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

April 24th and 25th, 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 March 15, 2014.

Location: 5200 Oakland Ave. NE, Albuquerque, NM

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

Thursday April 24, 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 April 24, 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 Ms. Saavedra, board voted unanimously to pass the motion.

Approval of January 2014 Minutes: Motion to approve the January 16th – 17th, 2014 minutes as amended. Ms. Mendez-Harper asked that the minutes be amended on page 16 under the rule hearing for 16.19.6.11 that the motion be deleted due to duplicity from page 12. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

2. New Licensee Applications:

a) Application List:

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

Motion: **19 Clinic/Home Health** 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: **4 Limited Drug Researcher** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to approve applications, 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 Mr. Anderson to approve applications, board voted unanimously to pass the motion.

Motion: 29 **Custodial/Nursing Home** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson to approve applications, board voted unanimously to pass motion.

Motion: **8 Pharmacy/Hospital** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Anderson to approve applications, board voted unanimously to pass motion. Mr. Cross recused himself for #3.

Motion: **52 Non-Resident Pharmacy** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Woodul to approve applications, board voted unanimously to pass motion.

Motion: **41 Wholesale/Broker** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Buesing to approve applications, board voted unanimously to pass motion.

NEW MEXICO BOARD OF PHARMACY
REGULAR MEETING
APPLICATION LIST
April 24 & 25, 2014

CLINIC /HOME HEALTH	*CONSULTANTPHARMACIST*
1.Christus St Vincent Plastics *& Reconstruction Services* *490 W Zia Road Suite 200* *Santa Fe, NM 87505*	*New* *Terri Stanford, R.Ph.*
2.Christus St Vincent Urology Associates *465 St Michaels Drive #110* *Santa Fe, NM 87505*	*Relocation* *Terri Stanford, R.Ph.*
3.First Choice Community Healthcare *120 S 9th Street* *Belen, NM 87002*	*Remodel* *Larry Georgopoulos, R.Ph.*
4.Gentiva Health Services *4401 Masthead NE Suite 100* *Albuquerque, NM 87109*	*Relocation* *Ken Wagg, R.Ph.*
5.MRN-MRI Control Room *DBA Mind Research Network* *1101 Yale Blvd NE 1st Floor* *Albuquerque, NM 87106*	*New* *Richard Gomez, R.Ph.*
6.New Mexico Treatment *6079 Apache* *Farmington, NM 87401*	*New* *Rick Mascarenas, R.Ph.*
7.PMS Sandoval County Commons Dental Services *1500 Idalia Road Blgd B* *Bernalillo, NM 87004*	*New* *Wes Langner, R.Ph.*
8.PMS Santa Fe Community Guidance Center *2960 Rodeo Park Drive East* *Santa Fe, NM 87505*	*Remodel* *Katie Klein, R.Ph.*
9.Presbyterian Medical Services Family Health Clinic *2300 Grande Blvd SE* *Rio Rancho, NM 87124-1636*	*New* *Wes Langner, R.Ph.*

10.Recovery Services of Southern New Mexico
1107 South Atkinson
Roswell, NM 88203

New
Judy Romero, R.Ph.

11.Rehab Hospital of New Mexico Pain Clinic
500 Walter NE #309
Albuquerque, NM 87109

Relocation
Joel Yan, R.Ph.

12.RGH Melrose Clinic
121 N Main
Melrose, NM 88124

New
William Harvery, R.Ph.

13.San Juan Regional Medical Center
Correctional Health Service
471 Andrea Drive
Farmington, NM 87401

Change of Ownership
William Lord, R.Ph.

14.Santa Fe Dialysis
DBA Jicarilla Apache Nation Dialysis
450 North Mundo Drive
Dulce, NM 87528

New
Jeff Carsten, R.Ph.

15.Southwest Care Center
901 W Alameda Street
Santa Fe, NM 87501

New
Erik Young, R.Ph.

16.UNM Center for Reproductive Health
2301 Yale Blvd SE Bldg E
Albuquerque, NM 87106

Relocation
Cynthia Lujan, R.Ph.

17.Valle del Sol-Bernalillo
872 S Camino del Pueblo
Bernalillo, NM 87004

New
Shelley Bagwell, R.Ph.

18.Valle del Sol of New Mexico
428 S Los Lentes
Los Lunas, NM 87031

New
Shelley Bagwell, R.Ph.

19.Women's Cancer & Surgical Care PC
4610 Jefferson Lane NE
Albuquerque, NM 87109

New
Dawit Kidane, R.Ph.

LIMITED DRUG RESEARCHER

1.Central New Mexico Correctional Facility
1525 Morris Road SW
Los Lunas, NM 87031

New

2.Lovelace Respiratory Researcher
Dr. Gensheng Wang
Kirtland Airforce Base Area Y
Albuquerque, NM 87115

New

3.Lovelace Respiratory Researcher
Dr. Janet Benson
Kirtland Airforce Base Area Y
Albuquerque, NM 87115

New

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H(1) licensing matters, H(2) limited personnel matters, H(3) administrative hearing deliberations, H(7) pending or threatened litigation.

4.Lovelace Respiratory Researcher — *New*
Dr. Phil Kuehl
Kirtland Airforce Base Area Y
Albuquerque, NM 87115

EMERGENCY MEDICAL SERVICE — *CONSULTANT PHARMACIST*

1.TriState Care Flight LLC — *Relocation*
4901 Aviation Drive — *George Gonzales, R.Ph.*
Santa Fe, NM 87507

2.Vaughn Ambulance Service — *New*
649 Hem Street — *Kathleen West, R.Ph.*
Vaughn, NM 88353

CUSTODIAL/NURSING HOME — *CONSULTANT PHARMACIST*

1.Ability First LLC — *New*
2825 Mesilla Street NE — *Annabel Roberts, R.Ph.*
Albuquerque, NM 87110

2.Advantage Communications — *New*
4708 Sam Bratton — *Ron Lujan, R.Ph.*
Albuquerque, NM 87114

3.Angel Merritt — *New*
6721 Mesa Mariposa Place NW — *Lori Carabajal, R.Ph.*
Albuquerque, NM 87120

4.Bright Horizon — *New*
8009 Lava Reach Avenue NW — *Jeff Campbell, R.Ph.*
Albuquerque, NM 87120

5.Collins Lake Ranch — *New*
246 Encino Road — *Eloy Aragon, R.Ph.*
Cleveland, NM 87715

6.Eight Northern Indian Pueblos Council Inc — *New*
1135 Butterfly Road — *Robert Duran, R.Ph.*
Taos, NM 87571

7.El Castillo — *Change of Ownership*
239 E De Vargas — *Joel Villarreal, R.Ph.*
Santa Fe, NM 87501

8.Enchanted Care Center Inc — *New*
2816 Pueblo Bonito — *Annabel Roberts, R.Ph.*
Santa Fe, NM 87507

9.Genneys Senior Care LLC — *New*
1504 37th SE — *Annabel Roberts, R.Ph.*
Rio Rancho, NM 87124

10.GoodLife Senior Living — *New*
906 Pistachio Trail — *Clover Wagner, R.Ph.*
Artesia, NM 88210

11.Lessons of Life LLC — *New*
4210 Kiva Place #E-6 — *Mahmood Hurab, R.Ph.*
Silver City, NM 88061

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12.Lessons of Life LLC *600 41st Street* *Silver City, NM 88061*	*New* *Mahmood Hurab, R.Ph.*
13.Lessons of Life LLC *2021 Cottage San Road* *Silver City, NM 88061*	*New* *Mahmood Hurab, R.Ph.*
14.Links of Life LLC *4865 Calle Bella* *Las Cruces, NM 88012*	*New* *Robert Adams, R.Ph.*
15.Muros de Salvacion *10405 Theresa Place* *Albuquerque, NM 87111*	*New* *Bill Weast, R.Ph.*
16.Marshall Infirmary *101 W College Blvd* *Roswell, NM 88201*	*New* *Daniel Baker, R.Ph.*
17.Native American Behavioral Health Services *1500 S 2nd Street* *Gallup, NM 87301*	*New* *Adrienne Patel, R.Ph.*
18.New Day Youth and Family Services *2820 Ridgecrest SE* *Albuquerque, NM 87108*	*New* *Perry Storey, R.Ph.*
19.Opti Health Inc *4504 Piedra Blanca* *Albuquerque, NM 87110*	*New* *Annabel Roberts, R.Ph.*
20.Pacifica Senior Living Santa Fe *2961 Galisteo Road* *Santa Fe, NM 87505*	*New* *Joel Villarreal, R.Ph.*
21.Phillip Martinez *10327 Oso Grande Road NE* *Albuquerque, NM 87111-3750*	*New* *Lori Carabajal, R.Ph.*
22.Rehab Suites at Las Estancias LLC *DBA The Rio at Las Estancias* *3620 Las Estancias* *Albuquerque, NM 87105*	*New* *Annabel Roberts, R.Ph.*
23.San Juan Regional Medical Center *Correction Health Services-Juvenile Detention Center* *871 Andrea Drive* *Farmington, NM 87401*	*New* *William Lord, R.Ph.*
24.San Juan Regional Medical Center *Correction Health Services-County Alternative Sentencing* *1006 Municipal Avenue* *Farmington, NM 87401*	*New* *William Lord, R.Ph.*
25.Tobosa Developmental Services *1003 S Wyoming* *Roswell, NM 88203*	*New* *Paul Tunell, R.Ph.*

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26.Tres Hermanas Assisted Living *6104 McKinney* *Albuquerque, NM 87109*	*New* *Clover Wagner, R.Ph.*
27.Tres Hermanas Assisted Living *6104 Mckinney* *Albuquerque, NM 87109*	*New* *Clover Wagner, R.Ph.*
28.Turning Point Detox, LLC *9808 Claremont Avenue NE* *Albuquerque, NM 87112*	*New* *Susan Meoli, R.Ph.*
29.Unlimited Care Inc II *7408 Osuna NE* *Albuquerque, NM 87110*	*New* *Reynolds Saenz, R.Ph.*
PHARMACY /HOSPITAL	*PHARMACIST IN CHARGE*
1.Cancer Center Pharmacy *1201 Camino de Salud NE* *Albuquerque, NM 87106*	*New* *Scott Roach, R.Ph.*
2.CVS Pharmacy Inc *DBA CVS Pharmacy* *715 West Bender Blvd* *Hobbs, NM 88240*	*New* *Leslie Wiedlocher, R.Ph.*
3.Farmers Uptown Pharmacy *2810 N Main* *Roswell, NM 88201*	*New* *Neal Dungan, R.Ph.*
4.Kaseman Presbyterian Hospital Pharmacy *8300 Constitution NE* *Albuquerque, NM 87110*	*Remodel* *Erica Downing, R.Ph.*
5.Mesa Group LLC *DBA Mesa Pharmacy* *30 Cherokee Hills* *Raton, NM 87740*	*New* *Ed Scott, R.Ph.*
6.Michael's Prescription Corner *1024 Main Street* *Eunice, NM 88231*	*New* *Michael Raburn, R.Ph.*
7.Michael's Prescription Corner *2410 N Fowler* *Hobbs, NM 88240*	*New* *Bart Gatewood, R.Ph.*
8.Saaktvik LLC *1323 N Main Street* *Las Cruces, NM 88001*	*New* *Bipinkumar Gajera, R.Ph.*
NON-RESIDENT PHARMACY	*PHARMACIST IN CHARGE*
1.A + K Medical Supply Inc *DBA Access Compounding Pharmacy* *1450 Emmerson Avenue #110* *McLean, VA 22101*	*New* *John Ayele, R.Ph.*

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2.Airport McKay Pharmacy *18648 McKay Drive Suite 110* *Humble, TX 77338*	*New* *Robert Yeau-Ming Hsu, R.Ph.*
3.Alicea Enterprises LLC *DBA Physician Specialty Compounding* *18964 N Dale Mabry Suite 102* *Lutz, FL 33548*	*New* *Ingrid Bendeck, R.Ph.*
4.American Integrative Pharmacy LLC *1852 Lomita Blvd Suite 204* *Lomita, CA 90717*	*New* *Zahra Sarajha, R.Ph.*
5.Arriva Medical LLC *500 Eagles Landing Drive B* *Lakeland, FL 33810*	*Change of Ownership* *Tamara Estrill-Lett, R.Ph.*
6.Assured RX LLC *13555 Automobile Blvd #230* *Clearwater, FL 33762*	*New* *Nitesh Patel, R.Ph.*
7.Aureus Pharmacy *305 Merchant Lane* *Pittsburgh, PA 15205*	*New* *Edward Finn, R.Ph.*
8.Canyon Creek Pharmacy *2235 Thousand Oaks Drive #114A* *San Antonio, TX 78232*	*New* *Rohit Chaudhary, R.Ph.*
9.Cardinal Health 414 LLC *7920 Georgetown Road Suite 100* *Indianapolis, IN 46268*	*New* *Keith Koontz, R.Ph.*
10.Complete Medical Homecare Inc *14309 W 95th Street* *Lenexa, KS 66215*	*New* *Jeff Hinchey, R.Ph.*
11.Coral Springs Specialty Pharmacy *10231 W Sample Road* *Coral Springs, CO 33065*	*New* *Margaret Bradley, R.Ph.*
12.Dennard Drugs *794 Second Street* *Soperton, GA 30457*	*New* *Richard Dennard, R.Ph.*
13.Destrehan Discount Pharmacy *3001 Ormond Blvd Suite A* *Destrehan, LA 70047*	*Change of Ownership* *Bruce Burkenstock, R.Ph.*
14.Distinguished Pharmacy *12134 Beechnut Street* *Houston, TX 77407*	*New* *Ezinne Ozurumba, R.Ph.*
15.Emerald Hills Pharmacy LLC *3000 Stirling Road Suite 120* *Hollywood, FL 33021*	*New* *Neil Chonin, R.Ph.*

16.Enclara Health LLC *1480 Imperial Way* *West Deptford, NJ 08066*	*New* *Walter Valentine, R.Ph.*
17.Entracell Pharmacy *10435 Santa Monica Blvd 1st Floor* *Los Angeles, CA 90025*	*New* *Michelle Kalay, R.Ph.*
18.Express Scripts Pharmacy Inc *DBA Express Scripts* *255 Phillipi Road* *Columbus, OH 43228*	*Change of Ownership* *Joanne Colegrove, R.Ph.*
19.Express Scripts Pharmacy Inc *DBA Express Scripts* *One Millennia Drive* *Willingboro, NJ 08046*	*Change of Ownership* *Lynda Doremus, R.Ph.*
20.Express Scripts Pharmacy Inc *DBA Express Scripts* *4750 E 450 South* *Whitestown, NJ 46075*	*Change of Ownership* *Rhonda Yates, R.Ph.*
21.Express Scripts Pharmacy Inc *DBA Express Scripts* *6225 Annie Oakley Drive* *Las Vegas, NV 89120*	*Change of Ownership* *James Stupnik, R.Ph.*
22.Henry Ford Pharmacy Advantage Southfield *735 John R Road Suite 150* *Troy, MI 48083*	*New* *Douglas Samojedny, R.Ph.*
23.Imperial Point Pharmacy Center Inc *6310 North Federal Highway* *Fort Lauderdale, FL 33308*	*New* *Lawrence Mann, R.Ph.*
24.Independence Holding Company LLC *DBA Complete Care Pharmacy* *14 E Washington Street Suite C* *Champaign, IL 61820*	*New* *Bruce Strike, R.Ph.*
25.Kare Pharmacy Inc *2901 Coral Hills Drive* *Coral Springs, FL 33065*	*New* *Wilhelm Garcia, R.Ph.*
26.KV Supply LLC *3190 N R2* *David City, NE 68632*	*New* *Aaron Stutzman, R.Ph.*
27.LDI Specialty Pharmacy *701 Emerson Road Suite 332* *Creve Coeur, MO 63141*	*New* *Jessica Emrich, R.Ph.*
28.Llewellyn's Pharmacy *703 Main Street* *Avoca, PA 18641*	*New* *Sandra Scavo, R.Ph.*

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29.Liberty for All Pharmacy Inc *8444 W Oakland Park Blvd* *Sunrise, FL 33351*	*New* *Markus Titto, R.Ph.*
30.MWI Veterinary Supply Co *DBA Ivesco* *910 Shaver Street* *Springdale, AR 72762*	*Change of Ownership* *Linda Lou Phillips, R.Ph.*
31.My Pharmacy LLC *2920 Motley Drive Suite 200* *Mesquite, TX 75150*	*New* *Mohammed Yousuf, R.Ph.*
32.National Wellness Supply *643 Merchant Street* *Ambridge, PA 15003*	*New* *Heather Zuzo, R.Ph.*
33.Oak Creek Pharmacy *8607 F Street* *Omaha, NE 68127*	*New* *Amanda Haynie, R.PH.*
34.Pegasus Pharmacy *DBA Legacy Pharmacy* *2050 Springdale Road Unit 500* *Cherry Hill, NJ 08003*	*New* *April Jones, R.Ph.*
35.Pharmacy Creations LLC *540 Route 10West* *Randolph, NJ 07869*	*New* *Scott Karolchyk, R.Ph.*
36.Pharmacy Services Inc *212 Millwell Drive Suite A* *Maryland Heights, MO 63043*	*New* *Mitchell Graumenz, R.Ph.*
37.Pillpack Inc *250 Commercial Street Suite 2012* *Manchester, NH 03101*	*New* *Timothy Parker, R.Ph.*
38.Pinnacle Compounding *1120 W Kensington Avenue Suite E* *Missoula, MT 59801*	*New* *Amy Frost, R.Ph.*
39.PRN RX *5478 S Westridge Drive Suite B* *New Berlin, WI 53151*	*New* *Michelle Kutcher, R.Ph.*
40.Premier Pharmacy Services *2657 Saturn Street* *Brea, CA 92821*	*New* *Myrna Cortez, R.Ph.*
41.Santa Cruz Biotechnology Inc *3600 Dry Creek Road Suite E-3* *Paso Robles, CA 93446*	*New* *Paul Magnuson, R.Ph.*
42.Shiva Shakthi LLC *DBA SS Pharmacy* *2919 Markum Drive* *Haltom City, TX 76117*	*New* *Viroopaksha Velishala, R.Ph.*

43.SmartPractice Allergen Bank *3400 E McDowell Road* *Phoenix, AZ 85008*	*New* *Christine Coopman, R.Ph.*
44.Suncoast Radio Pharmacy Services Inc *3102 Cherry Palm Drive Suite 120* *Tampa, FL 33619*	*New* *Adria Jackson, R.Ph.*
45.Sunflower Discount Pharmacy *840 N Oak Avenue* *Ruleville, MS 38771*	*New* *Angela Lang, R.Ph.*
46.Topical Solutions Pharmacy *20612 N Care Creek Road #150* *Phoenix, AZ 85024*	*New* *Tiara Patten, R.Ph.*
47.Vet Meds N More Inc *DBA National Animal Hospital* *300 Ohukai Road Suite C315* *Kihei, HI96753*	*New* *Jodi Miller, R.Ph.*
48.Walgreen Co #15312 *901 South Rancho Drive Suite 20* *Las Vegas, NV 89406*	*New* *Kanika Toston, R.Ph.*
49.Walgreens Co#11255 *4545 E 9th Avenue* *Denver, CO 80220-3902*	*New* *Joshua Whittington, R.Ph.*
50.White Drug #61 *706 38th Street NW Unit A* *Fargo, ND 85102*	*New* *Tanya Schmidt, R.Ph.*
51.Woodland Hills Pharmacy *23299 Ventura Blvd Suite 200* *Woodland Hills, CA 91364*	*New* *Steven Levin, R.Ph.*
52.Zynex Medical Inc *DBA Pharmazy* *9990 Park Meadows Drive* *Lone Tree, CO 80124*	*New* *William Rosenfelder, R.Ph.*
<u>WHOLESALER/BROKER</u>	
1.Acura Pharmaceuticals Inc *616 N North Court Suite 120* *Palatine, IL 60067*	*New*
2.Amatheon Inc *4300 SW 73rd Avenue Suite 110* *Miami, FL 33155*	*New*
3.Amneal Institutional LLC *118 Beaver Trail* *Glasgow, KY 42141*	*New*
4.API Solutions Inc *7998-E American Way* *Daphne, AL 36526*	*New*

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5.Austarpharma LLC *New*
18 Mayfield Avenue
Edison, NJ 08837

6.Areva Pharmaceuticals Inc *new*
7112 Areva Drive NE
Georgetown, IN 47122

7.Bayer Healthcare Pharmaceuticals Inc *New*
100 Bayer Blvd
Whippany, NJ 07981

8.Crown Laboratories Inc *New*
349 Lafe Cox Drive
Johnson City, TN 37604

9.Crown Pharmaceuticals Inc *New*
1414 Distributors Row
Harahan, LA 70123

10.Cipla USA Inc *New*
9100 S Dadeland Blvd Suite 1500
Miami, FL 33156

11.Diamond Animal Health Inc *New*
2538 S.E. 43rd Street
Des Moines, IA 50327

12.Durata Therapeutics US Limited *New*
200 S Wacker Drive Suite 2550
Chicago, IL 60606

13.ECR Pharmaceuticals Company Inc *New*
3969 Deep Rock Road
Richmond, VA 23233

14.Emerson Ecologics *New*
1750 Ruffin Mill Road
Colonial Heights, VA 23834

15.E. R. Squibb & Sons LLC *New*
5104 Eisenhower Blvd
Tampa, FL 33634

16.Exel Inc *New*
101 Commerce Drive
Mechanicsburg, PA 17050

17.G & W Laboratories Inc *New*
111 Colidge Street
South Plainfield, NJ 07080

18.Gemini Laboratories LLC *New*
1200 US Highway 22 East Suite 2000
Bridgewater, NJ 08807

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19.H2-Pharma LLC *2010 Berry Chase Place* *Montgomery, AL 36117*	*New*
20.Harvard Drug Group LLC *5960 E Shelby Drive* *Memphis, TN 38141*	*New*
21Healix Infusion Therapy Inc *1075 West Park One Drive Suite 200* *Sugar Land, TX 77478*	*New*
22.INO Therapeutics LLC *12874 Florence Avenue* *Santa Fe Springs, CA 90670*	*Change of Ownership*
23.INO Therapeutics LLC *875 Sandy Lake Road Suite 300* *Coppell, TX 75019*	*Change of Ownership*
24.Mastek Pharmacal Co. *575 Prospect Street Unit 213* *Lakewood, NJ 08701*	*New*
25.McKesson Drug Company *1900 South 4490 West* *Salt Lake City, UT 84104*	*New*
26.McKesson Drug Company *9700 SW Commerce Circle* *Wilsonville, OR 97070*	*New*
27.ME Wholesale Distribution LLC *185 Philmont Avenue Suite B* *Feasterville-Trevose, PA 19053*	*New*
28.Medac Pharma Inc *29 N Wacker Drive Suite 704* *Chicago, IL 60606*	*New*
29.Medline Industries Inc *11075 E 40th Avenue* *Denver, CO 80239*	*New*
30.Modern Medical Products *9420 Lurline Avenue Unit A* *Chatsworth, CA 91311*	*New*
31.Nivagen Pharmaceuticals Inc *3100 Fite Circle Suite 208* *Sacramento, CA 95827*	*New*
32.Ozburn-Hessey Logistics LLC *450 Lillard Drive* *Sparks, NV 89434*	*New*

33.Premium Rx National LLC *New*
43720 Trade Center Place Suite 125
Sterling, VA 20166

34.Professional Hospital Supply Inc *New*
42500 Winchester Road
Temecula, CA 92590

35.Reckitt Benckiser LLC *New*
1670 Champagne Avenue
Ontario, CA 91761

36.RGH Enterprises Inc *New*
7000 Cardinal Health Place
Dublin, OH 73017

37.Sanofi-Aventis US LLC *New*
50 Stauffer Industrial Park
Taylor, PA 18317

38.Smith & Nephew Inc *New*
2225 Cedars Road Suite A
Lawrenceville, GA 30043

39.Therakos Inc *New*
10 North High Street Suite 300
West Chester, PA 19380

40.Twin Med LLC *New*
10401 Miller Road Unit
Dallas, TX 75238

41.US Compounding Inc *New*
1270 Dons Lane
Conway, AR 72032

b) Pharmacist Clinicians:

Motion: Approve registration as pharmacist clinician without prescriptive authority for Dawit Kidane, Damian Vigil and John Togami, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: Approve registration as pharmacist clinician with prescriptive authority, no controlled substances for Lynn Robert Moore and Juliette Brewer-Smith, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

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

Motion: New protocol approved for Shannin Dyke, Angela Weimerskirtch and Tischa Becker, motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion.

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

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

Ms. Kate Woods was present from the Monitored Treatment Program to present the report.

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

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

4. 10:00 a.m. Dr. Steven Jenkusky, M.D., Vice-Chair – NM Medical Board Discussion on substance abuse treatment and Suboxone:

Dr. Steven Jenkusky from the NM Medical Board gave a presentation regarding the use of suboxone as a treatment therapy for opioid abuse. Dr. Jenkusky discussed induction, detoxification, maintenance therapy and use of suboxone.

5. 10:30 a.m. Rules Hearings:

The Chairman Danny Cross opened the rule hearing at 10:30 and took roll call. Present were Ms. Saavedra, Mr. Anderson, Mr. Mazzoni, Ms. Buesing, Ms. Mendez-Harper, Ms. Yarbrough, Mr. Woodul, and Chairman Danny Cross. Also present were board counsel Mary Smith, Executive Director, Larry Loring, Administrative Secretary, Debra Wilhite and Inspectors, Kris Mossberg, Cheranne McCracken and Adela Padilla.

The Chairman entered the notice of hearing as exhibit #1, new language for 16.19.36 NMAC, as exhibit #2 proposed language for 16.19.6.11 NMAC as exhibit #3, proposed language for 16.19.20 NMAC as exhibit #4, written comments from UNM/SPOT committee as exhibit #5, written comments from San Juan Oncology Associates as exhibit #6, written comments from SPOT/sub-committee as exhibit #7, NMBOP inspectors' revisions as exhibit #8 and sign in sheet as exhibit #9.

a. 16.19.36 NMAC Compounded Sterile Products – New Rule: See Appendix A

The hearing for 16.19.36 NMAC took approximately five hours throughout the day and numerous comments and lengthy discussions were held by board members, committee members, board inspectors and audience members.

Motion: Adopt the new rule 16.19.36 NMAC as presented. Motion made by Ms. Buesing, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

b. 16.19.6 .11 B, C NMAC Sterile Compounding – Repeal: See Appendix B

Motion: Adopt language as amended in Paragraph B of 16.19.6.11 NMAC. Motion made by Ms. Buesing, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: Adopt language as amended in Paragraph C of 16.19.6.11 NMAC. Motion made by Ms. Buesing, seconded by Mr. Woodul, board voted unanimously to pass the motion.

c. 16.19.20 NMAC Sections 65,66, and 67 -Controlled Substances: See Appendix C

Motion: Adopt the language as amended in Sections 65, 66 and 67 of 16.19.20 NMAC. Motion made by Mr. Woodul, seconded by Mr. Anderson, board voted unanimously to pass the motion.

6. 12:30 Noon – 1:56 p.m. Recess for Lunch

7. Disciplinary Hearing:

1:45 p.m. Notice of Hearing 2013-039 – Armin Quedzuweit
(Bean & Associates will record hearing)

The Chairman opened the hearing at 2:00 p.m. and took roll call. Present were Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Anderson, Ms. Saavedra and Chairman Danny Cross. Mr. Mazzoni recused himself. Absent was Mr. Carrier.

Present was the Administrative Prosecutor Ms. Gloria Lucero for the state and board counsel, Ms. Mary Smith. Also present were Mr. Larry Loring, Debra Wilhite and Inspector, Bobby Padilla.

Respondent, Armin Quedzuweit and his attorney Neil Blake were not present.

Ms. Gloria Lucero stipulated and entered into record exhibits 1 through 18. The witness, Inspector Bobby Padilla was duly sworn.

Testimony by all parties present was heard and the Chairman closed the hearing at 2:51 p.m.

Deliberation of case 2013-039 Armin Quedzuweit will be discussed during closed session and upon which time, Ms. Mary Smith with the help of Ms. Saavedra and Mr. Woodul, she will prepare the decision and order.

8. 4:00 p.m. Pharmacy Security Initiative*:
Ann M. Rule, PharmD, CPE, Purdue Pharma – Adam Perea, detective APD

Ms. Ann M. Rule was present to discuss pharmacy security initiatives in closed session. Counsel for the board, Ms. Mary Smith stated that since this was not a licensing issue, therefore it could not be presented in closed session. Ms. Rule stated that due to the security initiative, it could not be presented in open session. The board apologized for the confusion and thanked Ms. Ann Rule for her attendance.

Mr. Adam Perea was present and discussed the current increase of robberies in pharmacies and initiatives that are currently being implemented to prevent and capture these individuals.

9. Committee Reports and Board Actions:

Rich Mazzoni – Rules Committee: See Appendix D

Mr. Mazzoni will present proposed language for rule 16.19.11.8(B)(6)(a) automated dispensing at the June 2014 board meeting.

Danny Cross – Clinic Committee: See Appendix E

Mr. Cross stated that the discussions were productive regarding revisions of outdated rules and waivers.

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to go into closed session to discuss Daniel Hall, deliberate on Armin Quedzuweit and personnel issues. Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni, and Mr. Anderson and Mr. Cross voted unanimously to pass the motion. Mr. Mazzoni stepped out of the conference room during the deliberation of Armin Quedzuweit.

The board went back into open session and the only issues discussed were Daniel Hall, deliberation of Armin Quedzuweit and personnel issues.

10. Recess for the day: The Pharmacy Board meeting was recessed at 6:25 p.m. and will reconvene at 9:00 a.m. tomorrow, Friday January 17, 2014.

Friday April 25, 2014

1. Procedural Items:

9:00 a.m. Reconvene: The meeting of the Pharmacy Board was reconvened by Vice-Chair Amy Buesing at approximately 9:00 a.m. on April 25, 2014.

Roll Call: Vice-Chair, Amy Buesing called roll and a quorum was established with the following members present: (**P** = Present **A** = Absent)

A 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

2. 9:15 a.m. Daniel Hall – Request for license reinstatement:

Mr. Hall asked the board to consider once again, reinstating his license that had been voluntarily surrendered February 15, 2013. Mr. Hall stated that his attorney Mr. Steven Gonzalez was present and gave a brief synopsis of Mr. Hall's ongoing recovery which includes Monitored Treatment Program participation, counseling, and involvement in church activities, and feels that Mr. Hall has shown the board that he has taken responsibility for his drug recovery.

The board asked if Mr. Hall was current with the required CE for the current licensing period for renewal and stated that they would require Mr. Hall to participate in the MTP program for a period of five years. Mr. Hall stated that he was current with CE and that he was aware of the required participation with MTP.

During closed session on Thursday April 24, 2014, the board discussed Mr. Hall's request.

Motion made by Ms. Saavedra, seconded by Mr. Woodul to reinstate Mr. Daniel Hall's license, Mr. Anderson voted yes, Mr. Mazzoni voted no, Ms. Buesing voted yes, Ms. Mendez-Harper voted yes, and Ms. Yarbrough voted yes, the motion was passed.

Ms. Mary Smith stated that she would prepare the reinstatement order for Mr. Hall.

3. Disciplinary Hearing:

9:30 a.m. Notice of Hearing: 2013-031 – ECO Medical Supply/Bobby M. Arther
(Bean & Associates will record hearing)

Due to the absence of Chairman, Danny Cross, Vice-Chair Amy Buesing asked that Mr. Mazzoni proceed as the Hearing Officer for this case.

Mr. Mazzoni, opened the hearing at 9:30 a.m. and took roll call. Present were Ms. Yarbrough, Ms. Saavedra, Mr. Anderson, Ms. Buesing, Ms. Mendez-Harper, and Mr. Woodul. Absent were Mr. Cross and Mr. Carrier.

Present was the Administrative Prosecutor Ms. Gloria Lucero for the state and board counsel, Ms. Mary Smith. Also present were Mr. Larry Loring, Debra Wilhite and Inspector, Adela Padilla.

Respondent, Bobby Arther for ECO was present.

Ms. Gloria Lucero stipulated and entered into record exhibits 1 through 12 for the state and exhibits A – R for the respondent. The witnesses, Bobby Arther and Inspector Bobby Padilla were duly sworn.

Testimony by all parties present was heard and the Hearing Officer, Mr. Mazzoni closed the hearing at 11:40 a.m.

Deliberation of case 2013-031 Bobby Arther for ECO will be discussed during closed session and upon which time, Ms. Mary Smith with the help of Mr. Mazzoni, she will prepare the decision and order.

4. 11:00 a.m. – 11:20 p.m. Public/Professional Requests/Waiver Petitions*:

Amanda Villa – Request for early release from Probation/MTP: Ms. Villa was not present, no action taken.

Emergency Meds in Schools – Michel Disco, Winona Stoltzfus, MD: See Appendix F

Ms. Disco and Ms. Stoltzfus presented proposed language regarding creating a new class of clinics for school based clinics (class D) that would stock drugs, epi-pens and albuterol. They will work with the clinic committee to develop recommendations for the baord.

Mr. James Brown in attendance stated that he would like to be involved in the clinic committee.

5. Litigation/Board Counsel Issues*:

a) Stephen Ellwood – District Court Memorandum and Opinion:

Counsel for the board, Ms. Mary Smith stated that she will file a motion to dismiss in the next couple of weeks.

b) James Glass – Appellants Motion for Voluntary Dismissal:

Counsel for the board, Ms. Mary Smith stated that Mr. Glass has chosen to ask for a dismissal.

c) Reinstatement Orders – Audited by HIPDB (Healthcare Integrity and Protection Data Bank):

Counsel for the board, Ms. Mary Smith stated that she and Debra Wilhite, Administrative Secretary for the board will work on a template for reinstatement orders. Ms. Wilhite stated that she will work on posting reinstatement orders to the website for current and pre-existing licensees.

d) 2006-145 – Douglas Krell – Order to Show Cause/non-payment of fine $1663.27 – CS Renewal:

Ms. Wilhite stated that licensee Douglas Krell currently renewed his controlled substance licensed with the board and has not paid fines related to his case 2006-145, she would like the board to issue an order to show cause to revoke CS license due to non-payment of fines.

Motion made by Mr. Mazzoni, seconded by Ms. Buesing to issue the order to show cause and set a hearing for the June 2014 board meeting, the board voted unanimously to pass the motion.

e) 2010-069 – Kenneth Sanchez – Order to Show Cause/non-payment of fine $400.00:

Ms. Wilhite stated that licensee Kenneth Sanchez petitioned the board to re-open his case 2010-069 in July 2012 and the board approved the request. Ms. Wilhite addressed the non-payment of the $400.00 fine with Mr. Sanchez at that time, and he stated that he would pay the fine. To date Mr. Sanchez has not paid the $400.00 fine.

Motion made by Mr. Mazzoni, seconded by Ms. Buesing to issue an order to show cause hearing and reinstate the default revocation for the June 2014 board meeting, the board voted unanimously to pass the motion.

6. 1:30 – 2:00 Compassion & Choices Group – "End of Life" Therapy: See Appendix G
Katherine Morris, MD – Mark Holdsworth, PharmD – Alexandra Smith, JD - Aroop Mangalik, MD

Ms. Erin Marshall and Dr. Aroop Mangalik, were present to discuss "End of Life" Therapy. Dr. Aroop and Ms. Marshall explained to the board that the goal of the organization "Compassion & Choices New Mexico" is to educate and normalize the choices that patients may have that are terminally ill to choose and have honored their "end of life" wishes, by providing information and support to patients and families, and by offering patient advocacy services.

Dr. Mangalik, Dr. Morris and Aja Riggs are plaintiffs in a case they have filed regarding a New Mexico woman, Aja Riggs, with advanced uterine cancer. Physicians Katherine Morris and Aroop Mangalik have asked New Mexico District court to rule that state law does not prevent doctors from providing aid in dying. The plaintiffs sought a declaratory judgment that aid in dying, prescribing medication to a terminally ill, mentally competent adult may self-administer for peaceful dying, is not a suicide. New Mexico law currently classifies assisted suicide as a felony.

Dr. Aroop Mangalik stated that District Court Judge Nan Nash granted the plaintiffs the requested injunctive relief prohibiting defendants from prosecuting physicians who provide aid in dying to mentally-competent, terminally-ill patients.

The board stated that the information presented was very informative and thanked Ms. Erin Marshall and Dr. Aroop Mangalik for attending the meeting

No action was taken.

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

Ms. Yarbrough left the board meeting at 2:32 p.m.

a) PMP Update – Carl Flansbaum:

Mr. Flansbaum will report to the board every quarter, licensees that are non-reporting/delinquent to the PMP, and request that NCA's be issued to licensees for not reporting after verification.

Mr. Flansbaum will submit proposed language at the June 2014 meeting to exclude veterinarians from the requirement of registering with the PMP in conjunction with their controlled substance registration and exclude veterinarians or veterinary clinics as dispensers.

b) FDA inter-governmental meeting on pharmacy compounding –Cheranne McCracken:

Ms. Cheranne McCracken briefly discussed issues regarding the review and coordination of federal and state oversight of compounding of human drugs, reviewed Drug Quality and Security Act as it relates to 503A and 503B and conditions that must be met for exemptions.

c) "Natural Rx" medical cannabis:

The board was notified regarding signage stating "Natural Rx" medical cannabis, and Mr. Loring stated that statute 61-11-21 prohibits the use of misleading language or signage and no person shall sell at retail any dangerous drug, compound any prescription or acquire and possess any dangerous drug without its being prescribed. The board will send information regarding the statute to the DOH so they can share with medical cannabis facilities to not us Rx in facility name.

d) Virtual Manufacturers:

Board staff will modify the current wholesale distributor application to enable virtual manufacturers to be licensed. This should not be confused with virtual distributors. The board does not want to license virtual distributors.

e) Personnel discussion*:

The board discussed personnel issues during closed session.

f) Naloxone press release – NMPhA: See Appendix H

Mr. Dale Tinker discussed the press release regarding New Mexico pharmacists can now prescribe naloxone to patients at risk for opioid overdose.

g) June Board meeting:

The June board meeting will be re-scheduled for Wednesday June 18th & Thursday 19th, 2014 due to the board members participation at the NMPhA meeting. Ms. Wilhite will confirm the reservation for the conference room and update the website to reflect the re-scheduled dates.

h) NAPLEX-MPJE Retake policy:

Mr. Loring stated that the current re-take policy allows up to 5 times and that it is up to each state. Ms. Sarah Trujillo stated that Texas only allows 3 times to retake the tests. Mr. Loring stated that the board will propose language to reflect a change to the number of times allowed to retake the NAPLEX-MPJE.

i) Pharmacy outsourcing facilities – FDA registered – Cheranne McCracken:

Ms. Cheranne McCracken briefly discussed the issues of outsourcing facilities, the classification and regulation of as it relates to interstate commerce and memorandum of understanding.

Mr. Loring stated that the board will rewrite the application to allow pharmacy outsourcing facilities to be licensed as a wholesaler.

j) August 2013 minutes revision:

Mr. Loring stated that a licensee requested that the August 2013 minutes be revised to omit language that reflected adversely towards the licensee. The board denied the request and stated that any revisions made to "official minutes" are due to inaccurate or accidental omission of factual information stated at a board meeting..

k) Alfaxalone schedule IV: See Appendix I

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

l) Pharmacist survey:

Mr. Loring stated that he will put the pharmacists' survey on the "Monkey Survey" website to fulfill the requirements of UNM.

m) Expedited Pharmacist licensure for military – proposed 16.19.4.15: See Appendix J

Motion: Notice 16.19.4.15 NMAC for the June 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion.

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to go into closed session to discuss the case presentations, deliberate on ECO and personnel issues, Ms. Saavedra, Mr. Anderson , Ms. Buesing, and Mr. Woodul, voted unanimously to pass the motion.

The board went back into open session and the only issues discussed were the case presentations, deliberation of ECO and personnel issues.

8. 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, and Mr. Anderson, voted unanimously to pass the motion.

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

Inspector Mossberg:	2013-075/close 2014-012/close	2014-006/close-DA 2014-013/close	2014-008/close-DA 2014-014/close
Inspector Kesner:	2013-053/NCA 2014-017/VS	2014-010/VS	2014-011/table
Inspector B. Padilla:	2013-078/close 2014-015/NCA	2014-002/close 2014-019/NCA	2014-009/NCA
Inspector A. Padilla:	2013-011/close	2014-007/close	
Inspector McCracken:	2014-003/close	2014-004/table	2014-005/AL

Motion: **Close case:** 2013-078, 2014-002, 2014-003 and 2014-007. Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself from the vote.

Motion: **Close cases:** 2013-075, 2014-006, 2014-008, 2014-012, 2014-013, and 2014-014. Motion made by Mr. Anderson, seconded by Mr. Mazzoni, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself.

Motion: **Table cases:** 2014-011, and 2014-004. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA to revoke** case 2013-053 and 2014-009. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: **Issue NCA w/pre-NCA to revoke** case 2014-015 and 2014-019. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue advisory letter** case 2014-005. Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra, board voted unanimously to pass the motion.

Motion: **Accept voluntary surrende**r for case 2014-010 and 2014-017. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

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

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

2012-051 – CVS Pharmacy/Mark Shortencarier RP5166 – Stipulated Agreement
2012-092 – New England Compounding Center PH2575 – Stipulation and Consent Order
2013-017 – Roden Smith Pharmacy/David Lansford – Stipulated Agreement
2013-033 – Flourish Interactive Pharmacy – Stipulated Agreement
2013-077 – Andrew Wood – Stipulated Agreement

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to approve the stipulated agreements for cases 2012-051, 2012-092, 2013-017, 2013-033, and 2013-077, board voted unanimously to pass the motion.

2013-026 – Geneva Cisneros – Default Revocation
2013-034 – John Ashcraft - Default Revocation
2013-056 – Jason Trimmer – Default Revocation

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to issue the default revocations for cases 2012-026, 2013-034 and 2013-056, board voted unanimously to pass the motion.

2013-073 – Michael Lopez PT9141 – Voluntary Surrender

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to accept the voluntary surrender for case 2013-073, board voted unanimously to pass the motion.

2014-010 – Gretchen Steininger – Voluntary Surrender
2014-017 – Renee Dimas – Voluntary Surrender

Motion made by Ms. Mendez- Harper, seconded by Mr. Anderson to accept the voluntary surrenders for cases 2014-010 and 2014-017, board voted unanimously to pass the motion.

10. **Adjournment:** With no further business, Mr. Mazzoni made a motion to adjourn the Pharmacy Board meeting at 6:23 p.m., seconded by Mr. Woodul, board voted unanimously to pass the motion.

Appendix A

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 facilities as defined in 61-11-14 B (1), (2), (5), (7) NMSA 1978, and all persons or entities that own or operate, or are employed by a facility 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. '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.

Q. "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.

R. "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).

S. "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.

T. "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.

U. "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).

V. "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).

W. "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).

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

Y. "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.

A. "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.

AA. "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.

BB. "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.

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

DD. **"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.

EE. **"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.

FF. **"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.

GG. **"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.

HH. **"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.

II. **"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).

JJ. **"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

KK. **"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.

LL. **"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.

MM. **'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.

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

OO. **"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.

PP. **"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.

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

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

SS. **'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.

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

UU. **"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.

VV. **"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.

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

XX. **"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 PHARMACIST IN CHARGE:

A. In order to obtain a license, all pharmacies compounding sterile preparations must designate a pharmacist in charge of operations. 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 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.

(5) must minimize particle generating activities including but not limited to corrugated cardboard boxes and packing materials.

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 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 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 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 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 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 hazardous drugs, pharmacists supervising compounding personnel, pharmacy interns compounding sterile hazardous, and pharmacy technicians compounding sterile hazardous drugs, shall have completed a board approved course in hazardous drug preparation as well as training in compounding sterile preparations as listed in H1 above, prior to compounding sterile hazardous 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 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 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 hazardous material 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]

Appendix B

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 C

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

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

Appendix D

16.19.11.8 MINIMUM STANDARDS:

B. POLICY AND PROCEDURES MANUAL:

(6) DRUG DISTRIBUTION

(a) All dangerous drugs ~~will~~ shall be obtained from a properly licensed facility. Stock dangerous drugs acquired, maintained and administered by or at the nursing home shall be listed in the nursing home policy and procedure manual ~~and approved by the Board of Pharmacy~~. The stock dangerous drugs shall be used when a licensed nurse (LPN or RN) is on duty. The following is the approved list of stock dangerous drugs:

(i) Sterile normal saline and water - injectable;

(ii) Sterile normal saline and water - irrigation;

(iii) Tuberculin testing solution;

(iv) ~~Hepatitis B vaccine.~~ Vaccines as recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices and appropriate for the facility population served.

(v) ~~Flu vaccine.;~~

(b) Any additional nursing home stock dangerous drugs must be defined and listed in the policy and procedure manual and must be approved by the Board of Pharmacy or Board's agent prior to obtaining or using.

~~(b)~~ (c) No drugs will be compounded by other than a pharmacist unless done in accordance with that exemption in the State Pharmacy Act - Section 61-11-22.

~~(c)~~ (d) The pharmacist shall be responsible for the proper removal and destruction of unused, discontinued, outdated or recalled drugs.

~~(d)~~ (e) The pharmacist shall require the person receiving a patient's drugs from the pharmacist or his agent to sign a drug receipt record listing those prescriptions received from the pharmacy.

~~(e)~~ (f) The pharmacist shall provide the staff with a receipt listing those prescriptions removed from the facility.

~~(f)~~ (g) Medications will be released to patients on discharge from the facility only upon the authorization of the physician.

16.19.6.7 DEFINITIONS:

A. "Automated filling system" means an automated system used by a pharmacy in the state of New Mexico to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or automated dispensing and

Comment [LB1]: Is there a reason that "will" is used here vs. "shall" in the rest of the section? It seems that unless there's an intended difference in meaning that this should be changed to "shall" for consistency. Good point

Comment [LB2]: Should this be changed to "by licensed nursing home personnel"? Drugs are under the custody of the licensed facility, rather than the licensed facility personnel… OK I guess its the "administered by the nursing home" that I'm getting hung up on. I understand that the nursing home is the licensed entity, but it really can't administer. Just another grammatical issue. You are right – please comment on proposed change.

Comment [LB3]: This removes the requirement for Board approval of the P&P manual. I agree with removing it because, as drafted, it's ambiguous as to what the Board should approve. However, if the Board intended for this to apply to the policy and procedures manual generally, perhaps that should be added back in somewhere else in the rules. We review and approve the policy and procedure manual with the facility's initial license application, but subsequently the facility may update/amend the manual without our express approval…based on this, the language in (v) may be sufficient to replace it, and clarify that even down the road they need approval to add additional dangerous drugs to their stock formulary (but other routine manual updates don't require approval prior to implementation).

Comment [LB4]: This is a substantive change that I don't recall discussing. Did I miss something? Also, would this be more appropriately located in a section that deals with administration or could it just be removed if you make the change I suggest above? If intended as an administration restriction, it seems out of context for this subsection (6). No, you didn't miss anything – I was attempting to clarify based on minimum required licensure for parenteral product administration in a nursing home, but it isn't an appropriate change because the same restriction doesn't apply to irrigation solutions…thanks for the feedback. I changed back to original language.

Comment [LB5]: I'm not a pharmacist. Are these considered dangerous drugs? Yes Ok

Comment [LB6]: OK – back to my structural picky-ness. Since (i) through (iv) is really a list of approved stock, it seems structurally inconsistent to add this additional direction as (v). That's why I tried to work this into (a) please comment on proposed change

storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient.

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

C.~~B.~~ "Drug utilization review" (DUR) means evaluating or reviewing the patient record in order to determine the appropriateness of the drug therapy for a patient and which includes the prospective drug review in 16.19.4 NMAC and the verification of data entries including the correct interpretation and input of written prescriptions and the drug regimen review (NMSA 61-11-2L) as required by the board.

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

E.~~D.~~ "Electronic signature" means an electronic sound, symbol or process attached to or logically associated with a prescription record.

F. "Electronic verification system" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system.

G. "Manufacturer unit of use package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

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

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

J.~~G.~~ "Prescriber" means a licensed practitioner who generates a prescription order and assumes responsibility for the content of the prescription.

K.~~H.~~ "Remote pharmacist DUR site means a remote pharmacist practice site electronically linked to the New Mexico licensed pharmacy it operates through at which a pharmacist conducts drug utilization reviews. No dispensing will occur from a remote pharmacist DUR site.

L. "Repackager" means a repackager registered with the United States Food and Drug Administration.

M. "Repacked" means any drug that has been removed from the original packaging of the manufacturer or a repackager's packaging and is placed in a container for use in an automated filling system.

[16.19.6.7 NMAC - Rp, 16 NMAC 19.6.7, 03-30-02; A, 06-30-06; A, 12-15-08]

16.19.6.27 AUTOMATED FILLING SYSTEMS:

A. Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist. Pharmacy repacked medication, cartridges, or containers shall comply with paragraph F of this section.

B. Verification. Except as provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any prescription container filled or packaged by an automated filling system, and any label affixed thereto, prior to dispensing, as required by 16.19.4 NMAC section 16 paragraph B subsection 1.

C. The pharmacist verification requirements of paragraph B of this section shall be deemed satisfied if the following are met:

(1) Pharmacy personnel establish and follow a policy and procedure manual that complies with paragraph D of this section;

(2) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the automated filling system that is ready for dispensing to the patient. No manual intervention with the medication or prescription may occur after the medication is loaded into the automated filling system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(3) A pharmacist verifies the accuracy and appropriateness of the prescription information used by or entered into the automated filling system for a specific patient prior to initiation of the automated fill process. The identity of the verifying pharmacist shall be recorded in the pharmacy's records;

(4) A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or repacked medication previously verified by a pharmacist;

(5) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer's unit of use package or a repacked pharmacy container;

(6) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient;

(7) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the automated filling system. The required sample size shall not be less than two percent (2%) of the prescriptions filled by the automated system on the date tested or two percent (2%) of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy's records;

(8) The product dispensed is a solid oral dosage form; and

(9) The product dispensed is not a controlled substance listed in DEA or Board of Pharmacy schedule II-IV.

D. Policies and Procedures. Pharmacists verifying prescriptions pursuant to paragraph C of this section shall follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be established by, and reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records. The required annual review shall be documented in the pharmacy's records.

At a minimum, pharmacy personnel shall establish and follow policies and procedures for the following:

(1) Maintaining the automated filling system and any accompanying electronic verification system in good working order;

(2) Ensuring accurate filling, loading, and stocking of the system;

(3) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(4) Reporting, investigating, and addressing filling errors and system malfunctions;

(5) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;

(6) Training persons authorized to access, stock, restock, or load the automated filling system in equipment use and operations;

(7) Tracking and documenting prescription errors related to the automated filling system that are not corrected prior to dispensing to the patient;

(8) Conducting routine and preventive maintenance and, if applicable, calibration;

(9) Removing expired, adulterated, misbranded, or recalled drugs;

(10) Preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(11) Identifying and recording persons responsible for stocking, loading, and filling the system;

(12) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements; and

(13) Maintaining an ongoing quality assurance program that monitors performance of the automated fill system and any electronic verification system to ensure proper and accurate functioning.

E. Recordkeeping. Records and documentation required by this section shall be maintained in the pharmacy's records electronically or in writing for a minimum of three years. Records shall be made available for inspection and produced to the board or the board's agent upon request.

F. A pharmacist, pharmacist intern or pharmacy technician under the direct supervision of a licensed pharmacist may repackage drugs for other than immediate dispensing purposes provided that the following conditions are met:

(1) Repackaging occurs at the licensed pharmacy utilizing the automated filling system;

(2) Only products which will be directly provided to the patient may be repackaged;

(3) Containers utilized or repackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the *United States Pharmacopoeia* (USP), which has been incorporated herein by reference. Where applicable, light resistant containers shall be used;

(4) The maximum expiration date allowed for repacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less; and

(5) Any repacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in paragraph F subsection 3 of this section, and lot number. Pharmacies that store drugs within an automated filling system may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(6) All drugs repackaged by a pharmacist intern or pharmacy technician must undergo a final check by the pharmacist.

[16.19.6.27 NMAC]

Appendix E

Minutes from Clinic Committee Agenda April 17, 2014.

Attendance:

Danny Cross
Bill Harvey
Bill Lord
George Gonzales absent Proxy: (Leo Duran, RPh, Charles Lacy-Martinez)
Charlie Vandiver
Katie Klein
James Brown
Christy Martinez-Vigil
Ben Kessner
Cheranne McCracken

Wes Langner (did not get the meeting notice, I had wrong email)
Tracy Atkinson (going to drop from the committee)

General Discussion

Each committee member introduced themselves and gave a little information about their background and top reasons for participation on this committee.

Topics:

- Rules outdated and need revision
- Clear direction for electronic records and remote consulting (online chart review)
- Discuss statutory authority for removing DOH clinics from clinic regulation by BOP or set-up new class of clinic for DOH clinics
- School based clinics as a different category without or with reduced square footage requirements.
- Rule to allow custodial care facilities for immunizations and TB testing (eg: jails)
- Clinic rule re patient assistance meds, clinics taking custody of patient meds, custody and administration record requirements
- Clarify technician duties vs clerical staff vs practitioner responsibilities in preparation and dispensing of orders. Who can prepare what. Dispensing process.

Agenda Issues discussed:

1. Look at rule revisions to address waiver's given. 7 waivers have been given to clinics (4 B1 & 3 School based). DOH waivers are associated with pharmacist clinic on site visits to bi-annually. Square footage variations have been mostly at school based clinics. DOH wants to be removed from BOP regulation due to the nature of their clinics.

2. Personnel: Concerns about the requirement that the practitioner is required to process the dispensing of medications is inconsistent with what is actually happening in the clinics where practitioners are delegating to others and just doing a final check. Pharmacy Technicians are not allowed to do this work in clinics by statute unless a pharmacist is present. Discussed how to improve this situation and possible statute changes.

3. School based clinics for albuterol and epinephrine. Sect 5 of law BOP re storage requirements. Application of drug, device and cosmetic act. Need to review the new law. New issues with liability concerns recently in the press.

4. Square Footage Requirements: Consensus is the square footage requirements are pretty reasonable. A clinic with VFC and 2 refrigerators definitely need adequate space for ventilation, temperature control and work space. Since most waivers for space are for school based clinics without VFC, maybe they need a separate license category.

5. Custodial Care facilities are licensed to house patients and help administer patient specific medications but not allowed to have stock meds such as TB test and immunizations. Specific concerns about use of MDV in this setting. Jails and prisons need to be able to TB test.

6. Use of telepharmacy, remote dispensing, remote and offsite electronic health records, off site chart reviews and general update of the regulation to accommodate the appropriate use of emerging technologies. Standards for retrievable records. Everyone feels this is important and we need to address, but time ran out on this meeting.

Issues for next meeting:

1. Look at statutory authority and current regulations to determine what sections need to be addressed for rule change.

2. Continue interim discussion to determine what potential issues we have missed so they can be included on the agenda for the next meeting.

3. Prioritize a to do list for this committee.

Plan for future meetings and interim projects.

Appendix F

16.19.10.11 PUBLIC HEALTH CLINICS:

A. CLINIC LICENSURE

(1) All clinics where dangerous drugs are administered, distributed or dispensed shall obtain a Limited Drug Permit (as described in Section 61-11-14 B (6) of the Pharmacy Act) which consists of the following types:

(a) Class A clinic drug permit for clinics where:

(i) dangerous drugs are administered to patients of the clinic;

(ii) more than 12,500 dispensing units of dangerous drugs are dispensed or distributed annually.

(b) Class B clinic drug permit for clinics where dangerous drugs are:

(i) administered to patients of the clinic; and

(ii) dispensed or distributed to patients of the clinic. Class B drug permits shall be issued by categories based on the number of dispensing units of dangerous drugs to be dispensed or distributed annually, as follows: 1. CATEGORY 1 up to 2,500 dispensing units; 2. CATEGORY 2 from 2,501 - 7,500 dispensing units; 3. CATEGORY 3 from 7,501 - 12,500 dispensing units.

(c) Class C clinic drug permit for clinics where dangerous drugs are administered to patients of the clinic.

(d) Class D clinic drug permit for school health offices where emergency dangerous drugs are maintained for administeration to students of the school.

B. FORMULARIES

(1) For all clinic types, drug procurement and storage is limited to the drugs listed in the dispensing formulary for the clinic. The formulary shall be developed by the Pharmacy and Therapeutics Committee of the facility, or if no such committee exists, by the pharmacist and Medical Director of the clinic. The formulary drugs shall be appropriate for the scope of medical services provided at the clinic facility. A dangerous drug with the same generic name is considered one drug within the formulary (ie) all dosage forms and packages of Ampicillin are considered one drug.

(2) For all clinic types, drug procurement and storage is limited to the drugs listed in the administration formulary for on-site administration. The formulary shall be developed by the Pharmacy and Therapeutics Committee of the facility, or if no such committee exists, by the pharmacist and Medical Director of the clinic. The formulary drugs shall be appropriate for the scope of medical services provided at the clinic facility. A dangerous drug with the same generic name is considered one drug within the formulary (ie) all dosage forms and packages of Ampicillin are considered one drug.

(3) For Class D clinic drug permits the approved drugs are albuterol for inhalation and epinephrine for injection.

~~(3)~~ (4) A clinic may petition the Board for an alternative dispensing formulary as set forth in 16.19.10.11.R.

16.19.4.11 CONSULTANT PHARMACIST:

C. CONSULTANT PHARMACIST - CLINIC FACILITY:
(1) The consultant pharmacist providing services to a clinic shall.
(a) Assume overall responsibility for clinic pharmacy services, for clinic pharmacy supportive personnel, and for procedures as outlined in the procedures manual, including all records of drugs procured, administered, transferred, distributed, repackaged or dispensed from the clinic.
(b) Assume responsibility for the destruction or removal of unwanted or outdated dangerous drugs, including controlled substances, as required by laws and regulations.
(c) Develop the pharmacy services procedures manual for the clinic establishing the system for control and accountability of pharmaceuticals.
(d) Provide in-service education and training to clinic staff, as applicable.
(e) Report in writing to the Board within ten (10) days, any termination of services to the clinic. Report in writing to the Board the names and places of employment of any pharmacy technicians under the supervision of the consultant pharmacist.
(f) Comply with all other provisions of Part 10, Limited Drug Clinics, as applicable to the individual clinic facility.
(g) The consultant pharmacist shall personally visit the clinic on the minimum basis described in subparagraphs (a) through (c) [(i) through ~~(iii)~~(iv)] to ensure that the clinic is following set policies and procedures. Visitation schedules are as follows.
(i) Class A clinics shall have the on-site services of a consultant pharmacist for the dispensing or distribution of dangerous drugs. The consultant pharmacist shall comply with Paragraphs 4, 5 and 7 of Subsection A of 16.19.4.17 NMAC of this regulation.
(ii) Class B clinics shall have the services of a consultant pharmacist as listed below: 1. Category 1 clinics shall be visited by the consultant pharmacist at least bi-monthly. 2. Category 2 clinics shall be visited by the consultant pharmacist at least monthly. 3. Category 3 clinics shall be visited by the consultant pharmacist at least bi-weekly.
(iii) Class C clinics shall be visited by the consultant pharmacist at least every three months.
(iv) Class D clinics shall be visited at least once yearly during school session.

Appendix G

The Clinical Practice Guidelines for Physician Aid in Dying

Submitted by:

The Physician Aid in Dying Committee 2014

For information call 1-800-247-7421

Appendix H

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New Mexico Pharmacists can prescribe life-saving medication!

New Mexico Pharmacists can now prescribe naloxone to patients at risk for opioid overdose. Naloxone is a prescription medication that reverses the effects of opioid overdose by blocking the opioid's action on the brain and restoring breathing. Opioids include morphine, hydrocodone, oxycodone, and most other prescription pain medications, as well as heroin and methadone.

New Mexico ranks 2nd in the nation for overdose deaths, with prescription pain medication being the most common cause of drug overdose. New Mexico Pharmacists have a chance to help change that statistic.

In January the New Mexico Board of Pharmacy adopted rules which allow pharmacists to prescribe naloxone. Last year, the New Mexico Pharmacists Association, working with Project ECHO, developed a protocol to allow pharmacists, with additional training, to prescribe this life saving medication. The protocol was approved by the New Mexico Medical Board, the New Mexico Nursing Board and the New Mexico Board of Pharmacy. All three approvals are required by law for pharmacists prescribing authority.

The naloxone prescribing authority is the fifth protocol for pharmacists in New Mexico. The protocols are developed around an area where pharmacists can have an impact on public health. New Mexico Pharmacists, with the additional certification, can prescribe immunizations, emergency contraception, tobacco cessation products, tuberculosis testing and now naloxone for opioid overdose prevention.

The first 60 pharmacists and 6 pharmacy students received the training on March 20th or 25th. The training was offered in person or through video conferencing technology, which allowed pharmacists from all over the state of New Mexico to participate in the training program.

# # #

The New Mexico Pharmacists Association is a membership organization representing pharmacists, pharmacy technicians and pharmacy owners and managers in New Mexico.

Project ECHO (Extension for Community Healthcare Outcomes) at the University of New Mexico Health Sciences Center uses telemedicine to expand access to treatment of chronic, common, and complex diseases in rural and underserved areas.

Appendix I

16.19.20.68 SCHEDULE IV: Shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section:

A. DEPRESSANTS: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its' salts, isomers, and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Alfaxalone
~~**(1)**~~**(2)** Alprazolam
~~**(2)**~~**(3)** Barbital
~~**(3)**~~**(4)** Chloral Betaine
~~**(4)**~~**(5)** Chloral Hydrate
~~**(5)**~~**(6)** Chlordiazepoxide
~~**(6)**~~**(7)** Clobazam
~~**(7)**~~**(8)** Clonazepam
~~**(8)**~~**(9)** Clorazepate
~~**(9)**~~**(10)** Clotiazepam
~~**(10)**~~**(11)** Diazepam
~~**(11)**~~**(12)** Estazolam
~~**(12)**~~**(13)** Ethchlorvynol
~~**(13)**~~**(14)** Ethinamate
~~**(14)**~~**(15)** Flurazepam
~~**(15)**~~**(16)** Halazepam
~~**(16)**~~**(17)** Lorazepam
~~**(17)**~~**(18)** Mebutamate
~~**(18)**~~**(19)** Meprobamate
~~**(19)**~~**(20)** Methohexital
~~**(20)**~~**(21)** Methylphenobarbital
~~**(21)**~~**(22)** Midazolam
~~**(22)**~~**(23)** Oxazepam
~~**(23)**~~**(24)** Paraldehyde
~~**(24)**~~**(25)** Petrichloral
~~**(25)**~~**(26)** Phenobarbital
~~**(26)**~~**(27)** Prazepam
~~**(27)**~~**(28)** Quazepam
~~**(28)**~~**(29)** Temazepam
~~**(29)**~~**(30)** Triazolam
~~**(30)**~~**(31)** Zopiclone

Appendix J

16.19.4.14 ACTIVE STATUS: Any pharmacist who maintains competency through the development and maintenance of knowledge, skill and aptitude, to ensure continuing competence as a pharmacy professional, and is able to demonstrate to the board said competence in the practice of pharmacy shall be issued an active license. Records of continuing education or continuous professional development shall be maintained and available for inspection by the board or the board's agent. A pharmacist shall be issued an active status license upon proper application and payment of fees.
[08-27-90; 16.19.4.14 NMAC - Rn, 16 NMAC 19.4.14, 03-30-02; A, 12-15-02; A, 10-25-12]

16.19.4.15 EXPEDITED PHARMACIST LICENSURE BY RECIPROCITY FOR MILITARY AND SPOUSES LICENSED IN ANOTHER JURISDICTION

A. If a military service member, the spouse of a military service member, or a recent veteran submits an application for a pharmacist license and is a qualified applicant pursuant to *this part*, the board shall expedite the processing of such application and issue the license as soon as practicable. The terms "military service member" and "recent veteran" are defined in the Uniform Licensing Act, NMSA 1978, Section 61-1-34 (2013). Any qualified veteran applicant seeking expedited licensure pursuant to this section shall submit a copy of form DD214, Certificate of Release or Discharge from Active Duty, with the application.

B. A license issued pursuant to this section shall not be renewed automatically, and shall be renewed only if the licensee satisfies all requirements for the issuance and renewal of a license pursuant to the Pharmacy Act, including NMSA 1978, Section 61-11-13 and 16.19.4.14 NMAC.

16.19.4.15~~6~~ INACTIVE STATUS:

A. A pharmacist not engaged or ceasing to be engaged in the practice of pharmacy for more than one year shall be issued an inactive status license upon proper application and payment of fees.

B. Pursuant to Section 61-11-13.B, an inactive status pharmacist applying for an active status license, who has not been actively engaged in pharmacy for over one year, may be required to serve an internship training program and submit evidence of continuing education relating to the practice of pharmacy, as required by Section 61-11-6 and Section 61-11-13 and the Board regulations.