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

January 16th and 17th, 2014 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 December 14, 2013.

Location: 5200 Oakland Ave. NE, Albuquerque, NM

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

Thursday January 16, 2014

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 January 16, 2014.

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

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

Approval of October 2013 Minutes: Motion to approve the October 17th – 18th, 2013 minutes as presented by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion

a) Approve amendment to page 13 of November 1999 minutes: The November 1999 minutes were presented by Ms. Debra Wilhite. Motion to approve the November 1999 minutes as presented by Mr. Cross, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion**.**

Mr. Woodul addressed the board with a message from former board member, Mr. Ray Nunley, thanking the board and stating that by approving his waiver for licensure, allowed him to spend this precious time with his daughter before her passing.

2. New Licensee Applications:

a) Application List

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

Motion: **29 Clinic/Home Health** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough to approve applications, board voted unanimously to pass motion. Mr. Cross abstained from voting on #18. Applications #22 and #23 will be tabled until tomorrow when Planned Parenthood presents their waiver request to the board.

Motion: **2 Clinic/Home Health** applications #22 and #23 are in order on 1/17/14. Motion made by Mr. Mazzoni, seconded by Mr. Woodul, Mr. Cross voted yes, Ms. Buesing voted yes, Ms. Mendez-Harper voted yes, Ms. Saavedra voted yes, Ms. Yarbrough voted no, the motion passed.

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

Motion: **2 Emergency Medical Service** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Motion: 4**2 Custodial/Nursing Home** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing to approve applications, board voted unanimously to pass motion.

Motion: **5 Pharmacy/Hospital** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Mazzoni to approve applications, board voted unanimously to pass motion.

Motion: **37 Non-Resident Pharmacy** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Buesing to approve applications, board voted unanimously to pass motion.

Motion: **32 Wholesale/Broker** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Saavedra 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 *Internal Medicine Associates of Alamogordo* *1101 9th Street Suite A* *Alamogordo, NM 88310-8411*	*New* *Marjorie Burns, R.Ph.*
10.GMRMC *Pediatrics of Alamogordo* *2559 Medical Drive Suite A* *Alamogordo, NM 88310-8704*	*New* *Marjorie Burns, R.Ph.*
11.GMRMC *General & Vascular Surgery* *1212 9th Street Suite A* *Alamogordo, NM 88310-5842*	*New* *Marjorie Burns, R.Ph.*
12.GMRMC *General Surgery* *1212 9th Street Suite C* *Alamogordo, NM 88310-8704*	*New* *Marjorie Burns, R.Ph.*
13.GMRMC *Women's Specialty Services* *2050 North Scenic Drive* *Alamogordo, NM 88310-3880*	*New* *Marjorie Burns, R.Ph.*
14.GMRMC *Champion Orthopedics* *2539 Medical Drive Suite 110* *Alamogordo, NM 88310-8720*	*New* *Marjorie Burns, R.Ph.*
15.GMRMC *Surgical Associates of Alamogordo* *1100 10th Street* *Alamogordo, NM 88310-6414*	*New* *Marjorie Burns, R.Ph.*
16.GMRMC *Journey to Wellness* *1401 10th Street Suite 1* *Alamogordo, NM 88310-5012*	*New* *Marjorie Burns, R.Ph.*
17.GMRMC *Champion Medical Group* *923 9th Street Suite A* *Alamogordo, NM 88310-6431*	*New* *Marjorie Burns, R.Ph.*

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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

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

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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

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

LIMIT 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

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3.Clayton Health Facilities *DBA Clayton Nursing & Rehab Center* *419 Harding Street* *Clayton, NM 88415*	*Change of Ownership* *Terrance Clark, R.Ph.*
4.Espanola Health Facilities *DBA Espanola Valley Nursing & Rehab* *720 E Hacienda Street* *Espanola, NM 87532*	*Change of Ownership* *Terrance Clark, R.Ph.*
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.*

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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.

19.Open Skies Health Care
534 Muscatel NE
Albuquerque, NM 87107

New
Perry Storey, R.Ph.

20.Opti Health Inc
10800 Menual NE
Albuquerque, NM 87112

New
Annabel Roberts, R.Ph.

21.Raton Health Facilities
DBA Raton Nursing & Rehab Center
1660 Hospital Drive
Raton, NM 87740

Change of Ownership
Terrance Clark, R.Ph.

22.Santa Fe Health Facilities
DBA Casa Real
1650 Galisteo Street
Santa Fe, NM 87505

Change of Ownership
Terrance Clark, R.Ph.

23.Santa Fe Health Facilities
DBA Santa Fe Care
635 Harkle Road
Santa Fe, NM 87505

Change of Ownership
Terrance Clark, R.Ph.

24.Silver City Health Facilities
DBA Silver City Care Center
3514 N Fowler Avenue
Silver City, NM 88061

Change of Ownership
Terrance Clark, R.Ph.

<u>PHARMACY /HOSPITAL</u>
1.ASAP
2600 Yale Blvd SE
Albuquerque, NM 87106

<u>PHARMACIST IN CHARGE</u>
Relocation
Gene Montoya, R.Ph.

2.CVS Pharmacy
2907 Cerrillos Road
Santa Fe, NM 87507

New
Peter Ryba, R.Ph.

3.Sirona Infusion LLC
2420 Comanche NE #A5
Albuquerque, NM 87107

Change of Ownership
Jerry Ritchie, R.Ph.

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

4.California Drug Compounding LLC — *New*
6878 Beck Ave — *Quon Phan, R.Ph.*
N Hollywood, CA 91605

5.Care Rx Pharmacy Group LLC — *New*
1865 Woolbright Road — *Myasha Hall, R.Ph.*
Boynton Beach, FL 33426

6.Conversion Health — *Change of Ownership*
720 Aerovista Place Suite D — *Kathryn Andrusko-Furphy, R.Ph.*
San Luis Obispo, CA 93401

7.CVS Pharmacy Inc — *New*
25 Blackstone Valley Place — *Kristin Alves, R.Ph.*
Lincoln, RI 02865

8.Dalton Pharmacy — *New*
1640 S Wilson Dam Road Suite A — *Charles Williams, R.Ph.*
Muscle Shoals, AL 36551

9.Dixon Farm Supply Inc — *New*
101 SW "A" Street — *Caleb K Gladd, R.Ph.*
Stigler, OK 74462

10.Elwyn Specialty Care — *New*
3070 McCann Farm Drive — *Stephen Seiden, R.Ph.*
Garnet Valley, PA 19060

11.Hometech Advanced Therapies Inc — *New*
505 Elmwood Ave — *Avery Huff, R.Ph.*
Sharon Hill, PA 19075

12.Inverness Apothecary Trinity — *New*
24333 Gordon Terry Parkway Suite B — *Christopher Simpson, R.Ph.*
Trinity, AL 35673

13.Linden Care LLC — *Change of Ownership*
123 Eileen Way — *Jordan Fogel, R.Ph.*
Syosset, NY 11791

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14.One Point Patient Care LLC — *New*
3006 S Priest Drive — *Gary Henglefelt, R.Ph.*
Tempe, AZ 85282

15.Pharmaceuticals Specialties Express — *New*
150 Cleveland Road Suite B — *W David White, R.Ph.*
Bogart, GA 30622

16.ProCare Pharmacy LLC — *New*
DBA CarePlus CVS/Pharmacy — *Gregory Russell, R.Ph.*
1002 East McDowell Road
Phoenix, AZ 85006

17.PMSI LLC — *Change of Ownership*
4502 Woodland Corp Blvd #105 — *Nancy Hatcher, R.Ph.*
Tampa, FL 33614

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

<u>WHOLESALER/BROKER</u>
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

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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

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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:

Ms. Sarah Trujillo stated that Ms. Teresa Castellano has not completed the assessment course to date. The board will check status at the April 2014 board meeting.

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*:

Mr. Jon Thayer was present from the Monitored Treatment Program to present the report.

Motion made by Mr. Woodul, seconded by Ms. Saavedra to go into closed session at 9:20 a.m., to discuss the MTP report. Mr. Cross, Ms. Saavedra, Mr. Anderson, Mr. Mazzoni, Ms. Buesing, Msd. Mendez-Harper, Ms. Yarbrough and Mr. Woodul voted unanimously to pass the motion.

The board went back into open session at 9:31 a.m. and the only issue discussed was the MTP report.

4. 10:00 a.m. Rules Hearings:

The Chairman Danny Cross opened the rule hearing at 10:00 and took roll call. Present were Ms. Saavedra, Mr. Anderson, Mr. Mazzoni, Ms. Buesing, Ms. Mendez-Harper, Ms. Yarbrough, Mr. Woodul, and Chairman Cross. Also present were board counsel Mary Smith, Executive Director, Larry Loring, Administrative Secretary, Debra Wilhite and Inspector, Kris Mossberg.

The Chairman entered the notice of hearing as exhibit #1, proposed language for 16.19.6.11 NMAC as exhibit #2, proposed language for 16.19.20.65 NMAC as exhibit #3, proposed language for 16.19.26 NMAC as exhibit #4, and sign in sheet as exhibit #5. There were not any written comments.

a) 16.19.6.11 B,C – Repeal Parenteral Pharmaceuticals, Sterile Pharmaceutical Preparation: See Appendix A

Due to the New Rule request for 16.19.36 NMAC being approved after the October 2013 board meeting the new rule could not be noticed for January 2014, therefore the board decided to re-notice 16.19.6.11 NMAC as repealed language from that rule is drafted into the new rule 16.19.36 NMAC and notice both rules for the April board meeting.

Motion: Notice 16.19.6.11 NMAC and New Rule 16.19.36 NMAC for the April 2014 board meeting. Motion made by Ms. Buesing, seconded by Ms. Saavedra, board voted unanimously to pass the motion.

b) 16.19.20.65 – Add substance to schedule I, Hallucinogenic Substances: See Appendix B

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

c) 16.19.26 – Add naloxone overdose protocol to Pharmacist Prescriptive Authority: See Appendix C

Motion: Adopt the language as amended in 16.19.26.13 NMAC. Motion made by Mr. Anderson, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

Mr. Dale Tinker stated that approval from all the boards has been obtained and that training, mostly web-based is scheduled to begin in March 2014.

5. Committee Reports and Board Actions:

Wholesale Committee – Chris Woodul: Mr. Woodul stated this is a great committee and that his committee met in December. Mr. Woodul proposed to keep the committee going and table discussion until further information and directives have been provided from the federal level. See Appendix D

Committee Structure – Danny Cross: Mr. Cross stated that committees will be developed to address the sixty-five waivers that have been approved by the board, by category. To start, a *rules committee, technician committee and* a *clinic committee* will address rules that allow waivers within the rule itself and waivers in general that have been approved. Mr. Cross also stated that he is developing guidelines of which the committees will function under.

Ms. Debra Wilhite, Administrative Secretary for the board will submit categorized copies of all the waivers by rule part number and the number of waivers approved for each of those rules to Mr. Cross, and Mr. Mazzoni.

Mary Smith, counsel for the board offered to help the committees with this task.

6. 2:00 p.m. Verified Pharmacy Program: Referenced under Executive Directors Report.

Ms. Saavedra left the board meeting at 3:12 p.m.

7. Recess for the day: The Pharmacy Board meeting was recessed at 5:07 p.m. and will reconvene at 9:00 a.m. tomorrow, Friday January 17, 2014.

Friday January 17, 2014

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 January 17, 2014.

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

2. 9:30 a.m. PMP Report – Carl Flansbaum, NMBOP- James Davis, DOH presentation:

Mr. Carl Flansbaum, PMP Director for the board, gave a brief update regarding PMP registrants non-reporting, and discussion regarding proposed language to either exclude veterinarians from reporting OR registering as practitioners. Mr. Flansbaum stated that he has sent out letters informing licenses of non-reporting to the PMP and suggested the possibility of disciplinary actions to occur if practitioners are consistently in violation of non-reporting.

The board requested that he proceed with removing veterinarians from required reporting and asked that he present cases to the board on failure to report to the PMP. The board discussed the clarification of the seven day reporting needing to be defined. Prescriptions need to be reported *within 7 days of* ***being filled*** as opposed to prescriptions being *reported every 7 days*.

Mr. James Davis from the DOH gave a brief power-point presentation and discussed that pharmacies are directed to report all controlled substance prescriptions to the Prescription Monitoring Program (PMP) within seven days of filling the prescription. He proposed that the seven day reporting requirement be changed to one day. The rationale behind this proposed change is that the seven day reporting lag may allow patients to fill multiple prescriptions within a week without being "flagged" in the PMP. Directing pharmacies to report filled prescriptions within one business day could potentially prevent individuals from filling multiple prescriptions within a small period of time, and thereby prevent deaths from overdose. A potential limitation of the proposed change is that it may increase the burden on pharmacies.

The board briefly discussed the proposed change and thanked Mr. James Davis for his attendance and presentation. No action was taken by the board at this time.

3. 10:30 a.m. – 12:00 p.m. Public/Professional Requests/Waiver Petitions*:

Colene West – request approval of didactic portion of pharmacy technicians training program: Coleen West was available telephonically for questions and comments, but was not contacted by the board.

The board stated that recommendations for approval of training programs are not done by the board.

Daniel Hall - request for reinstatement of pharmacist license (2013-004): Mr. Hall was present to make his request.

Mr. Hall asked the board to consider once again, reinstating his license that had been voluntarily surrendered February 15, 2013. He also gave a brief synopsis of his ongoing MTP participation; counseling and recovery for drug use which started while an intern in pharmacy school from 2003. Mr.

Hall gave information regarding his current drug therapy one of which includes prescription use of suboxone for opioid addiction. Mr. Hall also stated that he is unable to obtain employment since his termination from Lovelace and arrest in December 2012 which led to his surrender of licensure with the board.

The board stated that they would go into closed session to discuss Mr. Hall's current status.

Motion made by Mr. Mazzoni , seconded by Ms. Mendez-Harper to go into closed session to discuss Mr. Hall's current status, Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni and Mr. Cross, voted unanimously to pass the motion.

The board went back into open session and the only issue discussed was Mr. Daniel Hall's current status.

The board stated that they would like to obtain more information specific to his drug therapy. The board instructed Mr. Hall to meet with the Director, Larry Loring after the board meeting to discuss those details.

Upon further discussion the board tabled Mr. Hall's request to reinstate his license and would be addressed at the April 2014 board meeting.

Robert Rhyne, MD - HERO TRaILS program approval: Mr. Robert Rhyne was present to make his request.

Mr. Robert Rhyne requested to gather de-identified information from the PMP reports on prescribing patterns, types of medications prescribed, and dangerous prescribing behaviors of two different primary care providers who have consented to participate in the project, in order to disseminate best practices guidelines for treating chronic non-cancer pain.

The board approved the use of the PMP reports for this project and upon the signing of the required business agreement by board Director, Larry Loring, the reports will be released.

Mr. Rhyne will come back to the board to discuss the results of these practice systems and how they are used.

Motion: Approve the use of PMP reports for the HERO TRaILS project. Motion made by Mr. Mazzoni, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Renan Castillo, PhD – John Hopkins PMP study: Mr. Renan Castillo was present telephonically to make his request.

The board approved the use of the PMP reports for the PMP study and upon the signing of the required business agreement by board Director, Larry Loring, the reports will be released.

Motion: Approve the use of PMP reports for the John Hopkins PMP study. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Mary Albers – request for reinstatement of CS license (2013-012): Ms. Albers was present to make her request.

Ms. Albers presented documentation regarding the surrender of her DEA and CS licenses, due to an investigation by the DEA. Ms. Albers stated that she agreed to the findings of the investigation which led to the stipulation on her professional license with the NM Medical Board. The NM Medical Board released Ms. Albers stipulation of licensure from that order on December 2, 2013.

Upon discussion the board approved Ms. Albers request for reinstatement of her controlled substance license.

Motion: Approve the reinstatement of Ms. Albers controlled substance license. Motion made by Ms. Saavedra, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Amy Dickson/Connie Hyde – Planned Parenthood space variance request: Ms. Amy Dickson and Ms. Connie Hyde were present to make their request.

Motion: Approve the space variance for two years for the Central and the San Pedro facilities, contingent upon fulfilling and submitting the rule 16.19.32 NMAC waiver requirements within the next two weeks. Motion made by Mr. Mazzoni, seconded by Mr. Woodul, Mr. Cross voted yes, Ms. Buesing voted yes, Ms. Mendez-Harper voted yes, Ms. Saavedra voted yes, Ms. Yarbrough voted no, the motion passed.

Traci Neff/Jennifer Miller – San Juan County Detention Facility (2 facilities): Ms. Traci Neff and Ms. Jennifer Miller were present to make their request.

Motion: Approve the waiver for the DWI Detention/Treatment Project to allow stock and use of tuberculin testing solutions for inmates and staff for a period of two years. Motion made by Ms. Saavedra, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Motion: Approve the waiver for the San Juan County Juvenile Services Complex to allow stock and use of tuberculin testing solutions for inmates and staff, and also allow the stocking and administration of vaccines provided by the VFC program for two years. Motion made by Ms. Saavedra, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Diana Gabaldon – approval of CE: Ms. Gabaldon was present to make her request.

Ms. Gabaldon stated that she is a pharmacist at Presbyterian Hospital and asked the board for approval of the online CE titled "Pediatric Chemotherapy and Biotherapy" medications and administration course of which she has received certification. Upon brief discussion the board approved the 16 hour online CE course.

Motion: Approve the 16 hour online CE for Ms. Diane Gabaldon. Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion.

4. Litigation Update:

a) James Glass - Petition for Expungement of Record status:

Counsel for the board, Ms. Mary Smith stated that the case has been dismissed by the District Court.

b) Stephen Ellwood - Appellant's Statement of Appellate Issues:

Counsel for the board, Ms. Mary Smith stated that this case is pending in District Court for hearing and/or decision without hearing.

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

a) Three more synthetic drugs illegal – DEA 11/13/2013: See Appendix E

Motion: Notice 16.19.20 NMAC for the April 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

b) Request to amend clinic rule to identify DOH clinic:

The *clinic committee* will work on identifying waivers that are specific to Department of Health clinics and amending the language within those rules to address the needs of the DOH clinics. George Gonzales, Christine Vigil, James Brown, Danny Cross, Bill Harvey and Katie Klein will participate as members of that committee.

c) Change dronabinol schedule from II to III: See Appendix E

Motion: Notice 16.19.20 NMAC for the April 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

d) Verified Pharmacy Program (VPP) – NABP:

Mr. Loring informed the board of the NABP launching of the "Verified Pharmacy Program" which was developed in partnership with boards of pharmacy to facilitate the sharing of information and to help provide for consistency among requirements related to non-resident pharmacy licensure. Mr. Loring stated that the Virginia Board of Pharmacy has started to implement new regulations regarding inspection requirements and is accepting VPP inspections as meeting the new requirements if a non-resident pharmacy has not been inspected by the regulatory or licensing agency in which it is located.

Mr. Loring stated he would like the board to consider some of the language in the Virginia Board of Pharmacy rule and bring back to the April 2014 board meeting for discussion.

Motion: Present proposed language for consideration at the April 2014 board meeting **.** Motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

e) Placement of Perampanel into schedule III: See Appendix E

Motion: Notice 16.19.20 NMAC for the April 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

f) Tom Ortega: October 22, 1948 – January 4, 2014:

The board extended their condolences for former board member, Tom Ortega from Milan, NM due to his passing on January 4, 2014. Director, Larry Loring will submit the boards' recognition of outstanding service by Mr. Ortega at the NABP meeting.

g) RLD update & direction for 2014:

Mary Smith, board counsel suggested that Chairman, Danny Cross meet with the new Superintendent, Mr. Mike Upthank to introduce the board.

h) 16.19.36 –New Rule - Compounded Sterile Products: See Appendix F

Due to the new rule request for 16.19.36 NMAC being approved after the October 2013 board meeting the new rule could not be noticed for January 2014, therefore the board decided to re-notice 16.19.6.11 NMAC as repealed language from that rule has been drafted into the new rule 16.19.36 NMAC and notice both rules for the April board meeting.

i) NABP Annual meeting – Phoenix May 17-20, 2014, attendees, delegate:

Mr. Mazzoni as the voting delegate, Mr. Loring, Ms. Mendez-Harper and Ms. Buesing will be attending the NABP annual meeting. Mr. Cross stated that if Ms. Buesing is unable to attend he will then go in her place.

6. Case Presentations:

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

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

Inspector Mossberg:	2013-062/close-DA	2013-066/close	2013-070/close
	2013-076/close	2014-001/close	
Inspector B. Padilla:	2013-013/NCA	2013-039/NCA	2013-059/NCA
	2013-068close	2013-072/close	
Inspector A. Padilla:	2013-011/table	2013-030/NCA	2013-060/close
	2013-067/close	2013-071/close	2013-080/close

Inspector Kesner:	2013-053/table 2013-074/NCA	2013-063/close 2013-079/VS	2013-064/close
Inspector McCracken:	2013-018/NCA 2013-077NCA	2013-061/NCA	2013-073/table

Motion: **Close case:** 2013-070 and 2013-066. Motion made by Ms. Buesing, seconded by Ms. Saavedra, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself from the vote.

Motion: **Close cases:** 2013-060, 2013-062, 2013-063, 2013-064, 2013-067, 2013-068, 2013-071, 2013-072, 2013-076, 2013-080 and 2014-001. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Motion: **Table cases:** 2013-011, 2013-053 and 2013-073. Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA to revoke** case 2013-013, 2013-074. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA settlement agreement** cases 2013-061. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA settlement agreement** cases 2013-077. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA to revoke for 5 years** case 2013-030. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA to revoke and summary suspension** case 2013-039. Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion. Mr. Mazzoni recused himself from the vote.

Motion: **Issue NCA w/pre-NCA to revoke for 10 years and refer to NM Medical Board** case 2013-018. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA to cease and desist and refer to California Board** case 2013-059. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

NCA = Notice of Contemplated Action
VS = Voluntary Surrender
DA = Submitted to District Attorney

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

2013-005 – Valerie Endlich – Withdrawal of NCA:

Motion: Accept the withdrawal of NCA for Valerie Endlich. Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

2013-079 – Michael Means PT7195 – Voluntary Surrender:

Motion: Accept the voluntary surrender for Michael Means. Motion made by Ms. Buesing, seconded by Ms. Saavedra, 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 2:07 p.m., seconded by Ms. Saavedra, the board voted unanimously to pass the motion.

Appendix A

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS:

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

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

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

B. PARENTERAL PHARMACEUTICALS:

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

(2) Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) responsible for establishing a system to assure that the products prepared by the establishment are administered by licensed personnel or properly trained and instructed patients;
(e) responsible for developing an appropriate and individualized plan of care in collaboration with patient or caregiver and other healthcare providers for each patient receiving parenteral products in a home setting.
(4) Physical requirements:
(a) The parenteral products pharmacy must have sufficient floor space to assure that the products are properly prepared and stored to prevent contamination or deterioration prior to administration to the patient and meet the following:
(i) be separated physically from other pharmacy activities and enclosed on all sides except for doors and/or windows for the passage of materials;
(ii) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet; the stand alone parenteral product pharmacy must have a minimum of 240 square feet;
(iii) addition of a parenteral area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure;
(iv) a new parenteral pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.
(b) Equipment and materials. The parenteral products pharmacy has sufficient equipment and physical facilities to safely compound and store such products and includes the following:
(i) either a ISO class 5 clean air work station or a room which meets ISO class 5 conditions;
(ii) refrigeration capacity for proper storage of prepared parenterals at 2C to 8C after preparation and until prescriptions are received by the patient or their agent;
(iii) if bulk reconstitution of antibiotics is performed the facility has a freezer capable of freezing and storing the product at -20C for periods not to exceed the manufacturer's recommendations;
(c) References. Parenteral products pharmacies maintain in their library at least one current edition reference book from each category listed below in addition to other required references:
(i) drug monograph reference, i.e., USP-DI, AHFS: drug information service, martindale's extra pharmacopoeia, or other suitable reference;
(ii) stability and incompatibility reference; i.e., trissell's handbook of parenteral medications, king/cutter IV incompatibilities, or other suitable reference;
(iii) reference on pharmaceutical technology and compounding; i.e., remington's pharmaceutical sciences, block's disinfection sterilization and preservation, or other suitable reference;
(iv) periodicals, i.e., American journal of hospital pharmacy, ASHP's clinical pharmacy, American journal of parenteral and enteral nutrition, or other suitable periodical.
(5) Documentation requirements for parenteral product pharmacies: Written policies and procedures must be available for inspection and review by authorized agents of the board of pharmacy. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These records must include but are not limited to:
(a) cleaning, disinfection, evaluation and maintenance of the preparation area;
(b) regular recertification of the clean air unit or units by independent testing agencies;
(c) surveillance of parenteral solutions for microbiological contamination;
(d) surveillance of parenteral solutions for particulate contamination;
(e) personnel qualifications, training and performance guidelines;
(f) facility and equipment guidelines and standards;
(g) SOP's for dispensing all solutions and medications;
(h) SOP's for disposal of physical, chemical and infectious waste;
(i) quality control guidelines and standards;
(j) quality assurance guidelines and standards;
(k) SOP's for determination of stability, incompatibilities or drug interactions.
(6) Record keeping and patient profile: The parenteral products pharmacy is required to maintain complete records of each patient's medications which include but are not limited to the following:
(a) prescription records including the original Rx, refill authorization, alterations in the original Rx, and interruptions in therapy due to hospitalization;
(b) patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patients;
(c) patients receiving parenteral products in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;
(d) documentation that the patient receiving parenteral products in a home setting or their agent has received a written copy of their plan of care and training in the safe administration of their medication.

C. STERILE PHARMACEUTICAL PREPARATION:

(1) All compounded sterile products for human use shall be prepared in an appropriate aseptic environment which meets USP <797> standards. Devices used to provide an aseptic environment including laminar air flow workbenches, biological safety cabinets, compounding aseptic isolators and compounding aseptic containment isolators will:
(a) 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;
(b) have pre-filters which are inspected periodically and inspection/replacement date documented according to written policy; and
(c) have a positive pressure controlled area that is certified as at least a ISO class 8 which is functionally separate from other areas of the pharmacy and which minimizes the opportunity for particulate and microbial contamination; this area shall:
(i) have a controlled aseptic environment or contain a device which maintains an aseptic environment;
(ii) be clean, lighted, and at an average of 80-150 foot candles;
(iii) be a minimum of 100 sq. ft to support sterile compounding activities;
(iv) be used only for the compounding of sterile pharmaceuticals using appropriate aseptic technique including gowning and gloving;
(v) be designed to avoid outside traffic and airflow;
(vi) be ventilated in a manner which does not interfere with aseptic environment control conditions;
(vii) have non-porous, washable floor coverings, hard cleanable walls and ceilings (which may include acoustical ceiling tiles coated with an acrylic paint) to enable regular disinfection; (contain only compounding medication and supplies and not be used for bulk storage;
(d) store medications and supplies on shelves above the floor;
(e) develop and implement a disposal process for packaging materials, used supplies, containers, syringes, and needles; this process shall be performed to enhance sanitation and avoid accumulation in the controlled area;
(f) prohibit particle generating activities in the controlled area:
(i) removal of medications or supplies from cardboard boxes shall not be done in the controlled area;
(ii) cardboard boxes or other packaging/shipping material which generate an unacceptable amount of particles shall not be permitted; the removal of immediate packaging designed to retain sterility or stability will be allowed;
(g) cytotoxic drugs shall:
(i) be prepared in a vertical flow biological safety cabinet, micro-biological isolation chamber or equivalent containment device;
(ii) be prepared in a cabinet thoroughly cleaned prior to use for preparation of other products; said cleaning will be documented;
(iii) be prepared in a cabinet located in a controlled area as described in 11.C.(1).(c);
(iv) be disposed of according to written policies and procedures maintained at the facility;
(h) maintain a library of specialty references appropriate for the scope of services provided; reference material may be hard copy or computerized.
(2) Requirements for training.
(a) All pharmacists prior to compounding sterile pharmaceuticals, or supervising pharmacy personnel compounding sterile pharmaceuticals, all shall have completed didactic, experiential training and competency evaluation through demonstration and testing (written or practical) as outlined by the pharmacist-in-charge and described in the policy and procedures or training manual. Such training shall be evidenced by completion of a recognized course in a board approved accredited college of pharmacy or course which shall include instruction and hands-on experience in the following areas:
(i) aseptic technique;
(ii) critical area contamination factors;
(iii) environmental monitoring;
(iv) facilities;
(v) equipment and supplies;
(vi) sterile pharmaceutical calculations and terminology;
(vii) sterile pharmaceutical compounding documentation;
(viii) quality assurance procedures;
(ix) proper gowning and gloving technique;
(x) the handling of cytotoxic and hazardous drugs; and
(xi) general conduct in the controlled area.
(b) All pharmacist interns prior to compounding sterile pharmaceuticals shall have completed instruction and experience in the areas listed in Paragraph 2. Such training will be obtained through the:
(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy); or
(ii) completion of a board approved course;
(iii) certification by university of New Mexico college of pharmacy.
(c) All pharmacy technicians who compound sterile pharmaceuticals shall be a certified pharmacy technician, and complete instruction and experience in the areas listed in Paragraph 2. Such training will be obtained through the:
(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy) which provides instruction and experience in the areas listed in Paragraph 2; or

(ii) completion of a board approved course which provides instructions and experience in the areas listed in Paragraph 2.
(d) All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs shall have completed a board approved course in chemotherapy drug preparation. All pharmacy interns and technicians must complete this training prior to preparing sterile chemotherapy drug products.
(e) Documentation of training. A written record of initial and in-service training and the results of written or practical testing and process validation of pharmacy personnel shall be maintained and contain the following information:
(i) name of person receiving the training or completing the testing or process validation;
(ii) date(s) of the training, testing, or process validation;
(iii) general description of the topics covered in the training or testing or of the process validated;
(iv) name of person supervising the training, testing, or process validation;
(v) signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.
(f) No product intended for patient uses shall be compounded by an individual until the process validation test indicates that the individual can competently perform aseptic procedures.
(g) On an annual basis the pharmacist-in-charge shall assure continuing competency of pharmacy personnel through in-service education, training, and process validation to supplement initial training. A written record of such training will be maintained for 3 years.
(3) Patient or caregiver training for home sterile products.
(a) The pharmacist shall maintain documentation that the patient has received training consistent with regulation 16.19.4.17.5 NMAC.
(b) The facility shall provide a 24-hour toll-free telephone number for use by patients of the pharmacy.
(c) There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:
(i) routine performance of prospective drug use review and patient monitoring functions by a pharmacist;
(ii) patient monitoring plans that include written outcome measures and systems for routine patient assessment;
(iii) documentation of patient training; and
(4) Quality assurance/compounding and preparation of sterile pharmaceuticals.
(a) There shall be a documented, ongoing performance improvement control program that monitors personnel performance, equipment, and facilities:
(i) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;
(ii) if bulk compounding of parenteral solutions is performed using non-sterile chemicals, appropriate end-product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;
(iii) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits; a plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken; a periodic evaluation as stated in the policy and procedures of the effectiveness of the quality assurance activities shall be completed and documented;
(iv) the label of each sterile compounded product shall contain: patient name; if batch filling, lot or control number; solution, ingredient names, amounts; expiration date and time, when applicable; directions for use (only if the patient is the end user; not in a hospital setting), including infusion rates, specific times scheduled when appropriate; name or initials of person preparing the product and, if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check; when appropriate, ancillary instructions such as storage instructions or cautionary systems, including cytotoxic warning labels and containment bags; 8 device instructions when needed.
(b) There shall be a mechanism for tracking and retrieving products which have been recalled.
(c) Automated compounding devices shall:
(i) have accuracy verified on a routine basis at least every thirty days per manufacturer's specifications;
(ii) be observed every thirty days by the operator during the mixing process to ensure the device is working properly;
(iii) have data entry verified by a pharmacist prior to compounding; and
(iv) have accuracy of delivery of the end product verified according to written policies and procedures.
(d) If batch preparation of sterile products is being performed, a worksheet (log) must be maintained for each batch. This worksheet shall consist of formula, components, compounding directions or procedures, a sample label and evaluation and testing requirements, if applicable, and shall be used to document the following:
(i) all solutions and ingredients and their corresponding amounts, concentrations and volumes;
(ii) component manufacturer and lot number;
(iii) lot or control number assigned to batch;
(iv) date of preparation;
(v) expiration date of batch prepared products;
(vi) identity of personnel in preparation and pharmacist responsible for final check;

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

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

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

Appendix B

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

Appendix C

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 D

Committee Meeting December 18, 2013

Present by Teleconference:
Gaspar Laca
Mary Staples
AllenCarrier
Peter Ellman
Martha Russell
Larry Loring
Amy Buesing
Devin Boerm

Review of Legislation for wholesale & virtual distributors

Devin introduced Martha who explained "track & trace" legislation.

Martha spoke on the Drug Quality & security act- HR3204 passed by legislation on Nov. 27, 2013.

1. Track chain- This will be done by pedigree through the FDA
   a) The first phase will be from years 1-10. The federal government will be looking at drug trading partners & change of ownership through virtual wholesalers who take ownership but not custody of drugs. This will be a tool for inspectors.
   b) The second phase will start in 10 years with the interoperable exchange of unique prescription numbers. These will be unique product identifiers issued by the FDA for each retailer.
2. Licensing for all wholesalers
   a) There will be seven categories of licensing set be FDA
   b) All states must match all federal licensing standards. State laws on pedigree & tracing are preempted by federal laws.

Further discussion about committee & actions they should take. Decision was made to begin with defining "wholesalers & virtual wholesalers" for NM Regulation & Licensing.

Chris proposed to keep committee going & table discussion until further information has been provided from the federal level.

Appendix E

16.19.20.66 SCHEDULE II:

A. Shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Substance, vegetable origin or chemical synthesis. Unless specifically exempt or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(1) Opium and opiate, and any salts, compound, derivative, or preparation of opium or opiate excluding naloxone, dextrorphan, nalbuphine, naltrexone and apomorphine but including the following:

(a) raw opium
(b) opium extracts
(c) opium fluid extracts
(d) powdered opium
(e) granulated opium
(f) tincture of opium
(g) codeine
(h) ethylmorphine
(i) etorphine hydrochloride
(j) hydrocodone
(k) hydromorphone
(l) metopon
(m) morphine
(n) oxycodone
(o) oxymorphone
(p) thebaine
(q) alfentanil
(r) oripavine

(2) Any salt, compound derivative, or preparation thereof, which is chemically equivalent or identical with any of the substances referred to in 16.19.20.66.A.(1) NMAC, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative or preparation of coca leaves and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include de-cocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

B. OPIATES: Unless specifically excepted or unless in another schedule any of the following opiates, including its' isomers, esters, ethers, salts and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation except dextrose and levopropoxyphene.

(1) Alphaprodine
(2) Anileridine
(3) Bezitramide
(4) Diphenoxylate
(5) Dihydrocodeine
(6) Dextropropoxyphene (bulk) non-dosage form
(7) Fentanyl
(8) Isomethadone
(9) Levomethorphan
(10) Levorphanol
(11) Metazocine
(12) Methadone
(13) Methadone-Intermediate
(14) Monamide-Intermediate
(15) Pethidine
(16) Pethidine-Intermediate A
(17) Pethidine-Intermediate B
(18) Pethidine-Intermediate C
(19) Phenazocine
(20) Piminodine
(21) Racemethorphan
(22) Racemorphan

(23) Sufentanil
(24) Carfentanil
(25) Levo-alphacetylmethadol (LAAM)
(26) Tapentadol

C. STIMULANTS: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system. **(See 16.19.21 NMAC- Drug Precursors)**

(1) Amphetamine, its' salts, optical isomers and salts of its' optical isomers.
(2) Methamphetamine, its' salts, isomers and salts of isomers.
(3) Phenmetrazine and its' salts.
(4) Methylphenidate
(5) Lisdexamfetamine

D. DEPRESSANTS: Unless specifically exempt or unless listed in another schedule any material, compound mixture or preparation which contains any quantity of the substance having a depressant effect on the central nervous system, including its' salts, isomers and salts of isomers is possible within the specific chemical designation.

(1) Amobarbital
(2) Secobarbital
(3) Pentobarbital
(4) Phencyclidine
~~**(5)** Dronabinol (synthetic) - in sesame oil and encapsulated in soft gelatin capsules in a drug product approved by the U.S. food and drug administration~~
~~**(6)**~~**(5)** Glutethimide
~~**(7)**~~**(6)** 1-phenylcyclohexylamine
~~**(8)**~~ **(7)**1-piperidinocyclohexanecarbonitrile

E. HALLUCINOGENIC SUBSTANCES: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its' salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purpose of this paragraph only, the term "isomers" includes the optical position, and geometric isomers): Nabilone

F. MISCELLANEOUS:

(1) Dihydroetorphine
(2) Bulk dextropropoxyphene
(3) Remifentanil

[16.19.20.66 NMAC - Rp 16 NMAC 19.20.28(1), 07-15-02; A, 06-30-05; A, 01-15-08; A, 05-14-10]

16.19.20.67 SCHEDULE III: Shall consist of drugs and other substances, by whatever official name, common or usual name designated listed in this section.

A. STIMULANTS: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system.

(1) Those compounds, mixtures or preparations in dosage unit form containing any stimulant, amphetamine, phenmetrazine or methamphetamine previously exempt, for which the exemption was revoked by FDA Regulation Title 21, Part 308.13, and any other drug of the quantitative composition shown in that regulation for those drugs or which is the same except that it contains a lesser quantity of controlled substances.
(2) Benzphetamine.
(3) Phendimetrazine.
(4) Chlorphentermine.
(5) Clortermine.

B. DEPRESSANTS: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system.

(1) Any compound, mixture or preparation containing:
(a) amobarbital;
(b) secobarbital;
(c) pentobarbital;
(d) butalbital; or any salt thereof and one or more active medicinal ingredients which are not listed in any schedule.
(2) Any suppository dosage form containing:
(a) amobarbital;
(b) secobarbital;
(c) pentobarbital; or any salt of any of these drugs approved by the FDA for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt of a derivative of barbituric acid.
(4) Chlorhexadol
(5) Lysergic Acid
(6) Lysergic Acid Amide
(7) Methyprylon
(8) Sulfondiethylmethane
(9) Sulfonethylmethane
(10) Sulfonmethane
(11) Tiletamine/zolazepam (Telazol)
(12) Ketamine Hydrochloride
(13) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug and Cosmetic Act.
(14) Embutramide
(15) Dronabinol (synthetic) - in sesame oil and encapsulated in soft gelatin capsules in a drug product approved by the U.S. food and drug administration

C. **Nalorphine** (a narcotic drug).
D. **Buprenorphine**.
E. **NARCOTIC DRUGS:** Unless specifically exempt or unless listed in another schedule, any

****

Three more synthetic drugs illegal – DEA 11/13/2013 - Language not yet obtained

****

Placement of Perampanel into schedule III - Language not yet obtained

Appendix F

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 36 COMPOUNDED STERILE PRODUCTS

16.19.36.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.36.1 NMAC - N, 3-15-14]

16.19.36.2 SCOPE: All pharmacies as defined in 61-11-2 (S), (Y) NMSA 1978, and all persons or entities that own or operate, or are employed by a pharmacy for the purpose of providing pharmaceutical compounded sterile products or services. [16.19.36.2 NMAC - N, 3-15-14]

16.19.36.3 STATUTORY AUTHORITY: Section 61-11-6(A)(6) NMSA 1978 authorizes the board of pharmacy to provide for the licensing of all places where dangerous drugs are stored, dispensed, distributed or administered and for the inspection of their facilities and activities. Section 61-11-14(B)(7) NMSA 1978 authorizes the board to enforce the provisions of all laws of the state pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs and their standards of strength and purity [16.19.36.3 NMAC - N, 3-15-14]

16.19.36.4 DURATION: Permanent.
[16.19.36.4 NMAC - N, 3-15-14]

16.19.36.5 EFFECTIVE DATE: March 15, 2014, unless a different date is cited at the end of a Section or Paragraph.
[16.19.36.5 NMAC - N, 3-15-14]

16.19.36.6 OBJECTIVE: The objective of Part 36 of Chapter 19 is to establish standards to ensure that the citizens of New Mexico receive properly compounded contaminant-free sterile preparations.
[16.19.36.6 NMAC - N, 3-15-14]

16.19.36.7 DEFINITIONS:

A. "Air changes per hour" (ACPH) means the number of times a volume of air equivalent to the room passes through the room each hour.

B. **"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.

C. "Aseptic technique" means proper manipulation of preparations to maintain sterility.

D. "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.

E. "Biological safety cabinet" (BSC) means a ventilated cabinet that provides ISO Class5 environment for CSP's, 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.

F. "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 CSP's.

G. "Certification" means independent third party documentation declaring that the specific requirements of USP <797> have been met.

H. "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.

I. "Closed system vial-transfer device" means a vial-transfer system that allows no venting or exposure of substances to the environment.

J. "Compounded sterile preparations" (CSP's) include, but are not limited, to the following dosage forms which must be sterile when administered to patients:

(1) parenteral preparations;

(2) aqueous bronchial and nasal inhalations;
(3) baths and soaks for live organs and tissues;
(4) injections (e.g. colloidal dispersions, emulsions, solutions, suspensions);
(5) irrigations for wounds and body cavities;
(6) ophthalmic drops and ointments; and
(7) tissue implants.

K. **"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 and 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.

L. "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).

M. "Critical area" means An ISO Class 5 environment.

N. "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.

O. "Compounded sterile preparations (CSP's) 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.

P. "Cytotoxic drug" means a pharmaceutical that has the capability of killing living cells.

Q. '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.

R. "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.

S. "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).

T. "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.

U. "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.

V. "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).

W. "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).

X. "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).

Y. "Laminar airflow" means a non-turbulent, non-mixing streamline flow of air in parallel layers.

Z. "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.

AA. "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.

BB. "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.

CC. "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.

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

EE. **"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.

FF. **"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.

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

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

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

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

(4) 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.

HH. **"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.

II. **"Preparation"** means 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.

JJ. **"Primary engineering control"** (PEC) means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSP's. Such devices include, but may not be limited to, laminar airflow workbenches (LAFW's), biological safety cabinets (BSC's), compounding aseptic isolators (CAI's), and compounding aseptic containment isolators (CACI's).

KK. **"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

LL. **"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.

MM. **"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.

NN. **'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.

OO. **"Secondary engineering control"** means the ante area and buffer area or cleanroom in which primary engineering controls are placed

PP. **"Segregated compounding area"** means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSP's 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 CSP's and shall be void of activities and materials that are extraneous to sterile compounding.

QQ. **"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.

RR. **"Standard operating procedure"** (SOP) means a written protocol detailing the required standards for performance of tasks and operations within a facility.

SS. **"Sterile"** means free from bacteria or other living microorganisms.

TT. **'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.

UU. **"Sterilization by filtration"** means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

VV. **"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 non-sterile unit.

WW. **"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.

XX. **"USP"** means 'United States Pharmacopeia.

YY. **"USP/NF standards"** means USP/NF General Chapters: <797> Pharmaceutical Compounding- Sterile Preparations. [16.19.36.7 NMAC - N, 3-15-14]

16.19.36.8 NMAC PHARMACIST IN CHARGE:

A. 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.

B. The pharmacist-in-charge is responsible for:

(1) 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;

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

(4) 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.

[16.19.36.8 NMAC - N, 3-15-14]

16.19.36.9 NMAC FACILITIES:

A. The room or area in which compounded sterile preparations (CSP's) are prepared:

(1) 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)*;

(2) 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 three years;

(3) must have a minimum of 100 square feet dedicated to compounding sterile preparations;

(a) 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.;

(b) the stand alone parenteral product pharmacy must have a minimum of 240 square feet with 100 square feet exclusive to compounding sterile preparations; and

(4) must be clean, lighted, and at an average of 80-150 foot candles.

B. 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.

C. A new compounded sterile preparations pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.

[16.19.36.9 NMAC - N, 3-15-14]

16.19.36.10 NMAC EQUIPMENT: 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)*.

A. All equipment shall be cleaned, maintained, monitored, calibrated, tested, and certified as appropriate to insure proper function and operation with documentation retained for three years.

B. 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 six months and when relocated, certification records will be maintained for three years.

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

(1) *USP/NF* or *USP on Compounding: A Guide for the Compounding Practitioner*;

(2) New Mexico pharmacy laws, rules and regulations;

(3) specialty references (stability and incompatibility references, sterilization and preservation references, pediatric dosing, and drug monograph references) as appropriate for the scope of services provided.

D. Automated compounding devices shall:

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

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

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

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

[16.19.36.10 NMAC - N, 3-15-14]

16.19.36.11 NMAC DOCUMENTATION REQUIRED:

A. 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.

B. 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;

(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.

[16.19.36.11 NMAC - N, 3-15-14]

16.19.36.12 NMAC RECORD KEEPING AND PATIENT PROFILE:

A. The compounded sterile preparations pharmacy is required to maintain complete records.

B. 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.

[16.19.36.12 NMAC - N, 3-15-14]

16.19.36.13 NMAC 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.

A. Instructional topics shall include:

(1) aseptic technique;

(2) critical area contamination factors;

(3) environmental monitoring;

(4) facilities;

(5) equipment and supplies;

(6) sterile pharmaceutical calculations and terminology;

(7) sterile pharmaceutical compounding documentation;

(8) quality assurance procedures;

(9) proper gowning and gloving technique;

(10) the handling of cytotoxic and hazardous drugs; and

(11) general conduct in the controlled area.

B. Training shall be obtained through the:

(1) completion of a site-specific, structured on-the-job didactic and experiential training program (not transferable to another practice site); or

(2) completion of a board approved course; or

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

C. 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.

D. 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.

E. 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:

(1) initial training before compounding sterile preparations,

(2) annual refresher training and assessment in didactic topics,

(3) annual testing of glove fingertip and media fill for low and medium risk compounding,

(4) six-month testing of glove fingertip and media fill testing for high risk compounding.

F. 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 three years and

contain the following information:

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

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

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

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

(5) 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.

G. 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 three years and contain the following information:

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

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

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

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

(5) 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.

[16.19.36.13 NMAC - N, 3-15-14]

16.19.36.14 NMAC PATIENT OR CAREGIVER TRAINING FOR HOME USE OF COMPOUNDED STERILE PREPARATIONS:

A. The pharmacist shall maintain documentation that the patient has received training consistent with Subsection 5 of 16.19.4.17 NMAC.

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

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

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

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

(3) documentation of patient training.

[16.19.36.14NMAC - N, 3-15-14]

16.19.36.15 NMAC QUALITY ASSURANCE OF COMPOUNDED STERILE PREPARATIONS:

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

(1) 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;

(2) 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;

(3) 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;

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

B. There shall be a mechanism for tracking and retrieving products which have been recalled.3. 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:

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

(2) component manufacturer and lot number;

(3) lot or control number assigned to batch;

(4) date of preparation;

(5) expiration date of batch prepared products;

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

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

[16.19.36.15 NMAC - N, 3-15-14]