New Mexico Regulation and Licensing Department
BOARDS AND COMMISSIONS DIVISION
Board of Pharmacy
5200 Oakland Avenue, NE ▪ Suite A ▪ Albuquerque, New Mexico 87113
(505) 222-9830 ▪ Fax (505) 222-9845 ▪ (800) 565-9102
www.rld.state.nm.us/boards/pharmacy.aspx

October 17th and 18th, 2013 Meeting Minutes

Board Meetings are open to the public pursuant to the "Open Meetings Act" and notices to the public are posted in the Albuquerque Journal. Notice published September 24, 2013.

Location: 5200 Oakland Ave. NE, Albuquerque, NM

Scheduled Meeting Time: 9:00 a.m. – 5:00 p.m. Thursday and Friday

Thursday October 17, 2013

1. Procedural Items:

9:00 a.m. Call to Order: The meeting of the Pharmacy Board was called to order by Chairman Cross at 9:01 a.m. on October 17, 2013.

Roll Call: Chairman, Danny Cross called roll and a quorum was established with the following members present: (**P** = Present **A** = Absent)

P Danny Cross, Chairman	**A** Amy Buesing, Vice Chairman	**P** LuGina Mendez Harper, Secretary
P Richard Mazzoni	**P** Joe Anderson	**A** Buffie Saavedra
P Chris Woodul	**P** Anise Yarbrough	**A** Allen Carrier

Approval of the Agenda: Motion to approve the agenda as presented by Mr. Mazzoni, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Approval of August 2013 Minutes: Motion to approve the August 26th – 27th, 2013 minutes as presented by Mr. Mazzoni, seconded by Mr. Woodul, board voted unanimously to pass the motion.

2. New Licensee Applications:

a) Application List:

Ms. Mendez-Harper presented the application list to the board.

Motion: **35 Clinic/Home Health** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul to approve applications, board voted unanimously to pass motion.

Motion: **1 Animal Control** application is in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough to approve the application, board voted unanimously to pass the motion.

Motion: **3 Emergency Medical Service** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: **2 Researcher** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Motion: **1 Limited Drug Researcher** application is in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: **24 Custodial/Nursing Home** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough to approve applications, board voted unanimously to pass motion.

Motion: **3 Pharmacy/Hospital** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Yarbrough to approve applications, board voted unanimously to pass motion.

Motion: **1 Contact Lens** application is in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: **23 Non-Resident Pharmacy** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Yarbrough to approve applications, board voted unanimously to pass motion.

Motion: **28 Wholesale/Broker** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Yarbrough to approve applications, board voted unanimously to pass motion.

NEW MEXICO BOARD OF PHARMACY
REGULAR MEETING
APPLICATION LIST
October 17 & 18, 2013

CLINIC /HOME HEALTH	*CONSULTANTPHARMACIST*
1.ABQ Health Partners Journal Center Hand Clinic *5150 Journal Center Blvd NE* *Albuquerque, NM 87109*	*Relocation* *Martin Martinez, R.Ph.*
2.ABQ Health Partners Journal Center Internal Medicine *5150 Journal Center Blvd NE* *Albuquerque, NM 87109*	*Relocation* *Martin Martinez, R.Ph.*
3.ABQ Health Partners Journal Center Pediatrics Clinic *5150 Journal Center Blvd NE* *Albuquerque, NM 87109*	*Relocation* *Martin Martinez, R.Ph.*
4.Alt Recovery Group *1141 Mall Drive Suite E* *Las Cruces, NM 88001*	*New* *Michael Crawford, R.Ph.*
5.GMRMC *Center for Women's Health* *2559 Medical Drive Suite D* *Alamogordo, NM 88310-8704*	*New* *Marjorie Burns, R.Ph.*
6.GMRMC *Alamogordo Cardiology* *2559 Medical Drive Suite F* *Alamogordo, NM 88310-8704*	*New* *Marjorie Burns, R.Ph.*
7.GMRMC *Gastroenterology of Alamogordo* *2539 Medical Drive Suite 107* *Alamogordo, NM 88310-8704*	*New* *Marjorie Burns, R.Ph.*
8.GMRMC *Family Practice of Alamogordo* *1909 Cuba Avenue Suite 4* *Alamogordo, NM 88310-5646*	*New* *Marjorie Burns, R.Ph.*

9.GMRMC — *New*
Internal Medicine Associates of Alamogordo — *Marjorie Burns, R.Ph.*
1101 9th Street Suite A
Alamogordo, NM 88310-8411

10.GMRMC — *New*
Pediatrics of Alamogordo — *Marjorie Burns, R.Ph.*
2559 Medical Drive Suite A
Alamogordo, NM 88310-8704

11.GMRMC — *New*
General & Vascular Surgery — *Marjorie Burns, R.Ph.*
1212 9th Street Suite A
Alamogordo, NM 88310-5842

12.GMRMC — *New*
General Surgery — *Marjorie Burns, R.Ph.*
1212 9th Street Suite C
Alamogordo, NM 88310-8704

13.GMRMC — *New*
Women's Specialty Services — *Marjorie Burns, R.Ph.*
2050 North Scenic Drive
Alamogordo, NM 88310-3880

14.GMRMC — *New*
Champion Orthopedics — *Marjorie Burns, R.Ph.*
2539 Medical Drive Suite 110
Alamogordo, NM 88310-8720

15.GMRMC — *New*
Surgical Associates of Alamogordo — *Marjorie Burns, R.Ph.*
1100 10th Street
Alamogordo, NM 88310-6414

16.GMRMC — *New*
Journey to Wellness — *Marjorie Burns, R.Ph.*
1401 10th Street Suite 1
Alamogordo, NM 88310-5012

17.GMRMC — *New*
Champion Medical Group — *Marjorie Burns, R.Ph.*
923 9th Street Suite A
Alamogordo, NM 88310-6431

18.GMRMC — *New*
Endocrinology & Diabetes Care — *Marjorie Burns, R.Ph.*
2539 Medical Drive Suite B
Alamogordo, NM 88310-9740

19.GMRMC — *New*
Internal Medicine Group — *Marjorie Burns, R.Ph.*
2579 North Scenic Drive Suite A
Alamogordo, NM 88310-9740

20.Grant Middle School –Eagle School Based Health Center — *New*
1111 Easterday Drive NE — *Wesley Langner, R.Ph.*
Albuquerque, NM 87112

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21.Hidalgo Medical Services — *New*
1318 E 32nd Street — *Bill Weast, R.Ph.*
Silver City, NM 88061

22.La Clinica del Pueblo Teen Wellness Center — *New*
Escalante Mid-High School — *Charlie Vandiver, R.Ph.*
State Road #531
Tierra Amarilla, NM 87575

23.La Clinica del Pueblo Mobile Clinic — *New*
Hwy 84 Cr0324 #14 — *Charlie Vandiver, R.Ph.*
Tierra Amarilla, NM 87575

24.La Frontera New Mexico — *Change of Ownership*
206 Sudderth — *Kristi Espinosa, R.Ph.*
Ruidoso, NM 88345

25.La Frontera New Mexico — *Change of Ownership*
1900 E 10th — *Hal Sims, R.Ph.*
Alamogordo, NM 88310

26.La Frontera New Mexico — *New*
315 S Hudson Street — *Dana Pellegrino, R.Ph.*
Silver City, NM 88061

27.Miner's Colfax Medical Center — *New*
166 Hospital Drive — *Cindy Johnson, R.Ph.*
Raton, NM 87740

28.Presbyterian Healthcare Services Urgent Care Alameda — *New*
1648 Alameda Blvd NW — *Rich Gutierrez, R.Ph.*
Albuquerque, NM 87144

29.Turquoise Health & Wellness — *Change of Ownership*
110 E Mescalero Road — *Daniel Baker, R.Ph.*
Roswell, NM 88201

30.Turquoise Health & Wellness — *Change of Ownership*
914 N Canal — *Clover Wagner, R.Ph.*
Carlsbad, NM 88220

31.US Renal Care Inc — *Change of Ownership*
Junction of Highway 371 & Route 9 — *Arthur Macias, R.Ph.*
Crownpoint, NM 87313

32.US Renal Care Inc — *Change of Ownership*
725 Hospital Drive — *Arthur Macias, R.Ph.*
Gallup, NM 87301

33.US Renal Care Inc — *Change of Ownership*
5th Street & C Avenue — *Arthur Macias, R.Ph.*
Zuni, NM 87327

34.US Renal Care Inc — *Change of Ownership*
1910 Redrock Drive Suite B — *Arthur Macias, R.Ph.*
Gallup, NM 87301

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35.Wilson Middle School — *New*
Wildcat School Based Health Center — *Wesley Langner, R.Ph.*
1138 Cardenas Drive SE
Albuquerque, NM 87109

ANIMAL CONTROL — *CONSULTANT PHARMACIST*
Lovelace Respiration Research Institute — *Remodel*
2425 Ridgecrest Drive SE — *Billy Weast, R.Ph.*
Albuquerque, NM 87115

EMERGENCY MEDICAL SERVICE — *CONSULTANT PHARMACIST*
1.Air Methods/Deming Native Air 30 — *New*
2916 Corte de Loretta — *Raymond Rede, R.Ph.*
Deming, NM 88030

2.Health Safety & Emergency Response — *New*
2813 Don Quixote — *Charles Vandiver, R.Ph.*
Santa Fe, NM 87505

3.TriState Careflight 23 — *New*
111 East 21st Street — *Charles Vandiver, R.Ph.*
Roswell, NM 88201

RESEARCHER
1.ASAP — *Relocation*
2600 Yale Blvd SE
Albuquerque, NM 87106

2.Lovelace Respiration Research Institute — *New*
Bldg 9217 Area Y
Albuquerque, NM 87115

LIMITED DRUG RESEARCHER
Lovelace Respiration Research Institute — *New*
Bldg 9217, Area Y
Albuquerque, NM 87115

CUSTODIAL/NURSING HOME — *CONSULTANT PHARMACIST*
1.Agave Health/Pathways Program — *New*
2551 Coors NW — *Phil Griego, R.Ph.*
Albuquerque, NM 87120

2.Bloom Health Facilities — *Change of Ownership*
DBA Bloomfield Nursing & Rehab — *Terrance Clark, R.Ph.*
803 Hacienda Lane
Bloomfield, NM 87413

3.Clayton Health Facilities — *Change of Ownership*
DBA Clayton Nursing & Rehab Center — *Terrance Clark, R.Ph.*
419 Harding Street
Clayton, NM 88415

4.Espanola Health Facilities — *Change of Ownership*
DBA Espanola Valley Nursing & Rehab — *Terrance Clark, R.Ph.*
720 E Hacienda Street
Espanola, NM 87532

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5.Gallup Health Facilities *DBA Red Rocks Care Center* *3720 Church Rock Street* *Gallup, NM 87301*	*Change of Ownership* *Terrance Clark, R.Ph.*
6.High Desert Family Services Inc *913 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
7.High Desert Family Services Inc *908 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
8.High Desert Family Services Inc *905 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
9.High Desert Family Services Inc *902 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
10.High Desert Family Services Inc *1602 Grand* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
11.High Desert Family Services Inc *901 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
12.High Desert Family Services Inc *108 S 14th Street* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
13.High Desert Family Services Inc *914 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
14.High Desert Family Services Inc *910 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
15.High Desert Family Services Inc *907 Bullock Court* *Artesia, NM 88210*	*New* *Theresa Lewis, R.Ph.*
16.Hobbs Health Facilities *DBA Country Cottage Care & Rehab Center* *2101N Bensing Road* *Hobbs, NM 88240*	*Change of Ownership* *Terrance Clark, R.Ph.*
17.Legacy Healthcare Inc *9388 Valley View Suite 300* *Albuquerque, NM 87114*	*New* *Bill Harvey, R.Ph.*
18.Lordsburg Health Facilities *Sunshine Haven at Lordsburg* *603 Hadeco Drive* *Lordsburg, NM 88045*	*New* *Terrance Clark, R.Ph.*

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19.Open Skies Health Care — *New*
534 Muscatel NE — *Perry Storey, R.Ph.*
Albuquerque, NM 87107

20.Opti Health Inc — *New*
10800 Menual NE — *Annabel Roberts, R.Ph.*
Albuquerque, NM 87112

21.Raton Health Facilities — *Change of Ownership*
DBA Raton Nursing & Rehab Center — *Terrance Clark, R.Ph.*
1660 Hospital Drive
Raton, NM 87740

22.Santa Fe Health Facilities — *Change of Ownership*
DBA Casa Real — *Terrance Clark, R.Ph.*
1650 Galisteo Street
Santa Fe, NM 87505

23.Santa Fe Health Facilities — *Change of Ownership*
DBA Santa Fe Care — *Terrance Clark, R.Ph.*
635 Harkle Road
Santa Fe, NM 87505

24.Silver City Health Facilities — *Change of Ownership*
DBA Silver City Care Center — *Terrance Clark, R.Ph.*
3514 N Fowler Avenue
Silver City, NM 88061

PHARMACY /HOSPITAL — *PHARMACIST IN CHARGE*
1.ASAP — *Relocation*
2600 Yale Blvd SE — *Gene Montoya, R.Ph.*
Albuquerque, NM 87106

2.CVS Pharmacy — *New*
2907 Cerrillos Road — *Peter Ryba, R.Ph.*
Santa Fe, NM 87507

3.Sirona Infusion LLC — *Change of Ownership*
2420 Comanche NE #A5 — *Jerry Ritchie, R.Ph.*
Albuquerque, NM 87107

CONTACT LENS
Vision Direct Inc — *New*
411 108th Avenue NE Suite 1400
Bellevue, WA 98004

NON-RESIDENT PHARMACY — *PHARMACIST IN CHARGE*
1.A & A Drug Co — *Change of Ownership*
224 N Park Avenue — *William Arnold, R.Ph.*
Fremont, NE 68025

2.American Specialty Pharmacy — *New*
2436 S I-35 Suite 360 — *Darshak Tanna, R.Ph.*
Denton, TX 76205

3.BioCure LLC — *New*
8700 Commerce Park Drive Suite 241 — *Kathleen Kimball-Doyle, R.Ph.*
Houston, TX 77036

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4.California Drug Compounding LLC *6878 Beck Ave* *N Hollywood, CA 91605*	*New* *Quon Phan, R.Ph.*
5.Care Rx Pharmacy Group LLC *1865 Woolbright Road* *Boynton Beach, FL 33426*	*New* *Myasha Hall, R.Ph.*
6.Conversion Health *720 Aerovista Place Suite D* *San Luis Obispo, CA 93401*	*Change of Ownership* *Kathryn Andrusko-Furphy, R.Ph.*
7.CVS Pharmacy Inc *25 Blackstone Valley Place* *Lincoln, RI 02865*	*New* *Kristin Alves, R.Ph.*
8.Dalton Pharmacy *1640 S Wilson Dam Road Suite A* *Muscle Shoals, AL 36551*	*New* *Charles Williams, R.Ph.*
9.Dixon Farm Supply Inc *101 SW "A" Street* *Stigler, OK 74462*	*New* *Caleb K Gladd, R.Ph.*
10.Elwyn Specialty Care *3070 McCann Farm Drive* *Garnet Valley, PA 19060*	*New* *Stephen Seiden, R.Ph.*
11.Hometech Advanced Therapies Inc *505 Elmwood Ave* *Sharon Hill, PA 19075*	*New* *Avery Huff, R.Ph.*
12.Inverness Apothecary Trinity *24333 Gordon Terry Parkway Suite B* *Trinity, AL 35673*	*New* *Christopher Simpson, R.Ph.*
13.Linden Care LLC *123 Eileen Way* *Syosset, NY 11791*	*Change of Ownership* *Jordan Fogel, R.Ph.*
14.One Point Patient Care LLC *3006 S Priest Drive* *Tempe, AZ 85282*	*New* *Gary Henglefelt, R.Ph.*
15.Pharmaceuticals Specialties Express *150 Cleveland Road Suite B* *Bogart, GA 30622*	*New* *W David White, R.Ph.*
16.ProCare Pharmacy LLC *DBA CarePlus CVS/Pharmacy* *1002 East McDowell Road* *Phoenix, AZ 85006*	*New* *Gregory Russell, R.Ph.*
17.PMSI LLC *4502 Woodland Corp Blvd #105* *Tampa, FL 33614*	*Change of Ownership* *Nancy Hatcher, R.Ph.*

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18.Reeves-Sain Drug Store Inc — *New*
DBA Entrust Rx — *Kristy Humber, R.Ph.*
402 Wilkins Wise Road Suite 38
Columbus, MS 39705

19.Rx E-fill Solutions — *New*
28341 Constellation Road — *Christopher Gong, R.Ph.*
Santa Clarita, CA 91355

20.Sonexus Health Pharmacy Services LLC — *New*
2730 S Edmonds Lane Suite 400 — *Jon Kwiatkoski, R.Ph.*
Lewisville, TX 75067

21.Soothe Compounding Pharmacy — *Change of Ownership*
1824 59th Street W — *Terrance Myers, R.Ph.*
Bradenton, FL 34209

22.Specialty Medical Drug Store — *New*
264 Center Street Suite 1 Box 27 — *Ron Ferguson, R.Ph.*
Maimiville, OH 45147

23.Willow Pharmacy — *New*
1519 Hwy 22-W Madisonville Center #5 — *Jared Schwab, R.Ph,*
Madisonville, LA 70447

WHOLESALER/BROKER

1.Acella Pharmaceuticals LLC — *New*
11675 Great Oaks Way Suite 144
Alpharetta, GA 30022

2.Allegis Pharmaceuticals LLC — *New*
276 Nissan Parkway #F100
Canton, MS 39046

3.Cantrell Drug Company — *New*
7321 Cantrell Road
Little Rock, AR 72207

4.Citron Pharma LLC — *New*
2 Tower Center Blvd Suite 1101
East Brunswick, NJ 08816

5.Diversified Pharmaceutical Ingredients LLC — *New*
5867 S Garnett Road
Tulsa, OK 74146

6.Dispensary of Hope LLC — *New*
566 Main Stream Drive Suite 150
Nashville, TN 37228

7.DPT Laboratories Ltd — *Change of Ownership*
3300 Research Plaza
San Antonio, TX 78235

8.Exalenz Bioscience Inc — *New*
101 Hudson Street Suite 2100
Jersey City, NJ 07302

9.Grifols USA LLC *New*
8368 US 70 Bus Hwy W
Clayton, NC 27520

10.H & H Wholesale Services Inc *New*
1099 Rochester Road
Troy, MI 48083

11.Kuehne & Nagel Inc *New*
3735 S Workman Mill Rd Bldg D
Whither, CA 90601

12.Kuehne & Nagel Inc *New*
1800 Waters Ridge Drive Suite 100
Lewisville, TX 75057

13.Kuehne & Nagel Inc *New*
324 Half Acre Road
Cranbury, NJ 08512

14.KY Meds Inc *New*
11509 Shelbyville Road Suite D
Louisville, KY 40243

15.Lineage Therapeutics Inc *New*
2 Walnut Grove Drive Suite 190
Horsham, PA 19044

16.MedChem Manufacturing *New*
DBA Enovachem Manufacturing
381 Van Ness Avenue 1508/1507
Torrance, CA 90501

17.Medical Specialties Distributors LLC *New*
3922 Pembroke Road
Pembroke Park, FL 33021

18.Medical Specialties Distributors LLC *New*
800 Technology Center Drive
Stoughton, MA 02072

19.Medical Specialties Distributors LLC *New*
18545 East Gale Avenue
City of Industry, CA 91748

20.Medical Specialties Distributors LLC *New*
1549 Hunter Road
Hanover Park, IL 60133

21.Medical Specialties Distributors LLC *New*
8075C Troon Circle Unit C
Austell, GA 30168

22.Method Pharmaceuticals Inc *New*
2000 E Lamar Blvd Suite 600
Arlington, TX 76006

23.NextSource Biotechnology LLC — *New*
4300 SW 73rd Avenue Suite 108
Miami, FL 33155

24.Orexo US Inc — *New*
220 East 42nd Street Suite 409A
New York, NY 10017

25.Reliance Wholesale Inc — *New*
9325 Cordova Park Road
Cordova, TN 38018

26.Sanofi Pasteur Inc — *New*
1025 Sandhill Road
Reno, NV 89521

27.Triplefin LLC — *Change of Ownership*
6000 Creek Road
Cincinnati, Oh 45248

28.Turning Point Logistics LLC — *New*
4816 Hendron Road
Groveport, OH 43125

b) Pharmacist Clinicians:

Follow-up from August 2013 board meeting: Ms. Teresa Castellano has not completed the assessment course to date and the board will check status at the January 2014 board meeting.

Motion: Address the status of Ms. Teresa Castellano at the next PhC meeting scheduled for 1/2/14 and present the findings at the January 2014 board meeting, motion made by Mr. Anderson, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

Motion: Approve registration as pharmacist clinician without prescriptive authority for Adeniyi Alo, motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: Approve registration as pharmacist clinician with prescriptive authority, no controlled substances for Katherine Chavez, motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: Approve registration as pharmacist clinician with prescriptive authority to include controlled substances for Keith Warshany, motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: Attach to application list to the minutes, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

3. 9:30 a.m. Monitored Treatment Program Report*:

Ms. Kate Woods and Mr. Jon Thayer were present from the Monitored Treatment Program to present the report.

Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson to go into closed session at 9:26 a.m., to discuss the MTP report. Mr. Cross, Mr. Mazzoni, Ms. Yarbrough and Mr. Woodul voted unanimously to pass the motion.

The board went back into open session at 9:47 a.m. and the only issue discussed was the MTP report.

4. Disciplinary Hearings:

10:00 a.m. Notice of Hearing: Case No. 2012-086 – Ronald E. Inkrott
(Bean & Associates will record hearing)

The Chairman opened the hearing at 10:00 a.m. and took roll call. Present were Mr. Woodul, Ms. Yarbrough, Mr. Mazzoni, Mr. Anderson, Ms. Mendez-Harper and the Chairman Danny Cross. Absent were Ms. Buesing, Ms. Saavedra and Mr. Carrier. Present was the Administrative Prosecutor Ms. Gloria Lucero for the state and board counsel, Ms. Mary Smith. Also present were Mr. Larry Loring, Debra Wilhite and Inspector, Bobby Padilla.

Respondent, Ronald E. Inkrott and his attorney Michael T. Garrett were present.

Ms. Gloria Lucero stated that a settlement agreement was discussed between the respondent, his attorney and herself for presentation to the board for consideration. The Chairman asked to see the NCA and stated that the board will go into closed session for discussion of the settlement agreement.

The board heard preliminary statements from Ms. Gloria Lucero, Mr. Michael T. Garrett, Mr. Ronald E. Inkrott and Inspector Bobby Padilla regarding the case and the proposed settlement agreement.

Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson to go into closed session at 10:57 a.m. to discuss the settlement agreement proposed by Mr. Ronald Inkrott. Mr. Cross, Mr. Mazzoni, Ms. Yarbrough and Mr. Woodul voted unanimously to pass the motion.

The board went back into open session at 11:39 a.m. and the only issue discussed was the settlement agreement for Ronald E. Inkrott.

The board offered the revised settlement agreement of which Mr. Inkrott and his attorney Michael Garrett accepted and would return at 1:30 to be signed. The Chairman closed the hearing at 11:52 a.m.

The board took a recess for lunch from 11:58 a.m. to 1:30 p.m.

3:00 p.m. Notice of Hearing: Case No. 2013-002 – Stephen Lujan
(Bean & Associates will record hearing)

The Chairman opened the hearing at 3:12 p.m. and took roll call. Present were Mr. Woodul, Ms. Yarbrough, Mr. Mazzoni, Mr. Anderson, Ms. Mendez-Harper and the Chairman Danny Cross. Absent were Ms. Buesing, Ms. Saavedra and Mr. Carrier. Present was the Administrative Prosecutor Ms. Gloria Lucero for the state and board counsel, Ms. Mary Smith. Also present were Mr. Larry Loring, Debra Wilhite and Inspector, Cheranne McCracken.

Respondent, Stephen Lujan was present.

Ms. Gloria Lucero stipulated and entered into record exhibits 1 through 6. The witnesses, Inspector Cheranne McCracken and Stephen Lujan were duly sworn.

Testimony by all parties was heard and the Chairman closed the hearing at 3:52 p.m.

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to go into closed session at 3:58 p.m. to deliberate the case for Stephen Lujan. Mr. Cross, Mr. Anderson, Ms. Yarbrough and Mr. Woodul voted unanimously to pass the motion.

The board went back into open session at 4:12 p.m. and the only issue discussed was the

deliberation for Stephen Lujan.

Motion: Order that Mr. Lujan pay a fine of $100.00 for unlicensed activity within 60 days and instruct Mr. Lujan in writing the requirements of being licensed as a custodial home with 2 or more residents once the order has been filed with the board, motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

5. Committee Reports and Board Actions:

Sterile Products Committee: Repeal and Replace 16.19.6.11 NMAC: See Appendix A

Motion: Approve language as presented for 16.19.6.11 NMAC for notice at the January 2014 board meeting, motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

6. Recess: The Pharmacy Board meeting was recessed at 4:15 p.m. and will reconvene at 9:00 a.m. tomorrow, Friday October 18, 2013.

Friday October 18, 2013

1. Procedural Items:

9:00 a.m. Reconvene: The meeting of the Pharmacy Board was reconvened by Chairman Cross at approximately 9:00 a.m. on October 18, 2013.

Roll Call: Chairman, Danny Cross called roll and a quorum was established with the following members present: (**P** = Present **A** = Absent)

P Danny Cross, Chairman	**A** Amy Buesing, Vice Chairman	**P** LuGina Mendez Harper, Secretary
P Richard Mazzoni	**P** Joe Anderson	**A** Buffie Saavedra
P Chris Woodul	**P** Anise Yarbrough	**A** Allen Carrier

Ms. Buesing will join the meeting telephonically, later in the day.

2. 9:30 a.m. Rules Hearings:

The Chairman Danny Cross opened the rule hearing at 9:30 and took roll call. Present were Mr. Woodul, Ms. Yarbrough, Mr. Mazzoni, Mr. Anderson, Ms. Mendez-Harper, and Chairman Cross. Also present were Administrative Prosecutor Gloria Lucero, board counsel Mary Smith, Executive Director, Larry Loring and Administrative Secretary, Debra Wilhite.

The Chairman entered the notice of hearing as exhibit #1, proposed language for 16.19.4.15 NMAC as exhibit #2, proposed language for 16.19.5.7 and 8 NMAC as exhibit #3, proposed language for 16.19.20.65 NMAC as exhibit #4, proposed language for 16.19.30.9 NMAC as exhibit # 5, and sign in sheet as exhibit #6. There were not any written comments.

a) **16.19.4 NMAC Pharmacists:** Survey collection as required by law – See Appendix B

Motion: Adopt language as amended in 16.19.4.15 NMAC and delay filing until technology is available to conduct the survey. Motion made by Mr. Mazzoni, seconded by Ms. Yarbrough,
board voted unanimously to pass the motion.

b) **16.19.5 NMAC Internship Training Program:** Changing intern hours to 1500 – See Appendix C

Motion: Adopt the language as amended in 16.19.5 NMAC Sections 7 and 8. Motion made by Mr. Mazzoni, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

c) **16.19.20 NMAC Controlled Substances:** Synthetic cannabinoid additions as scheduled by the DEA – See Appendix D

Motion: Adopt the language as amended in 16.19.20.65 NMAC. Motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

d) **16.19.30 NMAC Compounding of Non-Sterile Pharmaceuticals:** Compounding products for veterinarians; changing the term prescriptions to products – See Appendix E

Motion: Adopt the language as amended in 16.19.30.9 NMAC. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

3. Public/Professional Requests/Waiver Petitions*:

Ron Erkens - Telepharmacy services in the Southwest: Mr. Erkens was present to make his presentation.

Ron Erkens the director of sales for the Southwest region and a pharmacist with Medication Review Inc. which is based out of Spokane WA, discussed how this company provides telepharmacy services for remote order entry, order review, clinical monitoring and pharmacy information for rural hospitals and is expanding into the Southwest. Their mission is to improve patient safety in the rural hospitals that do not have a 24/7 onsite pharmacist presence by providing prospective order review as well as being available to the medical staff for questions on a 24/7 basis.

Mr. Erkens stated that although this service has not yet been approved for the state of New Mexico, he is introducing himself throughout the state.

James Spencer – Wavier for San Miguel clinic: Mr. Spencer was present to make his request.

Motion: Accept extension of waiver for two years of minimum square footage requirements in rule 16.19.6.10(A) NMAC for two years. Motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Jennifer Steen – Rempex Pharmaceuticals – Requesting to be licensed as Wholesaler without being licensed in the primary State of California:

Motion: Deny the request as presented. Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

Executive Director, Larry Loring will contact Ms. Steen after the board meeting to inform her of the boards' decision.

Loreto Grimaldi, Bob DuFour - MedAvail Technologies – Automated pharmacy dispensing system: Mr. Grimaldi and Mr. DuFour were present to make their presentation.

Mr. Grimaldi and Mr. DuFour discussed how MedCenter is an automated pharmacy dispensing system that addresses pharmacy access issues to rural areas and provides after hours dispensing and improves access to a pharmacist by facilitating safe, secure and timely dispensing at the point of care.

Mr. Grimaldi and Mr. DuFour will work with the College of Pharmacy in developing a proposed pilot program that will be presented to the board in late spring 2014.

Ray Nunley - Waiver of live CE request: Mr. Nunley was present to make his request.

Motion: Waive live CE submission for October 2013 until January 2014. Motion made by Mr. Woodul, seconded by Mr. Mazzoni. Board voted unanimously to pass the motion.

Board member, Ms. Buesing joined the meeting telephonically @ 3:20 p.m.

William Harvey – Formulary addition for Legacy Healthcare: Mr. Harvey was present to make his request.

Motion: Approve the addition of Pneumococcal vaccine and Zoster vaccine to the Legacy Healthcare Formulary. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

4. Litigation Update:

a) Ellwood's argument: Appellant's Statement of Appellate Issues:

Counsel for the board, Ms. Mary Smith will file response to Mr. Ellwood's argument on 10/21/13.

b) James Glass: Petition for Expungement of Record status:

Counsel for the board, Ms. Mary Smith will ask for a dismissal and feels it will be granted for dismissal by the District Court Judge.

5. Executive Director's Report*: ***(May be heard at any time during the meeting)***

a) NABP District 6, 7, 8 meeting Sept. 9-11 update:

Mr. Mazzoni, Ms. Yarbrough and Mr. Loring attended the NABP District meeting in Boulder, CO. Topics covered were Prescription Drug Abuse, Medical and Recreational Use of Marijuana and Utilizing Team Based Learning. Mr. Mazzoni was nominated as for the executive committee and Ms. Mendez-Harper was elected as for the resolution committee.

b) NMMSIS update – Brian Sallee:

Mr. Brian Sallee reported that the NMMSIS servers are installed and operational.

c) PMP Report – Carl Flansbaum:

PMP Director, Carl Flansbaum gave a power point presentation detailing the number of registrants to be 3500 in 2013, 15000 currently using the reporting system and 2.4 million Rx's uploaded to the PMP as of September 2013.

d) 16.19.10 Clinics – proposed school clinic language:

The board will address proposed language for a "Class D clinic" drug permit for school health offices where emergency dangerous drugs are maintained for administration to students of the school. The approved drugs will be albuterol for inhalation and epinephrine for injection.

The board will table until after the legislative session.

e) 16.19.26 Prescriptive Authority – proposed naloxone protocol: See Appendix F

Motion: Approve proposed language as presented for notice at the January 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

f) Committee structure discussion – Danny Cross:

Chairman Danny Cross and the board discussed the current list and need for committees. Issues regarding their structure, roles, charges of the committee, and members were addressed. Development of a "Rules Committee" that works specifically towards revising rules that are antiquated and may not meet the needs of current standards was addressed.

g) Financial requirements of the Board – DFA representative (scheduled 1:30 PM):

Fernando Fernandez and Gabriel Sisneros were present to address BOP questions regarding accounting processes from RLD.

- RLD has oversight of personnel and operating costs
- CFO at agency (or RLD) will approve request from our board; requests must be processed within 45 days (require department to submit at least 41 days to allow 4 days to audit and approve); If not submitted on time; referred to as untimely submission, defined as more than 45 days from invoice, these will be pushed back to be processed AFTER timely submissions (there is a memo dated 4/2/12 from State Controller to CFO that outlines timely versus untimely categories and that it will take longer to process untimely requests); DFA is currently at 48 hour turnaround times for invoice processing; Issues at end of fiscal year may require additional approval
- Flow of invoices; requester at agency; reviewer at agency; approver (RLD CFO or agency CFO; DFA audit and approval
- RLD can only access pharmacy funds for BOP functions; pharmacy fund statute; licensing fees; 61-11-19, how pharmacy fund is appropriated to RLD fund; all amounts in pharmacy fund shall only be used in administration of BOP; all unused monies shall remain in pharmacy fund
- Medical board has own CFO; established separation of duties; they have an internal control process established with RLD
- Need to develop SOP's and policies and procedures on internal control process; would need to test and audit these; state requires CFO to oversee agency funds

h) Update on RLD discussion – Danny Cross:

Overview of Issues from BOP

- The BOP is unable to obtain basic office supplies and equipment
- Budget proposals for new vehicles have been removed and we have a fleet of aged and unsafe vehicles (Budget Adjustments Requests (BARS) 1). January 2013 not submitted to DFA, 2). March 2013 changed by ASD and submitted to DFA on May 7, 2013.)
- Requests for travel for budgeted meeting expenses are ignored and interfere with staff from planning and attending necessary training and meetings
- No one should be producing vouchers and purchase orders from the BOP fund without the BOP knowledge and consent. (June 11, 2013)
- Overhead allocation transfer: Documentation is not provided to Board. Consequently the Board does not know who, what, and how the transferred funds are used. Violation of NMSA 61-11-9 E.
- Fiscal year budget requests are incomplete. Control over budget request. The Board does not know what is being submitted. FY15 budget request August 6 and 12, 2013 emails
- Access to the majority of SHARE (accounting system) has been removed. Inhibits our ability to compile, research, and analyze financial data that is essential to managing the Board fund. Violation of NMSA 9-1-7 A. (1)
- No monthly reconciliation reports: Board fund is not reconciled monthly. Violation of NMAC 2.20.5.8(4)

Resolution from RLD:

- RLD agreed that correctly submitted request for supplies should be provided within a few days but recommend they be ordered quarterly only.
- RLD stated that the statewide ban for purchasing vehicles is the reason we have not had any new vehicles and that for law enforcement personnel, such as our inspectors, should be able to get new vehicles now. Mr. Dennis suggested we lease as opposed to purchase.
- Mr. Dennis stated that any request for travel should be processed within a few days and that we should contact them if travel is not being approved in a timely manner.
- RLD explained that the board of pharmacy does not have a CFO and Mr. Dennis is our acting CFO. Any expenditures must be reviewed by 3 individuals not from the same agency. RLD has to spend the BOP's money as part of the administrative attachment.
- Legislative authority regarding the language "Administratively attached" is still unclear. It is obvious that our AG attorney has a different opinion than RLD attorneys.
- Overhead allocation is not based on specific duties and functions invoiced to the BOP but an allocation formula based on the number of licensees. The BOP pays for all services offered regardless of whether we use them including a portion of RLD employee salaries.
- RLD assured us that our BOP financial manager had all the access to SHARE she was allowed to have based on her level.

RLD stated they would begin reconciling our accounts.

i) 16.19.4.11 consultant pharmacist – proposed language:

Table proposed language until after the legislative session.

j) Increasing the Safety of Prescription Drug Use Act – Sen. Udall:

Executive Director, Larry Loring and Ms. Mendez-Harper will provide a response regarding the SB introduced by Senator Udall titled "Increasing the Safety of Prescription Drug Use Act". The Act covers sections such as prescription drug abuse prevention, training and screening programs, FDA review of naloxone, and prescription drug disposal. The emphasis of the bill is to reduce prescription drug misuse and abuse.

k) 16.19.20.65.C(53) – Schedule I addition of pentylone: See Appendix G

Motion: Approve proposed language as presented for notice at the January 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

6. Case Presentations:

Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson to go into closed session at 11:40 a.m., to discuss the case presentations, Mr. Mazzoni, Ms. Yarbrough, Mr. Woodul and Mr. Cross, voted unanimously to pass the motion.

The board went back into open session at 1:20 p.m. and the only issue discussed was the case presentations.

Inspector Mossberg:	2013-048/close	2013-057/VS	
Inspector Loring:	2012-005/close	2012-005A/close	2012-009/close
	2012-013/close	2012-017/close	2012-029/close
	2012-030/close	2012-031/close	2013-065/NCA
Inspector B. Padilla:	2013-059/close		
Inspector A. Padilla:	2013-029/AL	2013-037/close	2013-054/NCA and AL

Motion: **Close case** 2013-048**.** Motion made by Mr. Anderson, seconded by Ms. Yarbrough, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself from the vote.

Motion: **Close cases** 2013-037, 2012-005, 2012-005A, 2012-009, 2012-013, 2012-017, 2012-029, 2012-030, 2012-031 and 2013-059 pending licensure with the board within 30 days, if not licensed bring back to the board for action. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Motion: **Send advisory letters** to 2013-029. Motion made by Ms. Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Motion: **Issue an NCA w/pre-settlement agreement** case 2013-054, letter of reprimand and cost of investigation to be paid by pharmacist, and send advisory letters to both technicians. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: **Issue an NCA to deny** case 2013-065. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

7. Stipulated or Settlement Agreements/Surrenders/Defaults and Orders*:

2013-057 - Joseph Alexander Morrow PT8260 – Voluntary Surrender:

Motion: Accept the voluntary surrender for Joseph Alexander Morrow. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

2013-049 – Joshua Smith – Proposed Stipulation of License:

After a brief discussion regarding the proposed stipulated agreement for Joshua Smith, the board would like the probation period revised from 3 years to 5 years, and for Mr. Smith to report his name change from Blevins to Smith, and correct the numbering on the agreement.

Motion: Resubmit the revised stipulated agreement for Joshua Smith to his attorney for approval, motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

8. Adjournment: With no further business, Mr. Mazzoni made a motion to adjourn the Pharmacy Board meeting at 3:36 p.m., seconded by Mr. Anderson, the board voted unanimously to pass the motion.

Appendix A 16.19.6.11 NMAC

16.19.6.11 Compounded Sterile Preparations:
Moved to E introduction Moved to E.3. Moved to E.3

B. *Rewritten to include all compounded sterile preparations*

A. Purpose:

1. To ensure that the citizens of New Mexico receive properly compounded contaminant-free sterile preparations,
   (a) all healthcare professionals without distinction to site or profession of practice shall comply with the requirements and standards of USP *(United States Pharmacopeia)*;
   (b) compliance with the standards of USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* are applicable to all preadminstration manipulations of preparations intended to be sterile at time of administration or use.
2. To establish regulations for the compounding of sterile preparations in accordance with the USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* for purposes of licensure, operation, and inspection of facilities by the state Board of Pharmacy.

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B. Definitions *New definitions extracted from USP <797>*

1. **'Air Changes per Hour' (ACPH)** means the number of times a volume of air equivalent to the room passes through the room each hour
2. **'Ante-Area'** means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.
3. **'Aseptic technique'** means proper manipulation of preparations to maintain sterility. (*Moved from B(2)f.*
4. **'Beyond-use date (BUD)**' means the date and time, as appropriate, after which a compounded preparation is not to be used and is determined from the date and time the preparation is compounded.
5. **'Biological Safety Cabinet (BSC)'** means a ventilated cabinet that provides ISO Class5 environment for CSPs. Provides personnel, preparation, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for preparation protection, and HEPA- filtered exhausted air for environmental protection.
6. **'Buffer Area'** means an area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the staging of components and supplies used when compounding CSPs.
7. **'Certification'** means independent third party documentation declaring that the specific requirements of USP <797> have been met.
8. **'Cleanroom'** means a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.
9. **'Closed System Vial-Transfer Device'** means a vial-transfer system that allows no venting or exposure of substances to the environment...
10. **'Compounded sterile preparations (CSP)'** include, but are not limited, to the following dosage forms which must be sterile when administered to patients:
    a. Parenteral preparations
    b. aqueous bronchial and nasal inhalations
    c. baths and soaks for live organs and tissues
    d. injections (e.g. colloidal dispersions, emulsions, solutions, suspensions)
    e. irrigations for wounds and body cavities
    f. ophthalmic drops and ointments
    g. and tissue implants.

11. **'Compounding Aseptic Containment Isolator (CACI)'** means an enclosed ISO Class 5 environment workspace for compounding of hazardous sterile preparations. Provides personnel protection with negative pressure and appropriate ventilation. Provides preparation protection by isolation from the environment and high-efficiency particulate air (HEPA)-filtered laminar airflow. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.
12. **'Compounding Aseptic Isolator (CAI)'** means an enclosed ISO Class 5 environment for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).
13. **'Critical Area'** means An ISO Class 5 environment. *Moved from B(2)o*
14. **'Critical Site'** means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.
15. **'Compounded Sterile Preparations (CSP) Pharmacy'** is a retail pharmacy which prepares and distributes prescriptions for compounded sterile preparations intended for parenteral administration to patients either at home or in or out of an institution licensed by the state. *Moved from B (2) a*
16. **'Cytotoxic Drug'** means a pharmaceutical that has the capability of killing living cells. *Moved from B(2) u*
17. **'Direct Compounding Area (DCA)'** means a critical area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
18. **'Disinfectant'** means an agent that frees from infection and destroys disease-causing pathogens or other harmful microorganisms, but may not kill bacterial and fungal spores. It refers to substances applied to inanimate agents, usually a chemical agent, but sometimes a physical one. *Moved from B(2)(g)*
19. **'Hazardous Drugs'** means drugs classified as hazardous if studies in animals or humans indicate exposures to them have a potential for causing cancer, development or reproductive toxicity or harm to organs. (Reference current NIOSH publications.)
20. **'Home care'** means health care provided in the patient's home (not a hospital or skilled nursing facility) by either licensed health professionals or trained caregivers. May include hospice care.
21. **'Immediate Use'** means administration begins not later than 1 hour following the start of the compounding procedure. Intended for those emergency events in which delay in preparation would subject patient to additional risk.
22. **'ISO 5'** means air containing no more than 100 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3520 particles per cubic meter. *Moved from B(2) m*
23. **'ISO 7'** means air containing no more than 10,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (352,000 particles per cubic meter).
24. **'ISO 8'** means air containing no more than 100,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3,520,000 particles per cubic meter). *Moved from B(2)(n)*
25. **'Laminar airflow'** means a nonturbulent, nonmixing streamline flow of air in parallel layers.
26. **'Laminar airflow workbench (LAFW)**' means a ventilated cabinet for compounding of sterile preparations. Provides preparation protection with high-efficiency particulate air (HEPA) filtered laminar airflow, ISO Class 5. Airflow may be horizontal (back to front) or vertical (top to bottom) in direction.
27. **'Media-Fill Test'** means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are media-fill procedures, media selection,

fill volume, incubation, time, and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

28. **'Multiple-Dose Container'** means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. Once opened or entered, a multiple dose container with antimicrobial preservative has a BUD of 28 days unless otherwise specified by the manufacturer.

29. **'Negative Pressure Room'** means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is *into* the room.

30. '**Parenteral product'** means any preparation administered by injection through one or more layers of skin tissue *Moved from B(2)(b)*

30. **'Personal Protective Equipment (PPE)'** means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

31. **'Pharmacy Bulk Packages'** means a container of a sterile preparation for parenteral use that contains many single doses. Contents are intended for use in a pharmacy admixture program and are restricted to use in a suitable ISO Class 5 environment.

34. **'Plan of care'** means an individualized care plan for each patient receiving parenteral products in a home setting to include the following:

A. a description of actual or potential drug therapy problems and their proposed solutions;

b. a description of desired outcomes of drug therapy provided;

c. a proposal for patient education and counseling; and

d. a plan specifying proactive objective and subjective monitoring (e.g. vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and noncompliance) and the frequency with which monitoring is to occur. *Moved from B(2)s*

35. **'Positive Pressure Room'** means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out* of the room. *Moved from B(2)(q)*

36. **'Preparation'** mean**s** a CSP that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products. *Moved from B(2)(d)*

37. **'Primary Engineering Control (PEC)'** means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

38. **'Process validation'**" means documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes *Moved from B(2)(p)*

39. **'Product'** means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

40. **'Quality assurance'** means a program for the systematic monitoring and evaluation of the various aspects of a service or facility to ensure that standards of quality are being met. *Moved from B(2)(l)*

41. **'Quality control'** means a system for verifying and maintaining a desired level of quality in a product or process, as by planning, continued inspection, and corrective action as required. *Moved from B(2)(k)*

42. **'Secondary Engineering Control'** means the ante area and buffer area or cleanroom in which primary engineering controls are placed

43. **'Segregated Compounding Area'** means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

44. **'Single-dose container'** means a single-dose, or a single-unit, container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

45. **'Standard Operating Procedure'** "SOP" means a written protocol detailing the required standards for performance of tasks and operations within a facility. *Moved from B(2)(j)*

46. **'Sterile'** free from bacteria or other living microorganisms.

*Moved from B(2)(c***)**

47. **'Sterilizing Grade Membranes'** means membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally at 0.22 μm or 0.2 μm porosity, depending on the manufacturer's practice.

48. **'Sterilization by Filtration'** means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

49. **'Terminal Sterilization'** means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a nonsterile unit.

50. **'Unidirectional Flow'** means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

51. **'USP'** means 'United States Pharmacopeia'

52. **'USP/NF standards'** means USP/NF General Chapters <797> "Pharmaceutical Compounding- Sterile Preparations". *Moved from B(2)(t)*

Moved to B.46. *Moved to B.36*
Deleted in entirety- inaccurate and outdated
(*Moved to B.3*
. Moved to B.18
Deleted in entirety-not needed *Deleted in entirety not needed* *Deleted- replaced with CAI & CACI*
Moved to B.34
Moved to B.52

C. Pharmacist-in-Charge

In order to obtain a license, all pharmacies compounding sterile preparations must designate a pharmacist in charge of operations who is licensed to practice pharmacy in the state of New Mexico and is responsible for:

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

2. responsible for providing a pharmacist who is available for twenty-four hour seven-day-a-week services; (*allows for non –staff pharmacist to provide service)*

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

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

D. Facilities

Floor space defined in D.1.c A standard of USP <797> included by reference in D.1.a

1. *Moved to D.1.c*The room or area in which Compounded Sterile Preparations (CSP) are prepared
   (a) must be physically designed and environmentally controlled to meet standards of compliance as required by USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*;
   (b) must be periodically monitored, evaluated, tested, and certified by environmental sampling testing as required by USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* with documentation retained for 3 years;
   (c) must have a minimum of 100 square feet dedicated to compounding sterile preparations *moved from C(1)(c)(iii)*
   (i) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet with 100 square feet exclusive to compounding sterile preparations.; *Moved from B(4)(a)(ii)*
   (d) (ii) the stand alone parenteral product pharmacy must have a minimum of 240 square feet with 100 square feet exclusive to compounding sterile preparations. *Moved from B(4)(a)(ii)* must be clean, lighted, and at an average of 80-150 foot candles. *Moved from C(1)(c)(iii)*

2. addition of a compounding sterile preparations area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure.
3. a new Compounded Sterile Preparations pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.

E. **Equipment**

: *Deleted and merged with information below*

Each facility compounding sterile preparations shall have sufficient equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparations of compounded sterile preparations drugs and parenteral products appropriate to the scope of pharmaceutical services provided and as specified in USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*. *Moved from A introduction*

; *Limited list of needed equipment; limited use of equipment, not inclusive of all equipment that might be applicable. Default to requirements specified in USP <797>*

1. All equipment shall be cleaned, maintained, monitored, calibrated, tested, and certified as appropriate to insure proper function and operation with documentation retained for 3 years...
2. Primary engineering controls used to provide an aseptic environment shall be tested in the course of normal operation by an independent qualified contractor and certified as meeting the requirements presented in USP <797> at least every 6 months and when relocated, certification records will be maintained for 3 years. *Moved from C(1)(a)*

Moved to D.3.(c)

3. A library of current references (hard copy or electronic) shall be available including:

(a) *USP/NF* or *USP on Compounding: A Guide for the Compounding Practitioner*;
(b) New Mexico pharmacy laws, rules and regulations; *Moved from A(2)*
(c) Specialty references (stability and incompatibility references, sterilization and preservation references, pediatric dosing, and drug monograph references) as appropriate for the scope of services provided. *Moved from A(1) and from B(4)(c)(i)-(iv) and C(1)(h)*

4. Automated compounding devices shall:
a. have accuracy verified on a routine basis at least every thirty days per manufacturer's specifications;
b. be observed every thirty days by the operator during the mixing process to ensure the device is working properly;
c. have data entry verified by a pharmacist prior to compounding; and
d. have accuracy of delivery of the end product verified according to written policies and procedures. M*oved from C(4)(c)*

F. **Documentation requirements**

Written policies and procedures (SOPs) consistent with USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* standards as well as those required below, must be available for inspection and review by authorized agents of the board of pharmacy. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These records must include but are not limited to:

1. cleaning, disinfection, evaluation, validation, testing, certification, and maintenance of the sterile compounding area;

Included in E.2

*Final product testing and validation is included in standards of USP <797>*2. personnel qualifications, training, assessment and performance validation;
3. operation, maintenance, validation, testing, and certification of facility and equipment;
4. SOP's for compounding, storing, handling, and dispensing of all components used and all compounded sterile preparations;
5. SOP's for disposal of physical, chemical, and infectious waste;
6. quality control guidelines and standards;
7. quality assurance guidelines and standards;
8. SOP's for determination of stability, incompatibilities, or drug interactions.

G. **Record keeping and patient profile**:

The Compounded Sterile Preparations pharmacy is required to maintain complete records of each patient's medications which include but are not limited to the following:

1. prescription records including the original Rx, refill authorization, alterations in the original Rx, and interruptions in therapy due to hospitalization;
2. patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patients;
3. patients receiving parenteral products in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;
4. documentation that the patient receiving parenteral products in a home setting or their agent has received a written copy of their plan of care and training in the safe administration of their medication.

Equivalent to D.1(a)

Equivalent to E.Introduction Moved to E.2 Prefilters are part of equipment operation and maintenance. Included in E. Refers to buffer area, not applicable to all compounding operations, Room requirements inferred in D.1, default to standards listed in USP as appropriate to practice setting. Equivalent to D.1 and E.1. Not applicable to all practice settings- depends on risk level. Default to standards listed in USP. Moved to D.1.(d) Moved to D.1(c) Included in D.1.(c). Enforceable by reference to USP Included in D.1, part of environmental control. Enforceable by reference to USP Included in D.1- part of environmental control, enforceable by reference to USP Included in D.1 part of environmental control, enforceable by reference to USP. Included in D.1 Part of controlled environment, enforceable by reference to USP. Included in F.4 - Part of controlled environment, enforceable by reference to USP Included in F.4- Part of controlled environment, enforceable by reference to USP Included in F.4- Part of controlled environment, enforceable by reference to USP All of (f) Included in F.4. enforceable by reference to USP <797> Included in E.1. enforceable by reference to USP Included in E.1. enforceable by reference to USP Included in E.1. enforceable by reference to USP Included in F.4 enforceable by reference to USP Moved to E.3

H. **Requirements for training**.

All personnel, including pharmacists, pharmacists who supervise compounding personnel, pharmacists interns and pharmacy technicians , shall have completed didactic and experiential training with competency evaluation through demonstration and testing (written or practical) as required by USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*and as outlined by the pharmacist-in-charge and described in the site policy and procedures or training manual, prior to compounding sterile preparations.

1. Instructional topics shall include:
:

(a) aseptic technique;
(b) critical area contamination factors;
(c) environmental monitoring;
(d) facilities;
(e) equipment and supplies;
(f) sterile pharmaceutical calculations and terminology;
(g) sterile pharmaceutical compounding documentation;
(h) quality assurance procedures;
(i) proper gowning and gloving technique;
(j) the handling of cytotoxic and hazardous drugs; and
(k) general conduct in the controlled area.

2. Training shall be obtained through the:

(a) completion of a site-specific, structured on-the-job didactic and experiential training program (not transferable to another practice site; or
(b) completion of a board approved course; or
(c) certification by University of New Mexico College of Pharmacy.

3. Experiential training shall include those areas of training as outlined in USP <797> with appropriate observational assessment and testing of performance as outlined in USP <797> including glove fingertip and –media fill tests.

moved to H. Introduction Moved to H.1 Moved to H.3
(i)-(iii) moved to H.2
moved to H. Introduction Moved to H.1Moved to H.3
(i)-(iii) moved to H.2

4. All personnel, including pharmacists compounding sterile chemotherap**y** drugs, pharmacists supervising compounding personnel, pharmacy interns compounding sterile chemotherapy, and pharmacy technicians compounding sterile chemotherapy drugs,

shall have completed a board approved course in chemotherapy drug preparation as well as training in compounding sterile preparations as listed in H1 above, prior to compounding sterile chemotherapy preparations.

5. Frequency of training and assessment shall be conducted as required by USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* to assure continuing competency and include:

(a) initial training before compounding sterile preparations,
(b) annual refresher training and assessment in didactic topics,
(c) annual testing of glove fingertip and media fill for low and medium risk compounding,
(d) 6-month testing of glove fingertip and media fill testing for high risk compounding.

6. Documentation of training.

Written documentation of initial and in-service training, the results of written or practical testing, and process validation of compounding personnel shall be retained for 3 years and contain the following information:

(a) name of person receiving the training or completing the testing or process validation;
(b) date(s) of the training, testing, or process validation;
(c) general description of the topics covered in the training or testing or of the process validated;
(d) name of person supervising the training, testing, or process validation;
(e) signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

Included in H.5 Included in H6.

I. Patient or caregiver training for home use of compounded sterile preparations

1. The pharmacist shall maintain documentation that the patient has received training consistent with regulation 16.19.4.17.5 NMAC.
2. The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy.
3. There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:

a. routine performance of prospective drug use review and patient monitoring functions by a pharmacist;
b. patient monitoring plans that include written outcome measures and systems for routine patient assessment;
c. documentation of patient training; and

J. Quality assurance of compounded sterile preparations.

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

(a) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;
((b) if bulk compounding of compounded sterile preparations is performed using non-sterile chemicals, appropriate end product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;
(c) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits; a plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken; a periodic evaluation as stated in the policy and

procedures of the effectiveness of the quality assurance activities shall be completed and documented;

(d) the label of each sterile compounded product shall contain: patient name; if batch filling, lot or control number; solution, ingredient names, amounts; expiration date and time, when applicable; directions for use (only if the patient is the end user; not in a hospital setting), including infusion rates, specific times scheduled when appropriate; name or initials of person preparing the product and, if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check; when appropriate, ancillary instructions such as storage instructions or cautionary systems, including cytotoxic warning labels and containment bags; 8 device instructions when needed.

2. There shall be a mechanism for tracking and retrieving products which have been recalled.

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

(a) all solutions and ingredients and their corresponding amounts, concentrations and volumes;
(b) component manufacturer and lot number;
(c) lot or control number assigned to batch;
(d) date of preparation;
(e) expiration date of batch prepared products;
(f) identity of personnel in preparation and pharmacist responsible for final check;
(g) comparison of actual yield to anticipated yield, when appropriate.

No changes made to section below—dependent upon BoP direction and notice.

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

[16.19.6.11 NMAC - Rp, 16 NMAC 19.6.11, 03-30-02; A, 01-15-2005; A, 01-15-08; A, 05-14-10; A, 01-20-13]

Appendix B 16.19.4 NMAC

16.19.4.15 ISSUANCE OR RENEWAL OF PHARMACIST LICENSE

A. The Board shall not approve the application for a pharmacist license or renewal of a pharmacist license until the applicant provides the data required by the Health Care Work Force Data Collection, Analysis and Policy Act.

B. The Board shall provide the applicant a survey to be completed and submitted with the application for licensure. On line applicants to renew a pharmacist license must complete an electronic version of the survey prior to submitting the renewal application.

C. Data collected on the survey shall include at a minimum:

1. Applicant demographics, including race, ethnicity, primary and other spoken languages,
2. Practice status, including active practices in New Mexico and other locations, practice type, practice setting (hospital, retail, nuclear pharmacy),
3. Education, training, primary and secondary specialties,
4. Average hours worked per week, average number of weeks worked per year,
5. Percentage of practice engaged in direct patient care, teaching, research, and/or administration,
6. Practice plans for the next 5 years, including retiring, moving out of state, changing work hours.

D. The board shall keep confidential and not release personally identifiable data collected under this section for any person licensed or registered by the board.

Data collected will be delivered to the chancellor for health sciences of the university of New Mexico.

Appendix C 16.19.5 NMAC

16.19.5.7 DEFINITIONS: As used in the internship program.

A. **"Approved training area"** means a place for instructing an intern for licensure subject to requirements of the board.

B. **"Approved program"** means a program of training as outlined by the **"standards of practice."**

C. **"Computed time"** means that time credited towards the training period which begins from the date of intern registration and continues under the requirements of the approved program. Computed time shall consist of a maximum of 48 hours per week acquired in the internship program; including those hours acquired in an academic clinical pharmacy program, extern program, radiopharmacy program, or a "demonstration project" approved by the board. Any internship acquired and submitted to the board prior to July 30, 1986, under the November 1980 amended 16.19.5 NMAC INTERNSHIP TRAINING PROGRAM, shall be credited toward the required internship hours, under this regulation.

D. **"Intern"** means a pharmacy student or a graduate from an accredited college of pharmacy and registered in an approved program of supervised training.

E. **"Intern certificate of registration"** means that certificate furnished by the board upon approval of, application for registration of intern, received from the intern applicant.

F. **"Training period"** means 1500 hours [~~if in the Bachelor of Science program, or 2150 hours~~] if in the doctor of pharmacy program of structured internship experience under the instruction of a licensed pharmacist **that is a board approved or college approved** preceptor, said hours to be acquired after the satisfactory completion of [~~30~~] **15** semester hours in a college of pharmacy curriculum, or its equivalent.

G. **"Structured internship experience"** may be obtained through [~~a combination of~~] academic internship hours [~~and employment~~] **for a minimum of 1500 internship hours satisfactorily completed and documented in an academic setting in the doctor of pharmacy program**.

[~~(1) Academic Internship Hours include:~~

~~(a) externship not to exceed 675 hours if in the Bachelor of Science program;~~

~~(b) A maximum of 1500 clerkship hours satisfactorily completed and documented in an academic setting in the Doctor of Pharmacy program may be counted toward the Structured Internship Experience.~~

~~(c) Radiopharmacy not to exceed hours set by Board policy;~~

~~(2) Internship as defined in Subsection A of 16.19.5.8 NMAC of this regulation;~~

~~(3) The sum of any or all of the above Structured Internship Hours shall equal no less than 1500 hours if in the Bachelor of Science program or 2150 hours if in the Doctor of Pharmacy program.~~]

H. **"Preceptor"** means a licensed pharmacist who meets those requirements for the supervision and training of an intern as stipulated in Subsection D of 16.19.5.8 NMAC of this regulation.

I. **"Supervision"** means that the preceptor shall maintain personal contact with the intern and shall be responsible for the required training at all times during the training period.

[08-27-90; 16.19.5.7 NMAC - Rn, 16 NMAC 19.5.7, 03-30-02; A, 12-19-13]

16.19.5.8 SUMMARY OF OBJECTIVES:

A. Internship training, using academic training as a foundation, is to provide a learning experience in real life situations that will result in a complete professional, who is competent to practice pharmacy, and render professional services on his own, without supervision, at the time of licensure. The objectives shall be.

(1) A practically, accurately and safely trained intern.

(2) An ethically trained intern.

(3) A legally trained intern. Standards of practice and internship program constitute the basic implementation of the approved internship program.

B. Instructional materials, affidavits, evaluation forms and reports.

(1) Forms shall be made available by the board.

(a) Application for registration of intern.

(b) Employers affidavit for internship.

(c) Employers affidavit for externship/clinical.

(d) Annual preceptors evaluation of intern.

(e) Annual intern evaluation of preceptor.

(f) Certification as approved preceptor by the board standards of practice.

(2) Reports and project assignments as may be required to accompany forms under the approved program.

(3) This regulation relating to the internship program shall be furnished to the intern. All other laws and regulations or manuals shall be available at a nominal fee or at reimbursement cost to the board.

C. Requirements for approved training: Areas will include retail and hospital pharmacies, radiopharmacies, state and county institutions, federal installations, agencies and clinics, and board approved researchers, drug manufacturers who participate in the approved NPI programs.

(1) General requirements include.

(a) Current license or permit.

(b) No deficiencies relevant to the observance of all federal, state and municipal laws and regulations governing any phase of activity in which the facility is engaged.

(c) Required references: [~~1.~~] One current professional reference book of choice **or internet access to approved resources**.

(2) A preceptor will be in direct supervision of all repackaging, labeling and dispensing of drugs for distribution in field offices by state and county health offices.

D. Requirements for preceptor. Each preceptor shall.

(1) Be certified as a preceptor by the board or be an approved preceptor for intern training in another state, by that state board of pharmacy.

(2) Have been actively engaged in the practice of pharmacy for one year.

(3) Be engaged in full-time practice of pharmacy.

(4) Not have been convicted of violation of any laws or regulations relating to pharmacy, unless this provision is waived by the board on an individual basis.

(5) Submit all required forms, [~~affidavits,~~] and evaluations to the board on or before the due date.

(6) Be aware and responsible for following regulations governing legal and ethical professional conduct as outlined in the standards of practice and train the intern in this area.

(7) Notify the board of any change of address or employment in writing, within ten (10) days. Change of employment shall serve to suspend certification as preceptor in the former place of employment where the individual was training an intern.

(8) Not be permitted to leave the intern alone to assume the responsibility of a pharmacist.

E. Requirements for intern.

(1) Application shall be made to the board on the required application form provided by the board prior to the beginning of internship. An applicant for registration as a pharmacist intern shall have satisfactorily completed not less than [~~30~~] **15** semester hours or the equivalent thereof, in a college of pharmacy curriculum accredited by the ACPE and meet other requirements established by regulations of the board.

(2) The intern shall wear the standard identification tag, approved and issued by the board during any pharmacy area employment. A nominal fee is applicable. The intern will be responsible for imprinting his/her name on the identification tag.

(3) The intern shall make such reports and certifications as required under the approved program.

(4) The intern is responsible for the knowledge and observation of the extent of his legal liability and legal restrictions applicable under the federal, state and municipal laws and regulations.

(5) The intern shall be responsible for ascertaining proper certification for [~~himself~~] **him or herself**, completion of all assignments, submittal of all forms, and reports under the approved program. After all assignments have been completed the preceptor will certify the affidavit and verify the completion of all requirements. Internship will not be evaluated or certified by the board until all forms are turned in to the board office in the form of certified affidavits.

(6) Employment and the internship training period are not to be interpreted as being the same. An intern may work in excess of his computed time. A maximum of 48 hours per week, however, shall be considered computed time for the purpose of completing the internship requirement of 1500 hours.

(7) The intern shall submit, annually, at the time of registration renewal, all completed required forms for the prior year or period of computed time.

(8) Any or all of the training period may be obtained after graduation.

(9) The intern shall notify the board of any change of address, employment or preceptor, in writing, within ten (10) days of such change.

(10) The intern certificate of registration and renewal shall be displayed in the training area where the intern is employed.

(11) The registration shall be renewable under the following conditions:

(a) the intern has received a degree from an ACPE accredited college of pharmacy, but has not completed the required intern hours to take the state board examination; or the intern has not completed the required number of hours and is enrolled as a pharmacy student;

(b) a candidate who has failed the NAPLEX exam and the state board jurisprudence examination may renew intern registration to be valid until the next scheduled examination date; provided the renewal does not exceed the period allowed under 16.19.2 NMAC; or

(c) by prior approval or by direction of the board.

(12) The intern registration must be renewed annually on/or before the last day of September. Annual renewal fee is $25.00.

F. Revocation of suspension of certification or certificate: A certification or certificate may be revoked or suspended upon violation of a statute or regulation; the failure to comply with the approved program or internship; or suspension of an intern from university or college attendance; and after due notice is filed pursuant to the Uniform Licensing Act.

G. Out-of-state training.

(1) New Mexico registered interns wishing to earn intern hours out of state must comply with the regulation relating to internship and the approved program, or the equivalent thereof; certification of the preceptor shall be made to the board by the board of pharmacy in the reciprocal state.

(2) Out of state registered interns or students wishing to earn internship hours in New Mexico must comply with the regulations relating to internship and the approved program of this state and shall register with the board.

(3) Computed time, under equivalent approved programs, submitted to the board by out-of-state applicants for licensure, will be evaluated.

[08-27-90; A, 03-02-99; 16.19.5.8 NMAC - Rn, 16 NMAC 19.5.8, 03-30-02; A, 07-15-02; A, 08-12-13; A, 12-19-13]

Appendix D 16.19.20 NMAC

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) Allylprodine
(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
(28) Ibogaine
(29) 2,.5 dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)
(30) Alpha-methyltryptamine (AMT)
(31) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT)
(32) Synthetic cannabinoids: Unless specifically exempted or unless listed in another schedule, any material, compound, mixture of preparation which contains any quantity of the following synthetic cannabinoids which demonstrates binding activity to the cannabinoid receptor or analogs or homologs with binding activity:

(a) CP 55,244 ((hydroxymethyl)-4-[2-hydroxy-4-(2-methyloctan-2-yl)phenyl] 1,2,3,4,4a,5,6,7,8,8a-decahydronaphthalen-2-ol)
(b) CP 55,940 (5-hydroxy-2-(3-hydroxypropyl) cyclohexyl]-5-(2-methyloctan-2-yl)phenol)
(c) JWH-081 (1-pentyl-3-[1-(4-methoxynaphthoy)]indole)
(d) JWH-122 (1-pentyl-3-(4-methyl-1-naphthoyl)indole)
(e) JWH-133 3-(1,1-dimethylbutyl)-6a,7,10,10a-tetrahydro -6,6,9-trimethyl-6H dibenzo[b,d]pyran
(f) JWH 203 1-pentyl-3-(2-chlorophenylacetyl)indole)
(g) JWH 210 4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone
(h) AM-694 (1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole)
(i) AM-1221 (1-(N-methylpiperdin-2-yl)methyl-2-methyl-3-(1-naphthoyl)-6-nitroindole
(j) AM-2201 (1-(5-fluoropentyl)-3-(1-naphthoyl)indole)
(k) RCS-4 or SR-19 (1-pentyl-3-[(4-methoxy)-benzoyl]indole)
(l) RCS-8 or SR-18 (1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)
(m) JWH-210 (1-pentyl-3-(4-ethylnaphthoyl)indole)
(n) WIN-49,098 (Pravadoline) (4-methoxyphenyl)-[2-methyl-1-(2-morpholin-4-ylethyl)indol-3-yl]methanone
(o) WIN-55,212-2 (2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo-1,4-benzooxazin6- yl)-1-naphthalenylmethanone)

(p) Any of the following synthetic cannabinoids, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation.

(i) Naphthoylindoles: Any compound containing a 3-(1- naphthoyl) indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, JWH-398 and AM-2201.

(ii) Naphthylmethylindoles: Any compound containing a1Hindol- 3-yl-(1-naphthyl) methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-175, JWH-184, and JWH-199.

(iii) Naphthoylpyrroles: Any compound containing a 3-(1- naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-307.

(iv) Naphthylmethylindenes: Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl,
cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent including, but not limited to, JWH-176.

(v) Phenylacetylindoles: Any compound containing a 3- phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent including, but not limited to, JWH-203, JWH-250, JWH-251, and RCS-8.

(vi) Cyclohexylphenols: Any compound containing a 2-(3- hydroxycyclohexyl) phenol structure with substitution at the 5- position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4-morpholinyl) ethyl group, whether or not substituted in the cyclohexyl ring to any extent including, but not limited to, Cannabicyclohexanol (CP 47,497 C8 homologue), CP 47,497 and CP 55,490.

(vii) Benzoylindoles: Any compound containing a 3-(benzoyl) [5] OTS-3833.4 indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, or 2-(4- morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether

or not substituted in the phenyl ring to any extent including, but not limited to, AM-694, Pravadoline (WIN 48,098), RCS-4, and AM-1241.

(q) UR-144 1-(pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone

(r) XLR11 1-(5-fluoro-pentyl)-1H-indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone

(s) AKB48 N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide

(33) Substances determined by the board to have the pharmacological effect of the substance, the risk to the public health by abuse of the substance and the potential of the substance to produce psychic or physiological dependence liability is similar to the substances described in Paragraph (1) or (2) of 30-31-23C NMSA 1978. Substances include but are not limited to:

(a) salvia divinorum

(b) salvinorin A (methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2*H*-benzo[f]isochromene-7-carboxylate)

(34) 4-methyl-ethylcathinone (4-MEC)

(35) 4-ethyl-methcathinone (4-EMC)

(36) 2-ethylamino-1-phenyl-propan-1-one (ethcathinone)

(37) 3',4'-methylenedioxyethcathinone (ethylone)

(38) beta-keto-N-methyl-3,4-benzodioxyolybutanamine (bk-MBDB, butylone)

(39) naphthylpyrovalerone (NRG-1, naphyrone)

(40) N,N-dimethylcathinone (metamfepramone)

(41) alpha-pyrrolidinopropiophenone (alpha-PPP)

(42) alpha-pyrrolidinobutiophenone (α-PBP)

(43) 4'-methoxy-alpha-pyrrolidinopropiophenone (MOPPP)

(44) 4'-methyl-α-pyrrolidinopropiophenone (MPPP)

(45) 3',4'-methylenedioxy-alpha-pyrrolidinopropiophenone (MDPPP)

(46) 3',4'-methylenedioxy-alpha-pyrrolidinobutiophenone (MDPBP)

(47) 4'-methyl-α-pyrrolidinobutiophenone (MPBP)

(48) alpha-pyrrolidinovalerophenone (alpha-PVP)

(49) 5,6-methylenedioxy-2-aminoindane (MDAI)

(50) alpha-methylamino-butyrophenone (buphedrone)

(51) beta-keto-ethylbenzodioxolylbutanamine (eutylone)

(52) beta-keto-ethylbenzodioxolylpentanamine (pentylone)

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) cloxazolam

(d) delorazepam

(e) ethylloflazepate

(f) fludiazepam

(g) flunitrazepam

(h) haloxazolam

(i) ketazolam

(j) loprazolam

(k) lormetazepam

(l) medazepam

(m) nimetazepam

(n) nitrazepam

(o) nordiazepam

(p) oxazolam

(q) pinazepam

(r) tetrazepam

(4) Gamma hydroxybutyric acid and any chemical compound that is metabolically converted to GHB.

(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

(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.

(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 isomers.

(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; A, 05-14-10; A, 11-27-11; A, 06-15-12; A, 08-31-12; A, 12-19-13]

Appendix E 16.19.30 NMAC

16.19.30.9 OPERATIONAL STANDARDS:

A. General requirements.

(1) Non-sterile drug products may be compounded in licensed pharmacies as a result of a practitioner's prescription order based on the practitioner-patient-pharmacist relationship in the course of professional practice.

(2) Preparing limited quantities of prescription drug orders in anticipation based upon a history of receiving valid prescriptions issued within an established practitioner-patient-pharmacist relationship in the course of professional practice.

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

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

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

(ii) facility's lot number;

(iii) beyond-use date;

(iv) quantity or amount in the container.

(3) Commercially available product 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; or

(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 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 veterinarian products.

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

(b) These [~~prescriptions~~] **products** are to be handled and filled the same as the human prescriptions.

(5) 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) When 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 board of pharmacy; and

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

(a) of appropriate design and capacity, and be operated within designated 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 appropriately prior to each use; and

(d) routinely inspected, calibrated when 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 or medication drug 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; and
(5) the beyond-use date after which the compounded preparation should not be used;

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

(i) non-aqueous liquids and solid formulations (where the manufactured drug product is the source of active ingredient) 25% of the time remaining until the manufacturer's product's expiration date or six (6) months, whichever is earlier;

(ii) water-containing formulations (prepared from ingredients in solid form) not later than fourteen (14) days when refrigerated between 2-8 degrees Celsius or 36-46 degrees Fahrenheit;

(iii) all other formulations: intended duration of therapy or 30 days, whichever is earlier;

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

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

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

(2) In the event that USP/NF grade substances are not available, documentation of stability and purity must be established and documented.

(3) A pharmacy may not compound a drug product which has been withdrawn or removed from the market for safety reasons.

F. Compounding process. The safety, quality and performance of compounded prescriptions depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. Each pharmacy shall develop and follow written SOP's based on established compounding procedures as outlined in chapter 795 of the USP/NF concerning pharmacy compounding of non-sterile preparations designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process.

G. Quality control.

(1) The safety, quality, and monitoring is used to insure that the output of compounded drug products for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity or pH of solutions are met. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795 of the USP/NF concerning pharmacy compounding of non-sterile preparations, chapter 1075 of the USP/NF concerning good compounding practices, and chapter 1160 of the USP/NF concerning pharmaceutical calculations in prescription compounding. 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 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.

[16.19.30.9 NMAC - N, 09-15-06; A, 06-29-13; A, 12-19-13]

Appendix F 16.19.26 NMAC Prescriptive Authority – proposed naloxone protocol:

16.19.26.13 NALOXONE FOR OPIOID OVERDOSE

A. PROTOCOL:

(1) Prescriptive authority for naloxone drug therapy shall be exercised solely in accordance with the written protocol for naloxone drug therapy approved by the board.

(2) Any pharmacist exercising prescriptive authority for naloxone drug therapy must maintain a current copy of the written protocol for naloxone drug therapy approved by the board.

B. EDUCATION AND TRAINING:

(1) The pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), in the subject area of naloxone for opioid overdose drug therapy provided by:

a) the new mexico pharmacists association; or

b) a similar health authority or professional body approved by the board.

(2) Training must include study materials and instruction in the following content areas:

(a) mechanisms of action;

(b) contraindications;

(c) identifying indications for the use of naloxone drug therapy;

(d) patient screening criteria;

(e) counseling and training patient and care-giver regarding the safety, efficacy and potential adverse effects of naloxone;

(f) evaluating patient's medical profile for drug interactions;

(g) referring patient for follow-up care with primary healthcare provider;

(h) informed consent;

(i) record management;

(j) management of adverse events;

(3) Continuing education: Any pharmacist exercising prescriptive authority for naloxone drug therapy shall complete a minimum of 0.2 CEU of live ACPE approved naloxone drug therapy related continuing education every two years. Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC.

C. AUTHORIZED DRUG(S):

(1) Prescriptive authority shall be limited to naloxone and shall include any device(s) approved for the administration of naloxone.

(2) Prescriptive authority for naloxone drug therapy shall be limited to naloxone as delineated in the written protocol for naloxone drug therapy approved by the board.

D. RECORDS:

(1) The prescribing pharmacist must generate a written or electronic prescription for any naloxone dispensed.

(2) Informed consent must be documented in accordance with the approved protocol for naloxone drug therapy and a record of such consent maintained in the pharmacy for a period of at least three years.

E. NOTIFICATION:

(1) Upon signed consent of the patient, the pharmacist shall notify the patient's designated physician or primary care provider within fifteen (15) days of naloxone dispensing.

Appendix G 16.19.20.65 C(53) NMAC Schedule I addition of pentylone:

16.19.20.65 SCHEDULE I:

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

(50) alpha-methylamino-butyrophenone (buphedrone)

(51) beta-keto-ethylbenzodioxolylbutanamine (eutylone)

(52) beta-keto-ethylbenzodioxolylpentanamine ~~(pentylone)~~

(53) beta-keto-methylbenzodioxolylpentanamine (pentylone)