
- (31) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.
- **G.** Exempt Anabolic Steroids: Compounds, mixtures, or preparations that contain an anabolic steroid that have been exempted by the board from Subsection E of 16.19.20.67 NMAC, schedule III to the same extent that the substance has been exempted from the application of the Federal Controlled Substance Act, if the substance is listed as an exempt anabolic steroid product under 21 C.F.R. Section 1308.34 and its subsequent amendments. [16.19.20.67 NMAC Rp 16 NMAC 19.20.28(2), 07-15-02; A, 02-15-03; A, 06-30-05; A, 01-31-07; A, 01-15-08]

**16.19.20.68 SCHEDULE IV:** Shall Consist of the Drugs and Other Substances, by Whatever Official Name, Common or Usual Name, Chemical Name, or Brand Name Designated, Listed in this Section:

- **A. DEPRESSANTS:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its' salts, isomers, and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:
  - (1) Alprazolam
  - (2) Barbital
  - (3) Chloral Betaine
  - (4) Chloral Hydrate
  - (5) Chlordiazepoxide
  - (6) Clonazepam
  - (7) Clorazepate
  - (8) Clotiazepam
  - (9) Diazepam

- (10) Estazolam
- (11) Ethchlorvynol
- (12) Ethinamate
- (13) Flurazepam
- (14) Halazepam
- (15) Lorazepam
- (16) Mebutamate
- (17) Meprobamate
- (18) Methohexital
- (19) Methylphenobarbital
- (20) Midazolam
- (21) Oxazepam
- (22) Paraldehyde
- (23) Petrichloral
- (24) Phenobarbital
- (25) Prazepam
- (26) Ouazepam
- (27) Temazepam
- (28) Triazolam
- (29) Zopiclone
- **B. FENFLURAMINE:** Any material, compound, mixture or preparation which contains any quantity of the following substance, including its' salts, isomers (whether optical position, or geometric) and its' salts, or such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Fenfluramine
- **C. STIMULANTS:** Unless specifically exempt or unless listed in another schedule any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its' salts, isomers (whether optical position, or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:
  - (1) Diethylpropion
  - (2) Phentermine
  - (3) Pemoline (including organometallic complexes and chelates thereon)
  - (4) Pipradrol
  - (5) SPA ((-)-1-dimethyl amino-1,2-diphenylmethane)
  - (6) Mazindol
  - (7) Cathine
  - (8) Fencamfamin
  - (9) Fenproporex
  - (10) Mefenorex
  - (11) Modafinil
  - (12) Sibutramine
- **D. OTHER SUBSTANCES:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its' salts:
  - (1) Dextropropoxyphene(Alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane)
  - (2) Pentazocine
  - (3) Carisoprodol
  - (4) Nalbuphine Hydrochloride
  - (5) Butorphanol Tartrate
  - (6) Dezocine
  - (7) Dichloralphenazone
  - (8) Zaleplon
  - (9) Zolpidem
- **E. NARCOTIC DRUG:** Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof: Not more than 1 milligram of different and not less than 25 micrograms of atropine sulfate per dosage unit.

- F. EXEMPTION OF CHLORAL: When packaged in a sealed, oxygen-free environment, under nitrogen pressure, safeguarded against exposure to the air. Chloral when existing under the above conditions, is a substance which is not intended for general administration to a human being or another animal, and contains no narcotic controlled substances and is packaged in such a form that the package quantity does not present any significant potential for abuse. All persons who engage in industrial activities with respect to such chloral are subject to registration; but shall be exempt from Section 30-31-16 through 19 of the New Mexico Controlled Substances Act and 16.19.20.19 NMAC through 16.19.20.52 NMAC of the Board of Pharmacy regulations.
- **G. EXEMPT COMPOUNDS:** Librax and Menrium are preparations which contain chlordiazepoxide, a depressant listed in Schedule IV, 16.19.20.68.A.5 NMAC and other ingredients in such combinations, quantity, preparation or concentration as to vitiate the potential for abuse of chlordiazepoxide, and are hereby exempt preparations.
  - (1) Librax
  - (2) Menrium, 5-2
  - (3) Menrium, 4-5
  - (4) Menrium, 10-4

[16.19.20.68 NMAC - Rp 16 NMAC 19.20.28(3), 07-15-02; A, 06-30-05]

#### 16.19.20.69 SCHEDULE V:

- **A.** Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone.
  - (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
  - (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
  - (3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
- (4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
  - (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
- (6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
- **B.** Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers.
  - (1) Pyrovalerone.
- (2) Pseudoephedrine as a drug that includes any compound, mixture, or preparation that contains any detectable quantity of pseudoephedrine, its salts or its optical isomers, or salts of its optical isomers. Pursuant to 30-31-10.C the following substances are excluded from Schedule V controlled substances: pseudoephedrine products in liquid form including liquid filled gel caps and pseudoephedrine products already classified as dangerous drugs.
- <u>C.</u> <u>Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:</u>
  - (1) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide]
- (2) <u>Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]</u>

[16.19.20.69 NMAC - Rp 16 NMAC 19.20.28(4), 07-15-02; A, 06-30-05; A, 06-30-06; A, 01-31-07]

**16.19.20.70 EXEMPT DANGEROUS DRUGS (PRESCRIPTION STATUS DRUGS):** The drugs set forth in the Federal DEA Table of Excepted Prescription Drugs published in a separate volume under Code of Federal Regulations, Title 21, Chapter II, Part 1308.32 have been exempt by the New Mexico Board of Pharmacy. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exemption to the Federal DEA in order that a drug may be exempt by DEA and the New Mexico Board of Pharmacy. [16.19.20.70 NMAC - Rp 16 NMAC 19.20.28(5), 07-15-02]

#### **RULE HEARING 16.19.6.11.C.2 NMAC STERILE PHARMACEUTICAL TRAINING REQUIREMENTS:**

The Chairman asked that the notice for hearing be listed as exhibit #1 and the proposed language for 16.19.6.11.C.2 NMAC be listed as exhibit #2.

Ms. Buesing read the proposed language and Mr. Harvey and Mr. Phil Sauceda clarified the changes made.

#### **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Mazzoni to approve the language as presented for 16.19.6.11.C.2 NMAC. The board voted unanimously to approve the motion.

# 16.19.6.11C(2) Requirements for training.

- a. All pharmacists prior to compounding sterile pharmaceuticals, or supervising pharmacy personnel compounding sterile pharmaceuticals, all shall have completed a minimum of 20 contact hours of didactic, experiential training and competency evaluation through demonstration and testing (written or practical) as outlined by the pharmacist-in-charge and described in the policy and procedures or training manual. Such training shall be evidenced by completion of a recognized course in an accredited college of pharmacy or and approved ACPE approved course which shall include instruction and hands-on experience in the following areas:
  - i. aseptic technique;
  - ii. critical area contamination factors;
  - iii. environmental monitoring;
  - iv. facilities;
  - v. equipment and supplies;
  - vi. sterile pharmaceutical calculations and terminology;
  - vii. sterile pharmaceutical compounding documentation;
  - viii. quality assurance procedures;
    - ix. proper gowning and gloving technique;
    - x. the handling of cytotoxic and hazardous drugs; and
  - xi. general conduct in the controlled area.
- b. All pharmacist interns prior to compounding sterile pharmaceuticals shall have completed a minimum of 40 hours of instruction and experience in the areas listed in paragraph +2. Such training will be obtained through the:
  - i. completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy); or
  - ii. completion of a <del>course sponsored by an ACPE</del> <u>board</u> approved <u>course</u> <del>provider</del>, <u>or</u>
  - iii. <u>certification by University of New Mexico College of Pharmacy. <del>upon</del> <del>graduation</del>.</u>
- c. All pharmacy technicians who compound sterile pharmaceuticals shall have a high school or equivalent education and be a certified pharmacy technician, and complete a minimum of 40 hours of instruction and experience in the areas listed in paragraph 42. Such training will be obtained through the:
  - i. completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy) which

- provides 40 hours of instruction and experience in the areas listed in paragraph 12; or
- ii. completion of a course sponsored by an board approved ACPE course or board approved provider which provides 40 hours of instructions and experience in the areas listed in paragraph 12.
- d. All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs shall, effective December 31, 2008, have completed a board approved course training program in chemotherapy drug preparation. All pharmacy interns and technicians must complete this training prior to preparing sterile chemotherapy drug products.

# RULE HEARING 16.19.6.15 DISPENSED PHARMACEUTICALS: COLLECTION AND DISPOSAL (to allow pharmacies to collect and dispose of pharmaceuticals collected from patients):

The Chairman asked that the notice for hearing be listed as exhibit #1 and the new language for section 15 of 16.19.6 NMAC be listed as exhibit #2.

Mr. Harvey and the board discussed the issues that have arisen regarding the need for the new section. Numerous issues were discussed regarding the language. Mr. Harvey asked the Chairman and Ms. Mary Smith if the rule hearing could be recessed and continued on Tuesday at 10:00 a.m. so he would be able to present the rule as it stands and with the inclusion of the proposed language that was currently being suggested by the board.

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

#### **RECESS FOR LUNCH:**

# **RECONVENE:**

The board reconvened at 1:30 p.m.

# **APPLICATIONS:**

#### **Application List:**

#### Clinic:

Ms. Buesing stated that there are 14 applications in this category and all are in order.

#### **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Nunley to approve all 14 applications in this category. The board voted unanimously to pass the motion.

#### **Animal Control:**

Ms. Buesing stated that one application in this category and all are in order.

# Motion:

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

# **Emergency Medical Service:**

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

#### **Motion:**

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

# **Custodial Nursing Home:**

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

#### **Motion:**

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

# **Hospital:**

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

#### **Motion:**

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

#### Pharmacy:

Ms. Buesing stated that there are 6 applications in this category and all are in order.

# **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve the 6 applications in this category. The board voted unanimously to pass the motion. Mr. Mazzoni abstained from voting.

# **Non-Resident Pharmacy:**

Ms. Buesing stated that there are 9 applications in this category and all are in order.

# **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve all 9 applications in this category. The board voted unanimously to pass the motion.

# Wholesale/Broker

Ms. Buesing stated that there are 16 applications in this category and all is in order.

# **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve all 16 applications in this category. The board voted unanimously to pass the motion.

#### **Pharmacist Clinician:**

Ms. Buesing presented 7 applications that were discussed by the committee on October 8<sup>th</sup> and 15<sup>th</sup>, 2009. The applicants are Quentin Florence, Olivier Waiman, Angela Weimerskirch, Chris McFarland, Jed Lynden ,Charles Mahan and Shawn Welch.

#### **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Nunley to approve the prescriptive authority recommendations by the credentialing committee for Quentin Florence, Olivier Waiman and Chris McFarland. The board voted unanimously to pass the motion.

#### **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Nunley to approve the pharmacist clinician recommendation by the credentialing committee for Angela Weimerskirch. The board voted unanimously to pass the motion.

#### **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Anderson to approve the pharmacist clinician protocols for Jed Lynden, Charles Mahan and Shawn Welch. The board voted unanimously to pass the motion.

# RULE HEARING 16.19.33 NMAC - NEW RULE FOR TELE-PHARMACY:

The Chairman asked that the notice for hearing be listed as exhibit #1 and the new rule language be listed as exhibit #2.

Ms. Saavedra thanked the committee for their hard work preparing the language for the tele-pharmacy rule. Mr. Dale Tinker commented on his approval of the new rule.

#### **Motion:**

A motion was made by Ms. Saavedra, seconded by Mr. Shaver to approve the new rule 16.19.33 NMAC. The board voted unanimously to pass the motion.

TITLE 16	OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19	PHARMACISTS
PART 33	TELE-PHARMACY AND REMOTE DISPENSING

- **16.19.33.1 ISSUING AGENCY:** Regulation and Licensing Department Board of Pharmacy.
- **SCOPE:** This section applies to hub pharmacies and remote tele-pharmacies. Both the hub pharmacy and all remote tele-pharmacies must be located within New Mexico. The remote tele-pharmacy must be greater than 25 miles from an existing community pharmacy to qualify under these rules.
- **16.19.33.3 STATUTORY AUTHORITY:** 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. Section 61-11-6(A)(1) NMSA 1978 requires the Board of Pharmacy to adopt, amend or repeal rules and regulations necessary to carry out the provisions of the Pharmacy Act.
- **16.19.33.4 DURATION:** Permanent
- **16.19.33.5 EFFECTIVE DATE:** (Set date), unless a later date is cited at the end of a section.
- **16.19.33.6 OBJECTIVE:** The objective of Part 33 of Chapter 19 is to ensure the safe and competent delivery of quality pharmaceutical products and the provision of pharmaceutical care to the public by establishing

standards for the operation of remote dispensing sites and tele-pharmacy, including but not limited to minimum space requirements and standards for equipment, accessories, personnel, dispensing, labeling.

**16.19.33.7 PURPOSE:** The Board of Pharmacy is responsible for maintaining, continuing and enhancing the development of the education and professional role of the pharmacist for the protection of the health, welfare and safety of the citizens of New Mexico. New Mexico is facing a pharmacy services accessibility problem due to the closing of pharmacies and the lack of registered pharmacists. In order to maintain or make pharmacy services available in communities that have no licensed pharmacy or are in jeopardy of losing their licensed pharmacy, rules are necessary to permit remote tele-pharmacy services and remote dispensing.

#### **16.19.33.8 DEFINITIONS:**

- **A.** "Average Number of Prescriptions Filled per Day (ANPFD) means the total number of prescriptions filled during a calendar month divided by the total number of days open that month.
  - B. "Electronic Link" means a real time, continuous computer, video and audio link between the hub pharmacy and the remote tele-pharmacy during all hours of operation and in compliance with 16.19.33.9A(4).
  - <u>C.</u> "Continuous video supervision" means a constant live video link with not less than 4 camera views which allows for real time live monitoring of the remote Tele-pharmacy remote dispensing site which is recorded for a minimum of 180 days.
  - <u>D.</u> "Patient-Pharmacist Audio Visual Link" means a real time audio visual link from the private patient counseling area of the remote tele-pharmacy to the pharmacist at the hub pharmacy
  - E. "Hub Pharmacy" means a New Mexico licensed pharmacy operating under the direct control of a pharmacist from which computer-aided pharmacist supervision of a remote tele-pharmacy occurs.
  - F. "Hub Pharmacist" means a New Mexico registered pharmacist who oversees the day to day operations of a remote tele-pharmacy via an electronic link that includes provisions for visual observations and inspection of the inside of the pharmacy and all prescription orders prior to dispensing. This oversight to include visual inspection of and patient consultation for any prescription order dispensed from the remote tele-pharmacy.
  - G.. "Pharmacist-in-Charge" means the pharmacist-in-charge for the hub pharmacy from which the hub pharmacist oversees the day-to-day operation of a remote tele-pharmacy and who shall comply with 16 NMAC 19.6.9.
  - H.. "Pharmacist site visits": defines how often a pharmacist must physically visit the remote tele-pharmacy.
    - at least once a month when the ANPFD is 1 to 50,
    - at least once every two weeks when the ANPFD is 51 to 100 per day,
    - at least once per week when the ANPFD is 101 to 150,
    - -at least twice per week when the ANPFD is 151 to 200.
    - -a pharmacist is required on site full time during normal operating hours if the ANPFD exceeds 200.
  - I. "Remote Dispensing Site" means a pharmacy location primarily staffed by technicians and remote dispensing technology "Electronic Link" and continuous video supervision with required supervision and in person visits from the hub pharmacy pharmacist.
  - J. "Remote Tele-Pharmacy" means a licensed pharmacy located in the State of New Mexico staffed by a remote tele- pharmacy technician who practices under the direct, computer aided, and

- supervision of a hub pharmacist working from the hub pharmacy by electronic link during all hours of operation.
- **K.** "Remote Tele-Pharmacy Technician" means a New Mexico registered pharmacy technician, employed by the hub pharmacy, with a minimum of two-thousand hours of experience working, as a certified registered pharmacy technician who, under the computer aided supervision of an off-site pharmacist, handles the day to day operation of a remote tele-pharmacy, including the preparation and dispensing of prescription drugs.
- L. "Practice of Tele-pharmacy" means the provision of pharmacist care by registered pharmacies and pharmacists through the use of telecommunications or other technologies to patients or their agents at a remote site.

#### **16.19.33.9 OPERATIONS**

- **A.** A remote tele-pharmacy shall comply with all sections of NMAC 16.19.6.8 governing the procedure for obtaining a license to operate a pharmacy in New Mexico:
  - (1) The license holder of the hub pharmacy must apply for a license to operate a remote tele-pharmacy. A remote tele-pharmacy license is established for the purpose of conducting a remote tele-pharmacy. The license is issued to a remote tele-pharmacy connected to a hub pharmacy via an electronic link. The initial licensure fee and subsequent license renewal fee are the same as those for retail pharmacies, as required by 16NMAC 19.12.13E.
  - (2) A remote tele-pharmacy that operates under different ownership than the hub pharmacy; to which it is attached; shall have a written contractual agreement outlining the responsibilities of each pharmacy. This written agreement shall be submitted with the initial licensure application for a remote tele-pharmacy. Any subsequent changes to that contractual agreement shall be submitted to the Board's executive director for approval.
    - a. The applicant must provide sufficient evidence that the proposed location is in an area of the State lacking access to a retail pharmacy. The Board will utilize the evidence supplied by the applicant and from other sources when making a determination that sufficient evidence exists to approve an application for a remote tele-pharmacy.
  - (3) A remote tele-pharmacy shall comply with all the applicable requirements for a pharmacy as contained in NMAC 16.19 Part 6. Pharmacies.
  - (4) A remote tele-pharmacy shall be connected to a hub pharmacy via an electronic link. All links must be fully operational during all hours of operation of the remote tele-pharmacy. If any link malfunctions, the remote tele-pharmacy must be closed unless a pharmacist is physically present at the remote pharmacy site.
    - a. Video equipment must be capable of providing an adequate number of simultaneous views of the pharmacy operation at the remote tele-pharmacy.
    - **b.** The video equipment at the remote tele-pharmacy site must be capable of resolution sufficient to allow for pharmacist identification of medication dosage forms and the reading of bottle labels via video camera.

- **c.** The video link between a hub pharmacy and a remote tele-pharmacy site must be capable of recording and maintaining at least one hundred eighty (180) days of video surveillance of the remote tele-pharmacy site and operations for future review.
- **d.** Only a remote tele-pharmacy technician designated for that site or a pharmacist who is physically present at the remote tele-pharmacy may access a remote tele-pharmacy site, linked to a hub pharmacy via an electronic link.
- **e.** The remote tele-pharmacy may only remain open as long as the designated pharmacy technician is present in the remote tele-pharmacy and the hub pharmacist is present at the hub pharmacy or at the remote site.
- f. The name of each certified pharmacy technician that works at a remote telepharmacy shall be recorded with the New Mexico Board of Pharmacy. Notification of any change of staff at a remote tele-pharmacy shall be made to the Board of Pharmacy immediately.
- (5) The pharmacist in charge of the hub pharmacy shall produce a policy and procedure for the safe and effective operation of the remote tele-pharmacy and the oversight by the hub pharmacy. This manual shall be available for Board inspection in both the remote tele-pharmacy and the hub pharmacy. The policy and procedure manual shall be reviewed by the pharmacist-in-charge annually and revised if necessary to promote improvements in safety and service at the remote tele-pharmacy. The annual review and any changes to the manual shall be documented.
- (6) The pharmacist-in-charge is responsible for an ongoing review of incident reports and outcomes, with appropriate corrective action taken.
- (7) A pharmacist employed by the hub pharmacy must visit and complete inspections of the remote tele-pharmacy according to the visitation requirements of 16.19.33.8.H. A list of inspection criteria shall be included in the policy and procedure manual for the remote tele-pharmacy. The pharmacist's inspection shall include a determination of the average number of prescriptions filled per day. A copy of the inspection report shall be reviewed and signed by the pharmacist-in-charge of the hub pharmacy and a copy of the inspection report shall be maintained at both the remote tele-pharmacy and at the hub pharmacy for Board of Pharmacy inspection.
- (8) The number of pharmacy technicians that a hub pharmacist may oversee shall be limited according to NMAC 16.19.22.10. Any pharmacy technicians on duty at the hub pharmacy site shall be taken into account along with any remote tele-pharmacy technicians working at remote tele-pharmacy sites, when computing the ratio of pharmacists to pharmacy technicians. Application for an increase in the ratio of pharmacy technicians to pharmacists may be made in accordance with NMAC 16.19.22.10B.
- (9) A remote tele-pharmacy may have a dangerous drug inventory. Any controlled substances shall be kept at the remote site in accordance with NMAC 16.19.20.
  - a. If controlled substances are kept, the remote tele-pharmacy shall be registered with the Drug Enforcement Administration and obtain its own DEA number.
  - b. If controlled substances are kept, the remote tele-pharmacy shall have a valid New Mexico Controlled Substance Registration as required in NMAC 16.19.20.
  - **c.** All controlled substances kept in inventory by the remote tele-pharmacy shall be listed on a perpetual inventory log, which shall be updated upon the dispensing of each controlled substance prescription or other disposition.
  - **d.** The pharmacist shall perform monthly audits of all controlled substances during regular inspection visits to the remote tele-pharmacy.
- (10) Prescriptions may be received, entered and filled or re-filled by the hub pharmacy and sent to the remote tele-pharmacy for distribution to the patient during hours when the technician is present in the remote tele-pharmacy. A pharmacist at the hub pharmacy must approve each prescription before it leaves the remote tele-pharmacy site.
  - a. The pharmacist's initials and the technician's initials shall be recorded.
  - **b.** The pharmacist shall compare the stock bottle, the drug dispensed, and drug strength. The entire prescription label must be checked for accuracy. All prescriptions

distributed by the remote tele-pharmacy must have the label affixed to the prescription container prior to being inspected by the pharmacist via electronic link.

(11) Patient counseling shall be done by a pharmacist via an electronic link. The pharmacist shall counsel the patient or the patient's agent on all new prescriptions and refills. All counseling, according to 16NMAC19.4.16E, remains the responsibility of the pharmacist at the hub pharmacy via an electronic link.

# STIPULATED OR SETTLEMENT AGREEMENTS/SURRENDERS/DEFAULT ORDERS\*:

**2009-083 Voluntary Surrender:** A voluntary surrender was presented to the board for Justin Nixon.

#### **Motion:**

A motion was made by Mr. Nunley, seconded by Ms. Saavedra to accept the surrender as presented for Justin Nixon. The board voted unanimously to pass the motion.

**2009-036 Order Accepting Voluntary Restriction of Pharmacist License:** An order was presented to the board for Katherine Field.

#### **Motion:**

A motion was made by Ms. Saavedra, seconded by Mr. Nunley to approve the order as presented to the board for Katherine Field. The board voted unanimously to pass the motion.

2009-007 Order Accepting Restriction of License: An order was presented to the board for Andrea Ryan.

# **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Nunley to approve the order as presented to the board for Andrea Ryan. The board voted unanimously to pass the motion.

# **PUBLIC/PROFESSIONAL REQUESTS:**

**Waiver Request – R.G. Groh, Director of Pharmacy:** Mr. Harvey discussed the waiver as Mr. Groh was not in attendance. The board suggested that the discussion resume on Tuesday October 20<sup>th</sup>, 2009 when Mr. Groh would be present.

The board resumed the discussion on Tuesday October 20<sup>th</sup>, 2009 but due to unforeseen circumstances being that Mr. Groh is no longer employed at Roswell Regional Hospital of which the waiver pertained to, no action was taken. FYI.

Mr. Harvey stated that Mr. Groh would like to be on the remote tele-pharmacy committee.

# **COMMITTEE REPORTS:**

**Tele-Pharmacy Committee:** Mr. Harvey discussed the waiver as Mr. Groh was not in attendance. The board suggested that the discussion resume on Tuesday October 20<sup>th</sup>, 2009 when Mr. Groh would be present.

The board resumed the discussion on Tuesday October 20<sup>th</sup>, 2009 but due to unforeseen circumstances being that Mr. Groh is no longer employed at Roswell Regional Hospital of which the waiver pertained to, no action was taken. FYI.

**Pharmacist CE Committee:** Mr. Anderson stated that the committee met in September. They will be meeting again on December 15, 2009 to compile the results from the survey that were sent out. They will also be discussing continuing professional development with the College of Pharmacy.

Pharmacist Practice Committee: No report at this time.

**Emergency Preparedness Committee:** No report at this time.

**Pharmacist Clinician Committee:** Mr. Anderson and Ms. Buesing discussed the recommendations for a 60-hour physical assessment course to be integrated into the curriculum. Mr. Harvey asked that the documents be provided to him and he would draft a letter to be sent regarding the boards approval.

#### **Motion:**

A motion was made by Ms. Saavedra, seconded by Mr. Shaver to approve the assessment course. The board voted unanimously to pass the motion. Mr. Anderson and Ms. Buesing abstained from the vote.

The Chairman asked for a 10-minute break at 2:30 p.m.

#### **RECESS:**

# **RECONVENE:**

The board reconvened at 2:40 p.m.

Ms. Linda Trujillo, Director of Boards and Commissions spoke to the board briefly regarding the special session and stated that cut-backs and furloughs are not affecting the board of pharmacy.

# **Committee Reports Cont'd:**

**Board of Pharmacy/Chiropractor Formulary Committee:** In attendance were Dr. Simmons, Dr. Schmidt, Mr. Joe Anderson and Inspector Ben Kesner. Mr. Harvey stated that initially the board of pharmacy was not included in the rule hearing for the formulary being presented and that statutorily the board must approve of the drugs being listed. Ms. Buesing discussed numerous issues and concerns regarding the listing of dangerous drugs, IV injections, indications and routes of administration were addressed. The board tasked Dr. Simmons and the committee members to address these concerns and provide documentation with the scope, purpose, practices and use of the drugs, minerals and vitamins being referenced on the formulary. The Chairman Mr. Cross stated that he felt the committee was moving in a good direction. Ms. Buesing recommended that the issues be addressed regarding the formulary and come back to the board with the changes suggested.

# **Motion:**

A motion was made by Ms. Saavedra, seconded by Ms. Buesing that clarification of "route of administration" be documented and acceptance of changes discussed and approval of "IM injectable route list" and exclusion of the "IV injectable medications" on the formulary presented. The board voted unanimously to pass the motion.

Ms. Buesing discussed the need for the chiropractic board to recognize the standards of <797> and consider continuing education as a benefit.

**Board of Pharmacy/BAOM Education Committee:** No report at this time.

**Pharmacist Technician Committee:** No report at this time.

# **EXECUTIVE DIRECTOR'S REPORT:**

**2010 NABP District 6, 7 and 8 Meeting Awarded to New Mexico:** Mr. Harvey and the board discussed that the NABP district meeting was being held in New Mexico. Ms. Saavedra is the board Chairperson for our district 8. Numerous events and activities are in the works for the upcoming meeting and will be addressed at the next two board meetings in 2010.

**Budget/Out of State Travel:** Ms. Linda Trujillo briefly discussed the budgets for the board and how cuts would affect out of state travel. The board discussed the attendance of staff and board members for the meeting in May 2010. Ms. Linda Trujillo stated that one member would be covered for travel by a grant and one staff member from the board budget and not two staff members as requested.

The board thanked Ms. Linda Trujillo for attending the board meeting.

The meeting was adjourned at 4:30 p.m.

# RECONVENE TUESDAY OCTOBER 20<sup>TH</sup>, 2009:

The Chairman reconvened at 9:05 a.m. and took roll call. Present were Mr. Mazzoni, Ms. Saavedra, Ms. Buesing, Mr. Nunley and Mr. Shaver. Mr. Cross stated that Mr. Anderson was running late and that Mr. Carrier and Mr. Ortega are absent. Mr. Cross stated that a quorum was present.

# Public /Professional Requests Cont'd:

# Bryan Krumm, CNP, New Mexicans for Compassionate Use:

Mr. Cross stated that Mr. Bryan Krumm was present. Mr. Krumm asked for the board to consider changing marijuana from the currently placed "schedule 1" to a "schedule 3". After a brief discussion the board informed Mr. Krumm that he would have to present his request to the legislature and executive branch.

**Waiver Request – R.G. Groh, Director of Pharmacy:** The board resumed the discussion on Tuesday October 20<sup>th</sup>, 2009 but due to unforeseen circumstances being that Mr. Groh is no longer employed at Roswell Regional Hospital of which the waiver pertained to, no action was taken. FYI.

Mr. Harvey stated that Mr. Groh would like to be on the remote tele-pharmacy committee.

Mr. Anderson was present at 9:12 a.m.

# **Executive Director's Report Cont'd:**

**Proposal – 16.19.6.22 NMAC Off-Site Pharmacy Records:** Discussion was held regarding the proposed language for off-site pharmacy records.

#### Motion:

A motion was made by Ms. Buesing, Seconded by Mr. Shaver to notice the language for 16.19.6.22 NMAC at the January 2010 board meeting. The board voted unanimously to pass the motion.

**Proposal Criminal Background Checks 16.19.34 NMAC and 16.19.12 NMAC Fees:** A lengthy discussion was held regarding a new rule to run criminal background checks on licensees. Issues covering fees, resources and companies used to retrieve vital information and how the information would be evaluated were addressed. The board agreed that more research and information was needed in order to go forward.

# TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING

**CHAPTER 19 PHARMACIST** 

# PART 34 CRIMINAL BACKGROUND CHECKS

**16.19.34.1 ISSUING AGENCY:** Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM, (505) 222-9830.

16.19.34.2 SCOPE: All persons subject to licensure or registration by the Board of Pharmacy.

**16.19.34.3 STATUTORY AUTHORITY:** Section 61-11-6.1. NMSA 1978 Criminal Background Checks. Allows for the Board to adopt rules that provide for criminal background checks.

16.19.34.4 DURATION: Permanent

16.19.34.5 EFFECTIVE DATE: XXXXXXXXXXXXX.

**16.19.34.6 OBJECTIVE:** To establish rules regarding criminal background checks and fingerprinting as authorized by law.

#### **16.19.34.7 DEFINITIONS:**

A. "Criminal history record," is information concerning a person's arrests, indictments, or other formal criminal charges and any dispositions arising there from, including convictions, dismissals, acquittals, sentencing and correctional supervision, collected by criminal justice agencies and stored in the computerized databases of the federal bureau of investigation, the national law enforcement telecommunications systems, the department of public safety or the repositories of criminal history information in other states.

B. "Criminal background check" is a nationwide criminal background investigation of an applicant for registration or licensure by the New Mexico Board of Pharmacy through the use of fingerprints reviewed by the department of public safety and submitted to the federal bureau of investigation, resulting in the generation of a criminal history record for that applicant.

# 16.19.34.8 PROCESS:

A. All applicants for initial licensure as a facility licensed pursuant to NMSA 1978 61-11-14, a pharmacist by examination, pharmacist by reciprocity, pharmacy intern or pharmacy technician by the New Mexico Board of Pharmacy are subject to fingerprinting to allow for a criminal background check, at their expense. All applicants must submit two (2) full sets of fingerprint cards, completed fingerprint certificate form; signed authorization for criminal background check and fees at the time of application. Drug wholesalers and manufacturers are exempt from 16.19.34. Nursing facilities, custodial care facilities, and public health clinics licensed by the New Mexico Department of Health are exempt from 16.19.34.

- B. Electronic live scans may be used for conducting a criminal background check, but must be printed on provided fingerprint cards.
- C. Criminal history record information received from and revealed through the criminal background check shall be privileged and shall not be disclosed to persons not directly involved in the decision affecting the applicant.
- D. If the criminal background check reveals that an applicant was arrested, investigated for, charged with, convicted of, sentenced, entered a plea of nolo contendere, or entered into any other legal agreements for any criminal offense in any state, territory or possession of the United States, or by the federal government, the applicant may be notified in order to submit copies of legal documents and other related information.
- E. Applications containing fraudulent or misrepresented information could be the basis for denial or revocation of registration.
- F. The applicant has the right to inspect and/or challenge the validity of the criminal background check, at their own expense.
- G. The board shall issue a registration or license when the applicant has met all requirements of the board of pharmacy.
- H. Exemptions from this section.
- 1. Nursing facilities, custodial care facilities, and public health clinics licensed by the New Mexico Department of Health.
- 2. Wholesalers and manufacturers licensed pursuant to NMAC 16.19.8
- 3. Persons or facilities providing documentation to the board of a recent criminal background check through a United States

or state government agency within the last three months of the initial application.

The Additions of FEE SECTIONS

16.19.12.12.I. Criminal Background Check \$75.00

The Chairman asked for a 10-minute break.

#### **RECESS:**

# **RECONVENE:**

The board reconvened at 10:45

#### 16.19.6.15 Dispensed Pharmaceuticals: Collection and Disposal:

The Chairman re-opened the hearing for 16.19.6.15 NMAC from Monday October 19, 2009 and took a roll call. Present were Mr. Mazzoni, Ms. Saavedra, Mr. Anderson, Ms. Buesing, Mr. Nunley, and Mr. Shaver. Mr. Carrier and Mr. Ortega were absent.

The Chairman stated that the notice be listed as exhibit #1 and

Mr. Harvey presented the language with the suggestions presented by the board from Monday. The board agreed that the language as presented clarified issues from the previous language.

#### **Motion:**

A motion was made by Mr. Shaver, seconded by Mr. Nunley to approve the languages as presented for 16.19.6.15 NMAC. The board voted unanimously to pass the motion.

# 16.19.6.15 DISPOSITION OF DANGEROUS DRUGS OR CONTROLLED SUBSTANCES:

<u>For pharmacy closure</u>: Permission shall be obtained, in writing, from the Board, <u>after inspection</u>, before any inventory of dangerous drugs or controlled substances may be sold, transferred, disposed of, or otherwise removed from the current premises. All sales shall be subject to the laws of the State.

DISPENSED PHARMACEUTICALS: VOLUNTARY COLLECTION AND DISPOSAL; Nothing in this section shall be interpreted to require a pharmacy to participate in this program as described herein.

- A. A pharmacy may choose to accept for destruction previously dispensed legend dangerous drugs and OTC medications that are unwanted or expired. The pharmacy must submit a protocol, or subsequent changes, to the Board, or the Board's agent, for approval. Once approved the pharmacy is authorized to collect pharmaceuticals for destruction. This section does not authorize a pharmacy to accept dangerous drugs for credit or return unless specific authority is given in another regulation.
- B. A protocol is to be submitted to the Board of Pharmacy for staff approval. Such protocol must also include:
  - (1) secure and enclosed collection unit, that does not allow for unauthorized access.
  - (2) A description of the dedicated area for collection unit inside the pharmacy, within sight of the pharmacy staff.
  - (3) method of collection that allows for safe and secure disposition.
  - (4) name of contracted disposal company that is licensed for pharmaceutical destruction.
  - (5) frequency of collection and destruction by disposal company.
  - (6) Records of collection and destruction supplied by the disposal company.
- C. <u>Items accepted at a take back site may include:</u>
  - (1) dangerous drugs (prescription drugs),
  - (2) controlled substances if authorized under Federal law or rule,
  - (3) over-the-counter medications,
  - (4) veterinary medications,
  - (5) medicated ointments and lotions, and
  - (6) <u>liquid medication in glass or leak-proof containers</u>
- D. <u>Items not accepted at a take back site may include</u>
  - (1) Needles,
  - (2) Thermometers,
  - (3) bloody or infectious waste,
  - (4) personal care products,
  - (5) controlled substances (unless authorized by Federal law),
  - (6) hydrogen peroxide,
  - (7) empty containers, and
  - (8) business waste.
- E. Collected medications shall not be re-dispensed.

- F. Directions for take back for patients and list of accepted and not-accepted products must be posted on the collection unit.
- G. <u>Suspension of the pharmacy's authority to collect and dispose of dispensed pharmaceuticals shall occur upon violation of the approved protocol.</u> The pharmacy may petition the Board for removal of that suspension.

#### **Executive Director's Report Cont'd:**

**Patient Bill of Rights:** Mr. Harvey stated that Angelina the current intern was tasked to modify a "model" bill of rights presented at the August board meeting. Feedback given by the board will be included and addressed once again.

**Emergency Authorizations Granted: Hospitals and Clinics:** Mr. Harvey discussed the issues regarding retail dispensing of medication from hospitals and clinics pharmacies without a retail license. Mr. Harvey posted information regarding this issue on the website and forwarded information to the department of health to access the link provided on the board of pharmacy website.

# **Legal Action\*:**

#### **Motion:**

A motion was made by Mr. Nunley, seconded by Ms. Buesing to go into closed session to discuss legal action\* regarding the chiropractic board discussion from August 2009 board request. A roll call vote was taken and Mr. Shaver, Mr. Nunley, Ms. Buesing, Mr. Anderson, Ms. Saavedra and Mr. Mazzoni voted unanimously to pass the motion.

The board went back into open session and the only issue discussed was the legal action\* regarding the chiropractic board at 12:08 p.m.

# **Case Presentation:**

#### Motion:

A motion was made by Mr. Nunley, seconded by Mr. Mazzoni to go into closed session to discuss case presentations. A roll cal vote was taken. Mr. Mazzoni, Ms. Saavedra, Mr. Anderson, Ms. Buesing, Mr. Nunley, Mr. Shaver and Mr. Cross voted unanimously to pass this motion.

The board went back into open session and the only issue discussed was case presentations.

# **Motion:**

A motion was made by Ms. Buesing, seconded by Mr. Shaver as follows; to close case #2009-021, #2009-076, #2009-105, #2009-007, 2009-096: issue and advisory letter to case #2009-108; table case #2009-104, #2009-053; issue pre-settlement agreements to case #2009-072, #2009-09; issue NCA's to case #2009-111, 2009-063. The board voted unanimously to pass the motion.

The board meeting was adjourned at 1:15 p.m.