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

January 22nd and 23rd, 2015 Draft Meeting Minutes

The NMBOP is going *GREEN*. Please bring your tablets and laptops if you plan to attend this meeting, as we will have Internet access available.

Board Meetings are open to the public pursuant to the "Open Meetings Act" and notices to the public are posted in the Albuquerque Journal. Notice published December 14, 2014.

Location: 5200 Oakland Ave. NE, Albuquerque, NM

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

Thursday, January 22, 2015

1. Procedural Items:

9:00 a.m. Call to Order: The meeting of the Pharmacy Board was called to order by Chairman Cross at 9:05 a.m. on January 22, 2015.

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

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

Mr. Carrier was in attendance at 9:20 and Ms. Saavedra was in attendance at 10:25.

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

Approval of October 2014 Minutes: Motion to approve the October 16th and 17th, 2014 minutes as presented by Ms. Mendez-Harper, seconded by Mr. Anderson, 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: **14 Clinic/Home Health** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **5 Emergency Medical Service** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: **32 Custodial/Nursing Home** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul to approve applications, board voted unanimously to pass motion. Mr. Cross recused himself from the vote for #9, #10 and #11.

Motion: **7 Pharmacy/Hospital** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Woodul to approve applications, board voted unanimously to pass motion. Mr. Mazzoni recused himself from the vote for #1 and #2.

Motion: **53 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: **35 Wholesale/Broker** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Woodul to approve applications, board voted unanimously to pass motion.

NEW MEXICO BOARD OF PHARMACY
REGULAR MEETING
APPLICATION LIST
January 22 & 23, 2015

CLINIC /HOME HEALTH	CONSULTANT PHARMACIST
1.Artesia Healthcare Professionals Cardiology/Internal Medicine Clinic 612 N 13th Street Suite F Artesia, NM 88210	New Kirk Irby, R.Ph.
2.Chalmers Wellness Clinic 3777 the American Road NW Albuquerque, NM 87114	Change of Ownership Karlyn Jensen, R.Ph.
3.Concentra Medical Centers DBA Concentra Urgent Care 801 Encino Place NE Suite E-12 Albuquerque, NM 87102	Change of Ownership Larry Cato, R.Ph.
4.Dona Ana Village Public Health Office 5220 Holman Road Las Cruces, NM 88012	Relocation George Gonzales, R.Ph.
5.Farmington Community Health Center 1001 W Broadway Suite E Farmington, NM 87401	Relocation Stephen Quesada, R.Ph.
6.Institute of American Indian Arts 83 Avan Nu Po Road Santa Fe, NM 87508	New Emily Bustos, R.Ph.

7.Lovelace Cancer Care Program
715 Martin Luther King Jr Avenue NE Suite 102
Albuquerque, NM 87102

New
Martin Martinez, R.Ph.

8.Memorial Home Health
2450 S Telshor Blvd Suite F
Las Cruces, NM 88011

Relocation
Janet Pate, R.Ph.

9.PHC-Las Cruces Inc
DBA Memorial Medical Center Wound Care Center
2735 Northrise Drive Suite B
Las Cruces, NM 88011

New
Janet Pate, R.Ph.

10.PMG Pan American
6100 Pan American Freeway
Albuquerque, NM 87109

Remodel
Rich Gutierrez, R.Ph.

11.Presbyterian GI Labs
301 Cedar SE
Albuquerque, NM 87106

New
Rich Gutierrez, R.Ph.

12.Renal Medicine Associates
3821 Masthead NE
Albuquerque, NM 87109

New
Karin Feldkamp, R.Ph.

13.Roswell Independent School District
Goddard High School
300N Kentucky
Roswell, NM 88201

Relocation
Paul Tunell, R.Ph.

14.UNM Hospital Carrie Tingley Clinic
2211 Lomas Blvd NE
Albuquerque, NM 87106

Relocation
Cynthia Lujan, R.Ph.

<u>EMERGENCY MEDICAL SERVICE</u>

1.Classic Air Medical
3927 W Rd Suite G01
Los Alamos, NM 87544

<u>CONSULTANT PHARMACIST</u>

New
Christine Martinez-Vigil, R.Ph.

2.Estancia Volunteer Fire & Rescue
1000 Highland Avenue
Estancia, NM 87016

New
Claud Dunlap, R.Ph.

3.Med-Trans Air Medical
DBA Aero Care
1600 N Main
Lovington, NM 88260

New
Ed Andrews, R.Ph.

4.Tri-State Care Flight LLC 1313-A E 32nd Street Silver City, NM 88061	New Charles Vandiver, R.ph.
5.Tri-State Care Flight LLC #1 West Prairie Star Road Bernalillo, NM 87004	New Charles Vandiver, R.ph.
CUSTODIAL/NURSING HOME	CONSULTANT PHARMACIST
1.A Better Way of *Living* 6302 Harper Place NE #21 Albuquerque, NM 87109	New Lori Carabajal, R.Ph.
2.A Better Way of Living 4612 Douglas Mac Arthur Albuquerque, NM 87110	New Traci Tadano, R.Ph.
3.A Better Way of Living 3404 Rhonda de Luechsas Albuquerque, NM 87120	New Traci Tadano, R.Ph.
4.Advantage Communications 5425 Lewis Court NW Albuquerque, NM 87114	New Ron Lujan, R.Ph.
5.Alta Mira Craig Branch 11233 Morocco NE Albuquerque, NM 87111	New Reynaldo Saenz, R.Ph.
6.Beehive Homes of Portales 1420 S Main Portales, NM 88130	New Marty Martinez, R.Ph.
7.Beehive Homes of Clovis 2305 North Norris Street Clovis, NM 88101	New Marty Martinez, R.Ph.
8.Bright Horizon 9016 Sun Court SW Albuquerque, NM 87121	New Martin Salas, R.Ph.
9.CARC Inc Orchard #2 902 W Cherry Lane Carlsbad, NM 88220	New Joseph Cross, R.Ph.

10.CARC Inc Orchard #3 902 W Cherry Lane Carlsbad, NM 88220	New Joseph Cross, R.Ph.
11.CARC Inc Orchard #4 902 W Cherry Lane Carlsbad, NM 88220	New Joseph Cross, R.Ph.
12.Casa Q P O Box 36168 Albuquerque, NM 87176	New Katy Morton, R.Ph.
13.CYFD/JJS/Paul Taylor Center 10015 Robert Larson Blvd Las Cruces, NM 88003	New Reed Sheridan, R.Ph.
14.Emeritus at the Cottages 3920 Juan Tabo NE Albuquerque, NM 87111	New Maureen Rogers, R.Ph.
15.Expressions of Life Inc 10527 Milky Way Street NW Albuquerque, NM 87114	New Lori Carabajal, R.Ph.
16.Expressions of Life Inc 10115 Corral Gate Lane Albuquerque, NM 87121	New Perry Storey, R.Ph.
17.Evershine LLC 4844 Calle Bella Ave Las Cruces, NM 88012	New Ivan Nwaogu, R.Ph.
18.Grace Adult Care Homes 7100 Carriage Road NE Albuquerque, NM 87109	New Reynaldo Saenz, R.Ph.
19.Hope Colfax Senior Care 251 Francis Avenue Raton, NM 87740	Change of Ownership Paul Blackburn, R.Ph.
20.L.A. In-Home Care 1668 Plum Road Rio Rancho, NM 87124	New Larry Turner, R.Ph.
21.Milagro de Vida Community Services 2115 College Street Apt#5 Las Cruces, NM 88012	New Ramon Rede, R.Ph.

22.Milagro de Vida Community Services
2595 Mars Avenue Apt 1102
Las Cruces, NM 88001

New
Ramon Rede, R.Ph.

23.Mountain View Manor LLC
2200 68th NW
Albuquerque, NM 87120

New
Reynaldo Saenz, R.Ph.

24.Namaste House Assisted Living
800 W 30th Street
Farmington, NM 87401

New
Stephen Burgess, R.Ph.

25.New Beginnings
9819 Haines Avenue NE
Albuquerque, NM 87112

New
Lori Carabajal, R.Ph.

26.Nezzy Care
102 Dipalo Hill Road Apt 29A
Ruidoso Downs, NM 88346

New
Uri Bassan, R.Ph.

27.Nezzy Care
6021 White Mountain Drive Unit 707
Ruidoso Downs, NM 88345

New
Uri Bassan, R.Ph.

28.Nezzy Care
102 Dipalo Hill Road Apt 16A
Ruidoso Downs, NM 88346

New
Uri Bassan, R.Ph.

29.Rio at Rust Centre LLC
DBA The Rio at Cabezon
2410 19th Street SE
Albuquerque, NM 87124

New
Jeffrey Schwaner, R.Ph.

30.Sandoval Group Home
2250 Isleta SE
Albuquerque, NM 87105

New
Richard Garcia, R.Ph.

31.Tohatchi Area of Opportunity & Services Inc
1706 Kiva Drive
Gallup, NM 87301

New
Nia Harris, R.Ph.

32.Tresco Inc
2040 Crescent
Las Cruces, NM 88001

New
Scott Wallis, R.Ph.

PHARMACY /HOSPITAL	PHARMACIST IN CHARGE
1.Albertsons Market Pharmacy 1300 E 10th Street Alamogordo, NM 88310	New Lisa Robles, R.Ph.
2.CVS 940 North Main Street Las Cruces, NM 88001	New Randall Jake, R.Ph.
3.Farmington Community Health Center 1001 W Broadway Suite E Farmington, NM 87401	Relocation Stephen Quesada, R.Ph.
4.Lowe's Pharmacy 675 10th Street Alamogordo, NM 88310	Remodel Gayle Watters, R.Ph.
5.Sonoma Pharmacy 4371 E Lohman Avenue Las Cruces, NM 88011	New Raul Najera, R.Ph.
6.Walmart Pharmacy 11018 Montgomery Blvd NE Albuquerque, NM 87111	New Sandra Templeton-Olona, R.Ph.
7.Zia Pharmacy 2820 C Broadbent Parkway Albuquerque, NM 87107	New Keun-Keu Yi, R.Ph.

NON-RESIDENT PHARMACY	PHARMACIST IN CHARGE
1.Absolute Pharmacy LLC 17907 Bimini Isle Court Tampa, FL 33647	New Michael Curman, R.Ph.
2.Alero Health 5 Cedar Brook Drive Suite 5 Cranbury, NJ 08512	New Reena Desai, R.Ph.
3.America Meds Direct Rx 3218 Beltline Road Suite 510 Farmers Branch, TX 75234	Change of Ownership Arvin Zeinali, R.Ph.
4.American Custom Compounding Pharmacy LLC 2607 Walnut Hill Lane Suite 220 Dallas, TX 75229	New Vy Tran, R.Ph.

5.Americare Infusion Centers LLC 15800 Dooley Road #185 Addison, TX 75001	New Kelly Swayden, R.Ph.
6.AMI Rx 5296 Old Hwy 11 Suite 4 Hattiesburg, MS 39402	New William Pierce, R.Ph.
7.Axium Healthcare Pharmacy Inc DBA Axium Healthcare Pharmacy West 1821 Kaiser Avenue Irvine, CA 92614	New Linh Lee Youk, R.Ph.
8.CareKineses Inc 704 East Main Street Suite K Moorestown, NJ 08057-3071	Change of Ownership Michael Greenhalgh, R.Ph.
9.Diamondback Drugs 7631 E Indian School Road Scottsdale, AZ 85251	New David Perkins, R.Ph.
10.DFW Wellness Pharmacy 711 E Lamar Blvd Suite 101 Arlington, TX 76011	New Ai-my (spelled on application) Nguyen, R.Ph.
11.Downing Labs LLC 4001 McEwen Road Suite 110 Dallas, TX 75244	New Kristi Kubosh, R.Ph.
12.ESI Mail Order Processing Inc DBA Express Scripts 8990 Duke Blvd Mason, OH 4540	New Andrew Wilhelm, R.Ph.
13.ESI Mail Order Processing Inc DBA Express Scripts 4700 N Hanley Road Suite C St Louis, MO 63134	New Christine Poling, R.Ph.
14.ESI Mail Order Processing Inc DBA Express Scripts 4800 East Street Trevose, PA 19053	New Kristine Breitenbach, R.Ph.
15.ESI Mail Order Processing Inc DBA Express Scripts 3001 S Priest Drive Tempe, AZ 85282	New Marion Rizer, R.Ph.

16.ESI Mail Order Processing Inc
DBA Express Scripts
4415 Lewis Road
Harrisburg, PA 17111

New
Matthew Roesch, R.Ph.

17.ESI Mail Order Processing Inc
DBA Express Scripts
5450 N Riverside Drive
Fort Worth, TX 76137

New
Thomas Viering, R.Ph.

18.ESI Mail Order Processing Inc
DBA Express Scripts
433 River Street Suite 800
Troy, NY 12180

New
Patrick Marks, R.Ph.

19.Express Scripts Pharmacy Inc
DBA Express Scripts
1810 Lincoln Hwy
North Versailles, PA 15137

New
Thomas Edinger, R.Ph.

20.Express Scripts Pharmacy Inc
DBA Express Scripts
5701 E Hillsborough Avenue Suite 1300
Tampa, FL 33610

New
Karen Hancock, R.Ph.

21.Express Scripts Pharmacy Inc
DBA Express Scripts
4700 N Hanley Suite A
St Louis, MO 63134

New
Dan White, R.Ph.

22.Express Scripts Pharmacy Inc
DBA Express Scripts
100 Parsons Pond Drive E1PH1
Franklin Lakes, NJ 07417

New
Salvatore Anselmi, R.Ph.

23.Express Scripts Pharmacy Inc
DBA Express Scripts
4865 Dixie Hwy
Fairfield, OH 45014

New
Eric Smither, R.Ph.

24.Express Scripts Pharmacy Inc
DBA Express Scripts
5151 Blazer Parkway Suite B
Dublin, OH 43017

New
Slater Nash, R.Ph.

25.Fresenius USA Marketing Inc
DBA Fresenius Medical Care North America
1586 S Lakeside Drive
Waukegan, IL 60085

New
Seth Feldman, R.Ph.

26.GenRx Pharmacy
17255 N 82nd Street Suite 130
Scottsdale, AZ 85255

New
Barbara Petronzio, R.Ph.

27.Hall's IV & Institutional Pharmacy Inc
DBA Xpress Compounding
1000 Weatherford Street Suite 120
Fort Worth, TX 76102

New
Ramzi Batrice, R.Ph.

28.Independence Holding Company LLC
DBA Complete Care Pharmacy
14 E Washington Street Suite C
Champaign, IL 61820

New
Bruce Strike, R.Ph.

29.Injectable Therapy Services Inc
DBA BiologicTX
1057 Gayley Avenue Suite B
Los Angeles, CA 90024

Change of Ownership
Albert Abe, R.Ph.

30.Injured Workers Pharmacy LLC
5029 E Sunrise Drive Suite 101
Phoenix, AZ 85044

New
Richard Gutoski, R.Ph.

31.Innovative Rx Gulf Coast Pharmacy
1035 Collier Center Way Suite 2
Naples, FL 34110

New
Michael Aquino, R.Ph.

32.LifeWatch Pharmacy
1838 Elm Hill Pike Suite 126
Nashville, TN 37210

New
Keri Wyatt, R.Ph.

33.Lumicera Health Services Inc
2601 West Beltline Hwy Suite 302
Madison, WI 53713

New
Jamie Wong, R.Ph.

34.Medical Center Pharmacy Inc
410 University Pkwy #2800
Aiken, SC 29801

New
Thomas Holley, R.Ph.

35.Monument Pharmacy Inc
115 C Second Street
Monument, CO 80132

Change of Ownership
Lee Frisbie, R.Ph.

36.Pagosa Specialty Pharmacy
426 Pagosa Street
Pagosa Springs, CO 81147

New
Linda Kutzko, R.Ph.

37.Pet 360 Inc
2815 Watterson Trail
Louisville, KY 40299

Change of Ownership
Justin Mills, R.Ph.

38.Petco Wellness LLC
DBA Doctors Foster & Smith Pharmacy
2253 Air Park Road
Rhinelander, WI 54501-8425

Change of Ownership
Brian Schafer, R.Ph.

39.PMOA Inc
676 S University Blvd
Mobile, AL 36609

New
Jason Hodges, R.Ph.

40.Pumps it Inc
10601 Grant Road Suite 101
Houston, TX 77070

New
Mark Window, R.Ph.

41.Quality Specialty Pharmacy
2233 West Lomita Blvd
Lomita, CA 90717

New
Vladislav Tenenbaum, R.Ph.

42.Rite Care Pharmacy
7560 Greenville Avenue
Dallas, TX 75231

New
Adesh Pundir, R.Ph.

43.RXpress Pharmacy
1000 W Weatherford Street Suite 100, 110 & 200
Fort Worth, TX 76107

New
George Paret, R.Ph.

44.Rx Pro of Alabama LLC
2355 Hartford Hwy Suite 6
Dothan, AL 36305

New
Ronnie Taylor, R.Ph.

45.RX Unlimited LLC
16673 Roscoe Blvd
North Hills, CA 91343

New
Clifton Braddy, R.Ph.

46.Science Pharmaceutical
7225 Fulton Avenue Suite H
North Hollywood, CA 91605

New
Cecilia Tse, R.Ph.

47.Shared Pharmacy Services
4843 Murray Blvd
Murray, UT 84123

New
Munir Merchant, R.Ph.

48.Sorkin's Rx LTD
DBA Caremed Pharmaceutical Service
Altamonte Springs, FL 32701-4913

New
Sarah Grieme-Thomas, R.Ph.

49.Total Vein Pharmacy
2428 Yale Street Suite B
Houston, TX 77008

New
Tamra Saam, R.Ph.

50.Trucare Pharmacy
1875 California Avenue
Corona, CA 92881

New
Mina Kolta, R.Ph.

51.Vital Life Pharmacy
6063 SW 18th Street #112
Boca Raton, FL 33433

New
Nicole Balarezo, R.Ph.

52.Walgreens Pharmacy Services Midwest LLC
521 W Avalon Avenue
Muscle Shoals, AL 35661-2814

New
Jared Otte, R.Ph.

53.Wright Specialty Pharmacy & Diabetic Supply
DBA Benevere Pharmacy
1162 West Popular Ave.
Collierville, TN 38017

New
Jenny Tucker, R.Ph.

<u>WHOLESALER/BROKER</u>

1.3M EPSE Dental Products
2111 McGraw
Irvine, CA 92614

New

2.Acadia Pharmaceuticals Inc
420 International Blvd #500
Brooks, KY 40109

New

3.Allermed Laboratories
7203 Convoy Court
San Diego, CA 92111

New

4.Argon Medical Devices Inc
1445 Flat Creek Road
Athens, GA 75751

New

5.BPI Labs LLC
140 Grimes Drive
Guntersville, AL 35976

New

6.Cameron Pharmaceuticals LLS — New
8695 Seward Road
Fairfield, OH 45011

7.Carlsbad Technology Inc — New
5922 Farnsworth Court
Carlsbad, CA 92008

8.Cetylite Industries Inc — New
9051 River Road
Pennsauken, NJ 08110

9.Ceva Animal Health LLC — New
8600 NE Underground Drive Pillar #303
Kansas City, MO 64161

10.Den-Mat Holdings LLC — New
1017 West Central Avenue
Lompoc, CA 93436

11.DPT Lakewood LLC — New
745 Airport Road
Lakewood, NJ 08701

12.Egalet US Inc — New
460 East Swedesdford Road Suite 1050
Wayne, PA 19087

13.EKOS Corporation — New
11911 North Creek Parkway South
Bothell, WA 98011

14.Exel Inc — New
5920 Corporate Drive
St Joseph, MO 64507

15.GF Health Products Inc — New
33 Plan Way Bldg 2
Warwick, RI 02886

16.Glenwood LLC — New
111 Cedar Lane
Englewood, NJ 07631

17.Haemonetics Corporation — New
549 Aldi Blvd
Mount Juliet, TN 37122

18.Halyard Sales LLC — Change of Ownership
6620 South Memorial Place Suite 100
Tucson, AZ 85756

19.Libertas Pharma Inc — New
780 Industrial Park Blvd Unit D
Montgomery, AL 36117

20.Lucid Pharma LLC — New
2 Tower Center Blvd Suite 1101B
East Brunswick, NJ 08816

21.Meda Consumer Healthcare Inc — New
1100 Circle 75 Parkway Suite 400
Atlanta, GA 30339

22.Medico-Mart Inc — New
2323 Corporate Drive
Waukesha, WI 53189

23.Medtronic Inc — New
1130 Commerce Blvd
Logan Township, NJ 08085

24.Midwest Veterinary Supply Inc — New
21467 Holyoke Avenue
Lakeville, MN 55044

25.Norbrook Inc — New
9733 Loiret Blvd
Lenexa, KS 66219

26.NOVA Biologics Inc — New
1714 Ord Way
Oceanside, CA 92056

27.Ortho Clinical Diagnostics Inc — Change of Ownership
1001 US Hwy 202
Raritan, NJ 08869

28.Owens & Minor — Change of Ownership
25 Haywood Road
Arden, NC 28704

29.ProPharma Distribution LLC — New
6531 West 56th Avenue Suite 31
Arvada, CO 80002

30.Questcor Pharmaceuticals Inc — Change of Ownership
2611 Research Road
Hayward, CA 94545

31.Sigma-Aldrich Inc — New
2425 South 2nd Street
St Louis, MO 63104

32.Sun Pharmaceutical Industries Inc — New
270 Prospect Plains Road
Cranbury, NJ 08512

33.Sunrise Pharmaceuticals Inc — New
665 East Lincoln Avenue
Rahway, NJ 07065

34.TWi (company spelling) International LLC — New
DBA TWi Pharmaceuticals USA
8001 Irvine Center Drive Suite 400
Irvine, CA 92618

35.Virtus Pharmaceuticals LLC — New
2649 Causeway Center Drive
Tampa, FL 33619

Mr. Carrier arrived at 9:20 a.m.

b) Pharmacist Clinicians:

Motion: Approve registration as pharmacist clinician with prescriptive authority to include controlled substances for Teri Rolan, 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 with no controlled substances for Larry Pineda, motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: Approve the new protocol for existing license for Linh Wilkinson, Monica Aragon and Terra Liddil, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

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

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

Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson to go into closed session at 9:15 a.m., to discuss the MTP report. Mr. Cross, Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Mr. Mazzoni and Mr. Anderson voted unanimously to pass the motion. Absent were Ms. Saavedra and Mr. Carrier.

The board went back into open session at 9:50 a.m. and the only issues discussed were the MTP report and licensees reporting to the examining committee.

a) Licensees ordered by examining committee to register with MTP or any board action will necessitate MTP reporting:

The board will send a list of licensees that are ordered to be interviewed by the examining committee to MTP to be included on the report that is presented at every board meeting.

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

The Chairman Danny Cross opened the rule hearing at10:00 a.m. and took roll call. Present were Mr. Carrier, Mr. Anderson, Mr. Mazzoni, Ms. Mendez-Harper, Ms. Yarbrough, Mr. Woodul and Chairman Cross. Absent was Ms. Saavedra. Also present were board counsel Roscoe Woods, Executive Director, Ben Kesner, and Administrative Secretary, Debra Wilhite.

The Chairman entered the notice of hearing as exhibit #1, exhibit #2 proposed language for 16.19.5 NMAC, no written comments; exhibit #3 proposed language for 16.19.6 NMAC, written comments exhibit #4 (to be discussed after rule hearing); exhibit #5 proposed language for 16.19.12 NMAC, no written comments; exhibit #6 proposed language for 16.19.20.67 NMAC; exhibit #7 proposed language for 16.19.29 NMAC, exhibit #8 proposal from Mr. Flansbaum, exhibit #9 written comments from Mary Staples; and the sign in sheet as exhibit #10.

Ms. Saavedra arrived at 10:25 a.m.

a) 16.19.5 Intern Training Period: See Appendix A

Motion: Adopt language as amended in 16.19.5 NMAC. Motion made by Mr. Anderson, seconded by Mr. Woodul, board voted unanimously to pass the motion.

b) 16.19.6.23 D (5) Prescription Transfer: See Appendix B

Motion: Adopt language as amended in 16.19.6.23 D(5) NMAC. Motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

c) 16.19.12 Intern Fee: See Appendix C

Motion: Adopt language as amended in 16.19.12 NMAC. Motion made by Mr. Woodul, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

d) 16.19.20.67 Hydrocodone proposed change: See Appendix D

Motion: Table language as amended in 16.19.20.67 NMAC until April board meeting. Motion made by Mr. Carrier, seconded by Mr. Anderson, board voted unanimously to pass the motion.

e) 16.19.29 Controlled Substances Prescription Monitoring: See Appendix E
i) Proposal from Carl Flansbaum

Motion: Adopt language as amended in 16.19.29 NMAC. Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

5. Carl Flansbaum – PMP Report (30 – 45 minutes): See Appendix F

The PMP Director, Carl Flansbaum stated that the PMP will cease to exist if issues regarding the grant being processed by RLD and the maintenance contract for Optimum are not addressed.

6. Committee Reports and Board Actions:

Rich Mazzoni/Cheranne McCracken -16.19.6 NMAC new section 28 automated filling systems proposed language: See Appendix G

Motion: Notice 16.19.6 NMAC new section 28 for the April 2015 board meeting. Motion made by Mr. Carrier, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

7. 1:30 p.m. – 2:00 p.m. Joe Anderson, Barbara Maddoux and Ernie Dole – 16.2.18.18 NMAC – 16.2.18.22 NMAC Proposed language for educational requirements for intravenous therapy prescriptive authority: See Appendix H
Barbara Maddoux, Ernie Dole, Fiquet Duckworth and Mr. Joe Anderson presented the proposed educational language for intravenous therapy prescriptive authority and asked for the boards' approval.

Motion was made by Ms. Mendez-Harper, seconded by Mr. Anderson to approve the proposed language as presented for section 16.2.18.18 NMAC – 16.2.18.22 NMAC, board voted unanimously to pass the motion.

8. Case Presentations:

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

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

Inspector Kesner:	2014-047/NCA	2014-073/close	2014-085/VS
Inspector B. Padilla:	2012-086/NCA	2013-039/NCA	2013-059/close
	2014-015/DR	2014-027/NCA-AL	2014-036/close-BCS
Inspector A. Padilla:	2014-066/VS	2014-068/NCA	
Cheranne McCracken:	2014-004/close	2014-046/close	2014-067/NCA
	2014-070/close-DA	2015-001/NCA	

PMP Director Carl Flansbaum:	2015-002P	2015-003P	2015-004P	2015-005P
	2015-006P	2015-007P	2015-008P	2015-009P
	2015-010P	2015-011P	2015-012P	2015-013P
	2015-014P	2015-015P	2015-016P	

Ms. Saavedra left at 4:22 p.m.

Motion: **All PMP cases issue NCA w/pre-nca settlement agreement:** 2015-002P, 2015-003P, 2015-004P, 2015-005P, 2015-006P, 2015-007P, 2015-008P, 2015-009P, 2015-010P, 2015-011P, 2015-012P, 2015-013P, 2015-014P, 2015-015P, 2015-016P. Motion made by Ms. Mendez-Harper,seconded by Mr. Woodul, board voted unanimously to pass motion.

Motion: **Close cases:** 2014-073, 2014-059, 2014-036 and 2014-004, 2014-046 and 2014-070. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: **Issue NCA to revoke:** 2015-001. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: **Issue an NCA to deny**: 2014-067. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue an NCA for suspension**: 2014-068. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue an NCA w/pre-settlement agreement and advisory letter**: 2014-027. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue an NCA w/pre-settlement agreement**: 2014-047. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

NCA = Notice of Contemplated Action
DR = Default Revocation
AL = Advisory Letter
VS = Voluntary Surrender
DA = District Attorney
BCSO = Bern. County Sheriff Office

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

2013-040 – Main Street Family Pharmacy PH3262 – Default Revocation:
2014-018 – Maria Martinez PT8050 – Default Revocation:

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to approve the default revocation for 2013-040 and 2014-018, board voted unanimously to pass the motion.

2014-054P – American Specialty Pharmacy PH3437 – Stipulated Agreement:

Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to approve the stipulated agreement for 2014-054P, board voted unanimously to pass the motion.

2014-015 – Gregory Looper PT9094 – Default Revocation:

Motion made by Ms. Mendez-Harper, seconded by Mr. Carrier to approve the default order for 2014-015, board voted unanimously to pass the motion.

2014-043 – Martin Fritsch PT309 – Stipulated Agreement:

Motion made by Ms. Mendez-Harper, seconded by Mr. Carrier to approve the stipulated agreement for 2014-043, board voted unanimously to pass the motion.

2014-055P – California Pharmacy & Compounding PH3136 – Stipulated Agreement:
2014-056P – Healthy Options Inc. PH1993 – Stipulated Agreement:

Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough to approve the stipulated agreement for 2014-055P and 2014-056P, board voted unanimously to pass the motion.

2014-058P – Lowe's #55 Pharmacy PH2516 – Stipulated Agreement (modification request):

Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul to deny the request of the licensee to modify the stipulated agreement for 2014-058P, Ms. Mendez-Harper voted yes, Mr. Woodul voted yes, Mr. Anderson voted yes, Ms. Buesing voted yes, Mr. Cross voted yes, Ms. Yarbrough voted yes and Mr. Carrier voted no. The motion passed.

2014-060P – Michael's Prescription Corner PH2509 – Stipulated Agreement:

Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul to approve the stipulated agreement for 2014-060P, board voted unanimously to pass the motion.

2014-066 – Voluntary Surrender:
2014-085 – Voluntary Surrender:

Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough to approve the voluntary surrender for 2014-066 and 2014-085, board voted unanimously to pass the motion.

10. Recess for the day: The Pharmacy Board meeting was recessed at 5:40. p. m. and will reconvene at 9:00 a.m. tomorrow, Friday January 23, 2015.

Friday, January 23, 2015

1. Procedural Items:

9:00 a.m. Call to Order: The meeting of the Pharmacy Board was called to order by Chairman Cross at 9:05 a.m. on January 22, 2015.

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	**P** Allen Carrier

Ms. Saavedra was in attendance at 9:15 a.m.

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

a) 16.19.6 NMAC new section 27 Automated Drug Dist. Systems in Health Care Facilities: See Appendix I

Motion: Table language as amended in 16.19.6 NMAC to take back to committee and present at the April board meeting. Motion made by Ms. Saavedra, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

b) 16.19.36 revised re Compounded Sterile Preparations: See Appendix J

Motion: Adopt language as amended in 16.19.36 NMAC. Motion made by Mr. Anderson, seconded by Ms. Buesing, board voted unanimously to pass the motion.

3. 11:00 a.m. – 12:00 p.m. Public/Professional Requests/Waiver Petitions*:

Los Angeles Biomedical Research Institute: Request to be exempt from 16.19.6.2 NMAC for registering in New Mexico as a non-resident pharmacy, will be shipping minimal medications to patients within NM.

Motion made by Ms. Saavedra, seconded by Mr. Anderson to approve the waiver for one (1) year, board voted unanimously to pass the motion.

DWI Detention-Treatment Project: Request to amend the existing waiver to add HEP B vaccine for the period of the original waiver expiration date of 2016.

San Juan County Juvenile Services Complex: Request to amend the existing waiver to add HEP B vaccine for the period of the original waiver expiration date of 2016.

Motion made by Ms. Saavedra, seconded by Mr. Woodul to approve the waivers for DWI Detention and San Juan County, board voted unanimously to pass the motion.

Turquoise Lodge Hospital: See Appendix K
Mr. Joel Villareal was present to request a waiver of 16.19.7.9 F to dispense Suboxone to individuals as outpatients for a clinical study to compare Vivitrol to Suboxone.

Motion made by Ms. Saavedra, seconded by Mr. Woodul to approve waiver of 16.19.7.9 F NMAC to dispense suboxone to individuals as outpatients for a clinical study for the duration of one year, Ms. Saavedra voted yes, Mr. Woodul voted yes, Mr. Carrier voted yes, Mr. Anderson voted yes, Ms. Buesing

voted yes, Mr. Cross voted yes, Ms. Mendez-Harper voted yes, Ms. Yarbrough voted yes and Mr. Mazzoni voted no. The motion passed.

The Retreat-Gardens: Shauna Porter was present to request that the *Retreat Gardens facility*, located on Jackie Rd, Rio Rancho, be added for approval to contain an emergency supply of controlled substances II-V, in the automated iStat dispensing machine and E-kits located at the Jackie Rd. facility.

Motion made by Ms. Saavedra, seconded by Mr. Mazzoni to approve the emergency supply of controlled substances to be contained within the iStat and E-kits, for the duration of 18 months, board voted unanimously to pass the motion.

4. Litigation Update*:

a) Clarify responsibilities/designate a board Custodian of Records and Chief Records Officer: The board staff will discuss administratively.

b) IPRA training for Records Custodian, Chief Records Officer and Records Liaison(s): The board staff will discuss administratively.

c) 2012-086 - Ronald Inkrott RP7132– Violation of Settlement Agreement – Immediate Suspension - Request for Notice of Hearing:

Motion: **Issue an NCA for immediate suspension**: 2012-086. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

d) 2013-039 - Armin Quedzuweit RP7774– Violation of Decision and Order – Request Order to Show Cause:

Motion: **Issue NCA to revoke for 10 years:** 2014-039. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion. Mr. Mazzoni recused himself from the vote.

e) 2006-145 – Douglas Krell CS10164 – Violation of Order – Request Order to Show Cause:

Motion: **Issue an NCA to deny**: 2006-145. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

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

a) Outsourcing Facilities 16.19.8 NMAC & 16.19.6 NMAC: See Appendix L
Director, Ben Kesner has appointed an "Outsourcing Committee" to be chaired by Inspector, Kris Mossberg and includes members Inspector, Cheranne McCracken, Teri Rolan and board member Chris Woodul. The committee will present proposed language at the April 2015 board meeting.

b) 16.19.11. Proposed Change: See Appendix M
Proposed language regarding "24-hour/365 day on-site nurse may use an emergency drug tray containing controlled substances" will be sent to the Tele-pharmacy committee to present at the April 2015 board meeting.

c) Class D clinics – Pre-licensing: See Appendix N
A self-assessment form will be required for licensing a class D clinic.

d) Arctic Lobo DMAT training: Director, Ben Kesner attended the training and had asked Mr. Piatt to attend the board meeting to give a presentation. Mr. Piatt was not in attendance.

e) Naloxone: Table until a later date for discussion.

f) MTP – Inspector B. Padilla: Discussed in closed session on Thursday during MTP report.

g) Christus St. Vincent remodel: Table until a later date for discussion.

h) Board policy regarding board actions: Inquiries have been made regarding the asterisk (*) on licenses due to disciplinary action and how long the asterisk will appear on their license.

Motion made by Ms. Buesing, seconded by Ms. Mendez-Harper to have the asterisk appear indefinitely on the license and all actions will be posted to our website and are reported to HIPDB, Ms. Buesing voted yes, Ms. Mendez-Harper voted yes, Ms. Saavedra voted yes, Mr. Anderson voted yes, Mr. Mazzoni voted yes, Mr. Cross voted yes, Ms. Yarbrough voted yes, Mr. Woodul voted yes, and Mr. Carrier voted no. The motion passed.

i) Inspectors – down two positions: The two positions will be posted via SPO and in the Albuquerque Journal within the month. Five applicants previously applied but did not meet the hiring matrix requirements.

j) Vehicles: The board inspectors have received 6 new vehicles and have returned the old vehicles to GSD in Santa Fe.

k) Legislature: See Appendix O
SB 21 (drug take back) and SB 22 (hotline to report opioid over-prescribing) are being presented and the board has taken a position in opposition of the bills due to financial impact and burden, and instructed Director, Ben Kesner to inform the legislature.

Motion made by Mr. Mazzoni, seconded by Mr. Anderson to direct Mr. Kesner to inform the legislature that the board is in opposition of SB 21 and SB22, the board voted unanimously to pass the motion.

l) Prescription drug abuse prevention bill introduction – Tom Udall: See Appendix P
The board instructed Director, Ben Kesner to send an email to Senator Tom Udall in support of the bill.

m) NABP Midyear – May 16-19, 2015 Delegates: Director, Ben Kesner, Mr. Mazzoni, Ms. Mendez-Harper and Ms. Saavedra and one inspector will request attendance to the NABP mid-year conference to be held in New Orleans, LA.

n) Office – discussion of new address: The board office will be moving to a new location of of San Antonio and I-25 sometime mid-year, arrangements are still in the discussion phase.

o) NMBOP staff training SNS (strategic national stockpile) – Adela: Inspector Adela Padilla and Mr. Larry Loring are on the SNS team and are in charge of operating the warehouse (undisclosed) in the event of a national emergency. In order to facilitate the arduous process and events of an emergency , the pharmacy board staff and inspectors will be obtain training by the CDC during two sessions to be scheduled in May 2015.

8. Adjournment: With no further business, Ms. Mendez-Harper made a motion to adjourn the Pharmacy Board meeting at 1:18 p.m., seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Appendix A

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 5 INTERNSHIP TRAINING PROGRAM

16.19.5.7 DEFINITIONS: As used in the internship program.

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

Appendix B

16.19.6.23 PRESCRIPTIONS:

A. A valid prescription is an order for a dangerous drug given individually for the person for whom prescribed, either directly from the prescribing practitioner to the pharmacist, or indirectly by means of a written order signed by the practitioner. Signed by the practitioner includes handwritten signature, stamped or printed images of the practitioners handwritten signature or electronic signature as defined in Paragraph (1) of Subsection F of 16.19.6.23 NMAC. Every prescription record shall contain the name and address of the prescriber, the name and address of the patient, the name and strength of the drug, the quantity prescribed, directions for use, the date of issue, and preferably the diagnosis or indication.

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

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

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

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

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

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

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

<u>(5) A pharmacy may not refuse to transfer original prescription information to another pharmacy who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescrpiton information must be done in a timely manner.</u>

Appendix C

16.19.12.9	**REGISTRATION FEES:**	
A.	Registration by Examination	$200.00
B.	Registration by Reciprocity	$200.00
C.	Registration as an Intern	~~$30.00~~ $25.00 per year

16.19.12.12	**LICENSE/REGISTRATION RENEWAL:**	
A.	Pharmacist license renewal for active	$200.00 bi-ennially
B.	Pharmacist license renewal for in-active	$70.00 bi-ennially
C.	Intern renewal	~~$30.00~~ $25.00 per year

Appendix D

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.

E. NARCOTIC DRUGS: Unless specifically exempt or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of the following narcotic drugs, or any salts thereof.

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage units, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~**(3)** Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.~~

~~**(4)** Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.~~

~~**(5)** Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.~~

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

Appendix E

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 29 CONTROLLED SUBSTANCE PRESCRIPTION MONITORING PROGRAM

16.19.29.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.29.1 NMAC - N, 07-15-04]

16.19.29.2 SCOPE: All persons ~~or entities~~ that dispense controlled substances pursuant to prescriptions from practitioners~~.~~ and practitioners who dispense controlled substances directly to a patient under their care.
[16.19.29.2 NMAC - N, 07-15-04]

16.19.29.3 STATUTORY AUTHORITY: ~~Section 30-31-16 of the Controlled Substance Act.~~ The Controlled Substances Act, NMSA 1978, Sections 30-31-1 through 30-31-~~42~~ 41 ~~NMSA 1978~~ authorizes the board of pharmacy to promulgate ~~regulations~~ rules and charge reasonable fees regarding controlled substances. Section 30-31-16 authorizes the board to collect information regarding controlled substances.
[16.19.29.3 NMAC - N, 07-15-04]

16.19.29.4 DURATION: Permanent.
[16.19.29.4 NMAC - N, 07-15-04]

16.19.29.5 EFFECTIVE DATE: 07-15-04, unless a later date is cited at the end of a section.
[16.19.29.5 NMAC - N, 07-15-04]

16.19.29.6 OBJECTIVE: The objective of Part 29 of Chapter 19 is to promote the public health and welfare by detecting and preventing substance abuse and misuse and encouraging appropriate treatment of pain and other conditions for which controlled substances are prescribed. The purpose of the program ~~system~~ is to improve access to controlled substance~~s~~ prescription information for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. The program's objectives will include education of the public and health care professionals regarding the nature and extent of the problem of drug abuse, appropriate prescribing and use of controlled substances, and the medical treatment options for abusers of controlled substances and pain management.
[16.19.29.6 NMAC - N, 07-15-04]

16.19.29.7 DEFINITIONS:

A~~B~~. "Board of pharmacy" or "board" means the state agency responsible for the functions listed in 16.19.29.8 NMAC.

B~~A~~. "Controlled substance" has the meaning given such term in NMSA 1978, Section 30-31-2 ~~NMSA~~.

C~~D~~. "Dispenser" means the person who delivers a Schedule II - V controlled substance as defined in Subsection B~~E~~ to the ~~ultimate user~~ patient, but does not include the following:

(1) a licensed hospital pharmacy that distributes such a substance~~s~~ for the purpose of inpatient hospital care;

(2) a practitioner, or other authorized person who administers such a substance; ~~or~~

(3) a practitioner who dispenses to the patient no more than twelve (12) dosage units or seventy-two (72) hours' worth (whichever is less) of such a substance

(4)~~(3)~~ a wholesale distributor of a Schedule II - V controlled substance;

(5)~~(4)~~ clinics, urgent care or emergency departments dispensing ~~no more than 12 dosage units to an individual patient within a 72 hour period~~ to the patient no more than twelve (12) dosage units or seventy-two (72) hours' worth (whichever is less) of such a substance or;

(5) a veterinarian~~s~~ or veterinary clinic~~s~~ dispensing to non-human patients

D~~C~~. "Patient" means the ultimate user of a drug for whom a prescription is issued and for whom a drug is dispensed.

E. "Person" means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture or any legal or commercial entity.

F. "PMP director" means the individual authorized by the board to administer the PMP

G. "PMP ~~R~~report" means a compilation of data generated from the PMP concerning a patient, a dispenser, a practitioner, or a Schedule II - V controlled substance.

H. "Practitioner" means a person maintaining licensure pursuant to state law that allows him or her to prescribe medications in accordance with that licensure

I~~E~~. "Prescription M~~m~~onitoring P~~p~~rogram" ~~(PMP)~~ or "PMP" means a program as described in 16.19.29.6 NMAC which includes a centralized system to collect, monitor, and analyze electronically, for Schedule II – V controlled substances, prescribing and dispensing data submitted by ~~pharmacies and dispensing practitioners~~ dispensers, of which the data is to be used to support efforts in education, research, enforcement and abuse prevention.

J ~~F~~. "Schedule ~~II, III, IV and V~~ II – V controlled substance" means a substance~~s that are~~ listed in Schedules II, III, IV, and V ~~of the schedules provided under~~ as set forth in NMSA 1978, Sections 30-31-5 to 30-31-10 ~~of NMSA~~ board regulations, or the federal controlled substances regulation (21 U.S.C. 812).

K. "State" means the state of New Mexico

[16.19.29.7 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12]

16.19.29.8 ~~REQUIREMENTS FOR THE~~ MANDATORY REPORTING OF PRESCRIPTION ~~MONITORING PROGRAM~~ INFORMATION TO THE PMP:

A. The board shall monitor the dispensing of all Schedule ~~II, III, IV and V~~ II - V controlled substances by all ~~pharmacies~~ dispensers licensed to dispense such substances to patients in this state.

B. Each dispenser shall submit to the board by electronic means information regarding each prescription dispensed for a drug included under Subsection A of this section. ~~Information to be reported shall conform to the standards developed by the American society for automation in pharmacy (ASAP) and published in the "ASAP telecommunications format for controlled substances", 2009 4.1 edition "Implementation Guide: ASAP Standard for Prescription Monitoring Programs Version 4, Release 2".~~ Information to be submitted for each prescription as well as the standards for how this information shall be formatted, not contrary to law, is defined in the PMP ~~Data Collection~~ Reporting manual available on the state PMP Website at http://nmpmp.org. shall include at a minimum:

(1) dispenser DEA number;
(2) date prescription filled;
(3) prescription number;
(4) whether the prescription is new or a refill;
(5) NDC code for drug dispensed;
(6) quantity dispensed;
(7) patient name;
(8) patient address;
(9) patient date of birth;
(10) prescriber DEA number;
(11) date prescription issued by prescriber;
(12) and payment classification.

C. Each dispenser shall submit the information in accordance with transmission methods and frequency established by the board; but shall report at least ~~every seven days~~ within one business day of the prescription being filled. The PMP ~~executive~~ director shall have the authority to approve submission schedules that exceed one business day ~~seven days~~. ~~A record of each controlled substance prescription dispensed must be transmitted to the boards' agent electronically~~.

D. Corrections to information submitted to the PMP must also be addressed including:

(1) File upload or "Outstanding Uncorrected Errors" as defined in the Data Reporting Manual;

(2) Prescriptions that were not dispensed to the patient must be voided from the PMP

(3) Incorrect information in prescriptions records submitted to the PMP must be corrected as soon as possible after the dispenser has been notified

[16.19.29.8 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12]

16.19.29.9 ~~ACCESS TO~~ DISCLOSURE OF PMP INFORMATION: ~~Practitioners registered with the program may designate one delegate per practice site to register with the program for the purpose of requesting and receiving reports for the practitioner.~~

A. Prescription information submitted to the board shall be confidential and not subject to public or open records laws the Inspection of Public Records Act, NMSA 1978, Sections 14-2-1 through 14-2-12, except as provided in Subsections C, D and E C though G of this 16.19.29.9 NMAC.

A Prescription information submitted to the board shall not be subject to the Inspection of Public Records Act, NMSA 1978, Sections 14-2-1 through 14-2-12 and shall be confidential except as provided in Subsections C though G of this 16.19.29.9 NMAC.

B. The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to persons except as provided in Subsections C, D and E C though G of this 16.19.29.9 NMAC.

C. After receiving a complaint, the board inspectors mayshall review the relevant prescription information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the board shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information as required for an investigation.

D. The board will establish written protocols for reviewing the prescription data reported. These protocols will be reviewed and approved by the board as needed but at least once every calendar year. These protocols will define information to be screened, frequency and thresholds for screening and the parameters for using the data. Data will be used to notify providers, patients and pharmacies to educate, provide for patient management and treatment options.

DE. The board shall be authorized to provide data in the prescription monitoring program PMP information to the following persons:

(1) persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients;

(2) a delegate designated by a practitioner. A practitioner (who must also maintain an active account) can designate only one delegate for the purpose of requesting and receiving PMP reports for the practitioner.

(3) New Mexico medical board, New Mexico board of nursing, New Mexico board of veterinary medicine, New Mexico board of dental health care, board of examiners in optometry, osteopathic examiners board, acupuncture & oriental medicine board, and podiatry board for their licensees;

(3) state licensing boards, including the medical board, board of nursing, board of veterinary medicine, board of dental health care, board of examiners in optometry, osteopathic examiners board, acupuncture & oriental medicine board, and podiatry board, as the PMP information relates to their licensees;

(4)(5) local, state and federal law enforcement or prosecutorial officials engaged in an ongoing investigation of an individual in the enforcement of the laws governing licit drugs;

(5)(6) the state human services department regarding medicaid program recipients;

(6)(7) a state metropolitan, magistrate and district courts, state or a federal court(s), as required by a under grand jury subpoena or criminal court order;

(7) state drug court personnel as authorized by the PMP director

(8) personnel of the board for purposes of administration and enforcement of this regulation rule or of 16.19.20 NMAC or;

(9) the controlled substance prescription monitoring program of another state or group of states with whom the state has established an interoperability agreement;

(10)(4) professional licensing authorities of other states if their licensees practice in the this state or prescriptions provided by their licensees are dispensed in the this state;

(11)(2) a an living individual who request's their his or her own prescription monitoring information PMP report in accordance with procedures established under NMSA 1978, Section 61-11-2(D) NMSA, 1978 and Subsection G H of 16.19.6.23 NMAC, or an agent authorized by the living individual along with a valid HIPAA release form or court issued subpoena, or;

(12)(10) a parent to have access to the prescription records about his or her minor child, as his or her minor child's personal representative when such access is not inconsistent with state or other laws;

E. (11) The board shall use de-identified data obtained from the prescription drug monitoring PMP database to identify and report to state and local public health authorities the geographic areas of the state where anomalous prescribing dispensing or use of controlled substances is occurring.

F. (12) The board shall share the prescription drug monitoring PMP database data with the department of health for the purpose of tracking inappropriate prescribing and misuse of controlled substances, including drug overdose.

G. Within the normal functions of PMP information management, analysis and review, any prescribing and/or dispensing patterns of Schedule II - V controlled substances that may be indicative of abuse, misuse or diversion of

~~these substances shall be reported to the appropriate law enforcement or professional licensing, certification or regulatory agency or entity and prescription information required for an investigation shall be provided to these persons.~~

H~~F~~. The board shall provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients and persons who have received prescriptions from dispensers.

I. PMP information gained from other states' prescription monitoring programs shall not be subject to civil subpoena, nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding for any reason.

[16.19.29.9 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12]

16.19.29.10 RESERVED ~~**REPORTS:** A written request will be filed with the board prior to release of a report.~~

~~**A.** Persons listed in Paragraphs (1) through (10) of Subsection E of 16.19.29.9 NMAC must submit a written request listing the information for the report.~~

~~**B.** Reports will be prepared and delivered to the requesting person via U.S. mail, facsimile, or other electronic means.~~

~~**C.** Reports may be provided by secured electronic means after verification of electronic request.~~

~~**D.** The program will produce reports for the board that evaluate the effectiveness of the program and assist in identifying diversion of controlled substances. The program will produce statistical reports to evaluate the dispensing of controlled substances and utilization of the program. These reports will be able to provide data on:~~

~~(1) number of solicited reports from prescribers for a specified time period;~~

~~(2) number of solicited reports from a specified prescriber for a specified time period;~~

~~(3) number of solicited reports from pharmacies for a specified time period;~~

~~(4) number of solicited reports from a specified pharmacy for a specific time period;~~

~~(5) number of solicited reports from other unauthorized individuals for a specified time period;~~

~~(6) number of individuals receiving a prescription for a specified schedule for a specified time period;~~

~~(7) threshold report of number of individuals receiving a prescription for a specified schedule from 6 or more prescribers or 6 or more pharmacies within a specified time period;~~

~~(8) number of solid dosage units for a specified schedule for pain relievers, tranquilizers, stimulants and sedatives for a specified time period;~~

~~(9) list of individual prescriptions for a specified zip code or state code;~~

~~(10) number of prescriptions for a specified zip code;~~

~~(11) number of dosage units for a specified drug and specified zip code.~~

~~**E.** The board shall receive a quarterly program outcomes report from staff or contractors. A statistical analysis of the data that does not include protected information should be reported on the web site or in the newsletter.~~

[16.19.29.10 NMAC - N, 07-15-04; A, 06-11-11]

16.19.29.11 AUTHORITY TO CONTRACT: The board ~~is authorized to~~ may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the PMP ~~prescription monitoring program~~. ~~Any~~ A contractor shall ~~be bound to~~ comply with the provisions regarding confidentiality of prescription information in 16.19.29.9 NMAC ~~of this regulation~~ and shall be subject to the penalties specified in 16.19.29.~~12~~ 14 NMAC ~~of this regulation for unlawful regulations~~.

[16.19.29.11 NMAC - N, 07-15-04]

16.19.29.12 REGISTRATION FOR ACCESS TO ~~PRESCRIPTION~~ PMP INFORMATION:

~~**A.** Practitioners with individual drug enforcement administration (DEA) issued numbers will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued to the practitioner. One subaccount per practitioner account is authorized for an agent of the practitioner. The agent designated by the practitioner will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued to the agent.~~

~~**B.** Pharmacies with DEA issued numbers will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued. Pharmacies will designate one individual who will complete and submit a hard copy written, signed and notarized~~

~~application. After verification of submitted information, a username and password will be issued to the individual. Pharmacies will not be permitted to obtain a subaccount.~~

~~**C.** All registrations will be renewed every three years by completing and submitting a new application.~~

~~**D.** All registrants to the prescription monitoring program will complete a web based training program approved by the board~~

A. Persons authorized for access to PMP information as listed in 16.19.29.9(D)(1)-(7) NMAC must apply for access as described at the PMP website located at http://nmpmp.org.or as otherwise indicated. Persons granted access must maintain individual accounts and shall not share access information with other persons.

B. All persons authorized for access to PMP information and applying for such access to the PMP shall successfully complete a web based training program as determined by the PMP director.

C. Persons reporting prescription information to the PMP, but not authorized for access to PMP information must also apply for access as described at the PMP website located at http://nmpmp.org. or ss otherwise indicated.

D. The PMP director shall have the authority to set account access and registration renewal requirements necessary for accounts to be considered active and shall also have the authority to cancel inactive accounts.

[16.19.29.12 NMAC - N, 07-15-04; 16.19.29.12 NMAC - N, 06-11-11; A, 08-31-12]

16.19.29.13 INFORMATION EXCHANGE WITH OTHER PRESCRIPTION MONITORING PROGRAMS:

A. The ~~New Mexico~~ board ~~of pharmacy~~ may provide ~~prescription monitoring~~ PMP information to other states' prescription monitoring programs and such information may be used by those programs consistent with the provisions of ~~the~~ this rule.

B. The ~~New Mexico~~ board ~~of pharmacy~~ may request and receive ~~prescription monitoring~~ PMP information from other states' prescription monitoring programs and may use such information under provisions of this rule.

C. The ~~New Mexico~~ board ~~of pharmacy~~ may develop the capability to transmit information to and receive information from other prescription monitoring programs employing the standards of interoperability.

D. The ~~New Mexico~~ board ~~of pharmacy is authorized to~~ may enter into written agreements with other states' prescription monitoring programs or other ~~entities~~ persons hosting compatible information sharing technologies for the purpose of describing the terms and conditions for sharing of ~~prescription~~ PMP information under this section

[16.19.29.13 NMAC - N, 07-15-04; 16.19.29.13 NMAC - N, 06-11-11]

16.19.29.14 PENALTIES:

A. A dispenser who knowingly fails to submit prescription ~~monitoring~~ information to the board as required by this ~~regulation~~ rule or knowingly submits incorrect prescription information shall be subject to disciplinary proceedings as defined in NMSA 1978, Section 61-11-20 ~~NMSA~~.

B. Prescription information submitted to the ~~New Mexico prescription monitoring program (~~PMP~~)~~ is protected health information. ~~Registrants~~ Persons with access to the PMP ~~are required to~~ shall exercise due diligence in protecting this information and access it only as necessary in the course of legitimate professional regulatory or law enforcement duties.

C. ~~Individual registrants~~ A person found to be in violation of this section may be subject to one or more of the following actions.

(1) Termination of access to ~~the program~~ PMP information.

(2) A complaint may be filed with his or her appropriate professional ~~regulatory~~ licensing entities.

[16.19.29.14 NMAC - Rn, 16.19.29.12 NMAC, 06-11-11; A, 08-31-12]

16.19.29.15 SEVERABILITY: If any provision~~s~~ of this ~~regulation~~ rule or its application ~~thereof~~ to any person or circumstance is held invalid or unenforceable, the ~~invalidity does not affect other provisions or applications of the regulation which can be given effect without the invalid provisions or applications, and to this end the provisions of this regulation are severable~~ remainder of this rule shall not be affected and shall be valid and enforceable.

[16.19.29.15 NMAC - Rn, 16.19.29.13 NMAC, 06-11-11]

HISTORY OF 16.19.29 NMAC: [RESERVED]

Appendix F

Case Number	CURRENT 6 month count	1/13/2015	12/30/2014	12/16/2014	12/2/2014	11/18/2014	10/28/2014	10/14/2014	9/30/2014	9/16/2014	9/2/2014	8/19/2014	7/29/2014	7/15/2014	7/1/2014
2015-002P	3					X							X		X
2015-003P	6		X	X		X		X	X		X				
2015-004P	4		X			X						X			X
2015-005P	4			X		X	X			X					
2015-006P	3						X	X		X					
2015-007P	3		X							X	X				
2015-008P	3						X					X		X	
2015-009P	3				X					X		X			
2015-010P	4	X				X	X		X						
2015-011P	3				X									X	X
2015-012P	3	X					X				X				
2015-013P	4	X				X	X			X					
2015-014P	4		X	X			X				X				
2015-015P	3		X					X			X				
2015-016P	4				X	X	X	X							

X	Initial delinquency
X	repeat delinquency
X	repeat delinquency threshold met to submit for NCA review

Past NCAs (Board Date 10/16/2014)															
Case #	Issue Date	Dates as Above													
2014-062P	10/31/2014				X										
2014-063P	10/31/2014					X	X								
2014-064P	10/31/2014		X	X											

***The board may go into Executive Session to discuss these items and any other items pursuant to Section 10-15-1H(1), Section 10-15-1H(2) or Section 10-15-1H(7) of the Open Meeting Act. Agenda items may be executed at any time during the meeting to accommodate hearings.**
H(1) are licensing matters, H(2) is limited to personnel matters, H(7) is pending or threatened litigation.

Appendix G

16.19.6.28 AUTOMATED FILLING SYSTEMS:

A. Definitions. The following definitions shall apply to this section:

(1) "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 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.

(2) "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.

(3) "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.

(4) "Repackager" means a repackager registered with the United States Food and Drug Administration (FDA).

(5) "Prepacked" means any drug that has been removed from the original packaging of the manufacturer or an FDA repackager and is placed in a properly labeled dispensing container by a pharmacy for use in an automated filling system for the purpose of dispensing to the ultimate user from the establishment in which the prepacking occurred.

B. 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.

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

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

(1) Pharmacy personnel establish and follow a policy and procedure manual that complies with paragraph E 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 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 system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(3) A pharmacist performs a prospective DUR and verifies the accuracy of the prescription information used by or entered into the 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 and strength, prepacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or prepacked medication previously verified by a pharmacist;

(5) The medication to be dispensed is selected, filled, labeled, and sealed in the dispensing container by the system or dispensed by the system in a manufacturer's unit of use package or a prepacked container;

(6) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication and strength, prepacked 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 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.

E. Policies and Procedures. Pharmacists verifying prescriptions pursuant to paragraph D 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 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 system and any accompanying electronic verification system. At a minimum, the 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 system or electronic verification system that changes or alters the filling or electronic verification process;
(6) Training persons authorized to access, stock, or load the system in equipment use and operations;
(7) Tracking and documenting prescription errors related to the 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;
(13) Ensuring proper drug storage within the system, consistent with the manufacturer's specifications and the *United States Pharmacopoeia* (USP);
(14) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification system to ensure proper and accurate functioning.

F. 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.

G. Prepacking. A pharmacist, or a pharmacist intern or pharmacy technician under the direct supervision of a licensed pharmacist, may prepack drugs for other than immediate dispensing purposes provided that the following conditions are met:
(1) Prepacking occurs at the licensed pharmacy utilizing the system;
(2) Only products which will be dispensed directly to the patient may be prepacked;
(3) Containers utilized for prepacking shall meet standards specified by the USP, which has been incorporated herein by reference (e.g. Preservation, Packaging, Storage and Labeling section of the General Notices and Requirements). Where needed, light resistant containers shall be used;
(4) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, quantity, the name of the manufacturer or distributor, the expiration date and lot number, the date prepacked, and the identity of the person who prepacked it.
(5) A record of drugs prepacked must be kept, and include the following: the name and strength of the drug, lot number, name of manufacturer or distributor, expiration date (per USP requirements), date of prepacking, total number of dosage units (tabs, caps) prepacked, quantity per prepacked container, number of dosage units (tabs, caps) wasted, initials of prepacker and of pharmacist performing final check.
(6) All drugs prepacked by a pharmacist intern or pharmacy technician must undergo a final check by the pharmacist.

[16.19.6.27 NMAC]

Appendix H

This IV Therapy Education 16.2.18.18-22 has been approved by the BAOM at their meeting December 17,
2014.
It is the final module of expanded practice education for BOP approval.

INTRA VENOUS THERAPY EDUCATIONAL COURSE REQUIREMENTS

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TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 2 ACUPUNCTURE AND ORIENTAL MEDICINE PRACTITIONERS
PART 18 EXPANDED PRACTICE EDUCATIONAL COURSES FOR CERTIFICATION

16.2.18.18 INTRA VENOUS THERAPY EDUCATIONAL COURSE APPROVAL REQUIREMENTS FOR CERTIFICATION: The board will approve an intravenous therapy
educational course for certification after the educational course provider submits to the board:

A. The completed application form provided by the board.
B. The payment of the application fee for expanded practice educational course approval specified in 16.2.10 NMAC.
C. Documentation of having complied with all educational course approval general requirements defined in section 16.2.18.8.
D. Documentation demonstrating that it will provide the educational course general curriculum defined in section 16.2.18.1 0 NMAC .
E. Documentation demonstrating that it will provide the intravenous therapy educational course hours defined in section 16.2.18.20. NMAC.
F. Documentation demonstrating that it will provide the intravenous therapy educational course curriculum defined in section 16.2.18.21 NMAC.
G. Documentation that proposed test instruments have been reviewed and approved by a credentialed PhD psychometrician, as described in the ICE Credentialing Standards.
[16.2.18.18 NMAC- N, XX-XX-XX]

16.2.18.19 INTRAVENOUS THERAPY COURSE PREREQUISITES:
Only a New Mexico licensed DOM, in good standing, and board certified in basic iqjcction therapy, may apply for an intravenous therapy educational course in expanded practice.
C. Proof of current BLS/CPR certification, that will be current for 2 years, from an American
Heart Association provider.
D. Proof of completion of at least three (3) semester hours of college level biochemistry from an
accredited institution that provides evaluation of competencies by examination. A board approved
co ege eve on me course IS accepTa e.
[16.2.18.19-N-XX-XX-XX]

16.2.18. 20 INTRA VENOUS THERAPY EDUCATIONAL COURSE HOURS: The intravenous therapy educational coursework shall be completed within 2 years of commencement
of the course, 16.2.18. 7 G, and shall consist of a minimum of one hundred thirty seven (137) total
hours and with the minimum number of hours of education in the areas listed below;
A. A minimum of eight (8) hours in the pharmacology, biochemistry, relevant pharmaceutical law, including 16.19.36 NMP, differential diagnosis and clinical application relative to the selection, prescription, compounding and administration of the authorized substances in the intravenous therapy formulary.
B. A minimum of ten (10) hours in the drawing and sterile compounding, (in compliance with USP-797) of the authorized substances intended for infusion and injection utilizing approved aseptic technique and proper record keeping, storage and dispensing of substances. At least half of
these required hours shall be clinical practice.
C. A minimum oftwenty-four (24) hours in all aspects of safely performing phlebotomy, intravenous infusions and intravenous pushes including calculation of osmolarity. At least half of
these required hours shall be clinical practice with documented evidence of having prepared and
started at least 10 IV s. Proof of completion of a board approved phlebotomy course may be applied
toward a portion of these hours.
D. A minimum of twenty-four (24) hours in oxidative medicine (defined in 16.1.7 B (39), including; ozone therapy, ultraviolet blood irradiation (photoluminescence), hyperbaric oxygen therapy and the use of oxygen therapeutically. At least half of these required hours shall be in clinical practice.
E. A minimum of twenty-four (24) hours in nutritional IVs; vitamin C, Meyers Cocktails, vitamins, minerals, and amino acids,
F. A minimum of twenty four (24)) hours in detoxification, utilizing glutathione, phosphatidylcholine and Calcium EDT A including practice standards that meet the requirements on
file in the board office.
G. A minimum of sixteen '(16) hours in blood chemistry analysis: including instruction of normal value ranges, critical values, clinical implications of abnormal values, and whether these
values warrant reconsideration of proceeding with any intravenous therapy.
H. A minimum of five (5) hours in urine analysis: including evaluation of unprovoked and provoked nutrient and toxic element testing.
I. A minimum of one (I } hour in pharmaceutical law as provided by the New Mexico board of pharmacy.
J. A minimum of one W hour in oriental medic ine scope of practice relative to the authorized substances and techniques.
[16.2.18.20 NMAC - N, XX-XX-XX]

16.2.18.21 INTRAVENOUS THERAPY EDUCATIONAL COURSE CURRICULUM: The
intravenous therapy educational course curriculum shall provide the doctor of oriental medicine,
2
who successfully completes the course, with the knowledge and skills defined in section 10 of 16.2.18 NMAC and the following specific knowledge and skills.
A. tagnoshc p ileoo omy:
(1) Skill in drawing blood for diagnostic purposes using appropriate aseptic procedure.
(2) Knowledge of the needles, lancets, winged sets, syringes, vacutainer tubes, and other equipment used to draw blood for diagnostic purposes; and
(3) Knowledge of the various blood tests most relevant to the protocols being taught.
B. Intravenous therapy:
(1) Knowledge_and skill in the use of the equipment used for intravenous infusions; and
(2) Knowledge of the equipment used for an intravenous push; and
(3) Knowledge of the equipment used for injecting a bolus into an infusion; and
(4) Knowledge of the local anatomy of common infusion sites and skill in selecting an appropriate infusion site; and
(5) Knowledge of the authorized substances that are appropriate or not appropriate for intravenous infusion or injection from the intravenous therapy formulary; and
(6) Knowledge ofthe concept and importance of osmolarity, pH and skill in determining pH and calculating a given solution's Cilsmolarity using an osmolarity chart • simple algebraic equation or computer software; and
(7) Knowledge of prerequisite lab tests that should be evaluated prior to initiating intravenous therapy of any kind; and
(8) Skill in preparing and administering an intravenous push, intravenous infusion and injecting a bolus into an IV infusion; and
(9) Knowledge of the possible complications that could occur during an intravenous infusion or push and know how to identify, treat and manage these
complications.
(1 0) Know ledge of compatibility and sterile compounding procedures of authorized substances in the intravenous therapy formulary in compliance with the
compounding requirements of the US Pharmacopeia (USP-797}.
C. Oxidative medicine, photo-oxidation and the use of oxygen therapeutically:
(1) Knowledge of the biochemistry of oxidative medicine including the biological electron transfer sequence (BETS) oxidation and reduction (redox) reactions; and
(2) Know ledge and skill in the relevant clinical application and use of the authorized substances in the intravenous therapy formulary; and
(3} Knowledge of the history, physics, equipment and therapeutic use of ultraviolet blood irradiation (photoluminescence); and
(4) Knowledge of the history, physics, physiology and therapeutic use, contraindications and safety considerations of hyperbaric oxygen chamber therapy.
(5} Knowledge of Blood Borne Pathogen Training.
D. Detoxification and chelation therapy:
3

(1) Knowledge of the diagnostic tools available for determining and tracking the therapeutic
elimination of body burden of toxic elements including hair analysis, blood
--.....:=n=atysts"anti"Ufinalysrs wtttt provo-c"Sti<:5n-lfgetllS"!'1111tl
(2) Knowledge of how to determine that the kidneys, colon and liver are functioning appropriately prior to commencement of detoxification or chelation diagnostic
and therapeutic procedures; and
(3) Knowledge of the critical importance of, and methods for, optimizing kidney and bowel function, and phase 1 /phase 2 liver detox pathways, prior to and
during detoxification or chelation therapy, how to recognize when these systems are overburdened
and what to do if they are overburdened; and
(4) Knowledge of the biochemistry, clinical use, and safety concerns relevant to all modes of
administration of the authorized substances used in detoxification or
chelation therapy.
(5) Knowledge of how to explain to the patient the purpose of the therapy,
the expected outcome, alternatives and possible complications of the therapy that could occur. [16.2.18.21 NMAC-N,XX-XX-XX]
16.2.18.22 INTRA VENOUS THERAPY EXPANDED PRACTICE CERTIFICATION: The board shall only issue certification to applicants after successful completion of the Intravenous Therapy Expanded Practice Course, and successful completion and documentation of a practicum to include 300 hours under the supervision of a board approved physician and 150 case studies to be completed within 2 years of completion ofthe coursework. [16.2.18.22 NMAC- N, XX-XXXX]
4

Appendix I

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 6 PHARMACIES

16.19.6.27 Automated Drug Distribution Systems in Licensed Health Care Facilities

A. Scope. This section applies only to the use of automated drug distribution systems located within the facilities specified in paragraph B.

B. Definitions. For purposes of this section only, the terms defined in this section have the meanings given.

(1) "Automated drug distribution system", or "automated medication system" or "system" means a mechanical system that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains transaction information and records.

(2) "Health care facility" means a facility licensed under NMAC 16.19.11; or an inpatient hospice facility licensed pursuant to NMAC 16.19.10.12.

(3) "Managing pharmacy" means an in-state retail pharmacy licensed by the board, pursuant to NMAC 16.19.6 , that controls and is responsible for the operation of an automated drug distribution system.

(4) "Multi-Disciplinary Committee" means the pharmacist in charge and one or more representatives of the health care faciliaty;

(5) "Override medication" means:

(a) A drug that may be removed from an automated medication system prior to pharmacist review because the Multidisciplinary Committee has determined that the clinical status of the patient would be compromised by delay; or

(b) A drug determined by the Multidisciplinary Committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, which may be removed from an automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

(6) "Practitioner controlled medication" is a drug ordered, prepared and administered by a practitioner or under the practitioner's direct supervision.

C. Authorization.

A managing pharmacy may use an automated drug distribution system to supply medications for patients of a health care facility. The automated drug distribution system may be located in a health care facility that is not at the same location as the managing pharmacy. When located within a health care facility, the system is considered to be an extension of the managing pharmacy. When the automated drug distribution system is used to deliver routine doses of controlled substances, the managing pharmacy must submit an addendum application for the managing pharmacy's State Controlled Substances Registration, identifying the location, if controlled substances are utilized in the automated distribution system in a health care facility. The managing pharmacy must also submit and maintain a separate registration with the Drug Enforcement Administration.

D. Notification.

(1) At least 60 days prior to the initial use of an automated drug distribution system, the pharmacist-in-charge of the managing pharmacy must provide the board with written notification of:

(a) the physical address at which the automated drug distribution system will be located,

(b) the health facility's board of pharmacy registration type and number,

(c) the managing pharmacy's registration number, address, and pharmacist-in-charge, and

(c) written policies and procedures that govern the operation of the system. The policies and procedures must address the requirements of paragraph F of this section and the rules of the board.

(d) The managing pharmacy/pharmacist-in-charge must notify the board within ten (10) days whenever an automated drug distribution system is taken permanently out of service.

E. Operation of automated drug distribution systems.

(1) The pharmacist-in-charge shall assure compliance with all requirements of the Pharmacy Act, Drug Device and Cosmetic Act, Controlled Substances Act and this Section.

(2) The pharmacist-in-charge shall be responsible for:

(a) Maintaining a record of each transaction or operation;

(b) Controlling access to the automated medication system;

(c) Maintaining policies and procedures for:
(d) Operating the automated medication system;
(e) Training personnel who use the automated medication system;
(f) Maintaining patient services whenever the automated medication system is not operating; and
(g) Defining a procedure for a pharmacist to grant access to the drugs in the automated medication system or to deny access to the drugs in the automated medication system.
(h) Securing the automated medication system;
(i) Assuring that a patient receives the pharmacy services necessary for appropriate pharmaceutical care;
(j) Assuring that the automated medication system maintains the integrity of the information in the system and protects patient confidentiality;
(k) Establishing a procedure for stocking or restocking the automated medication system; and
(l) Insuring compliance with all requirements for packaging and labeling.
(m) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a drug except an override medication or a practitioner controlled medication.
(n) A pharmacist shall perform retrospective drug use review for an override medication.
(o) The pharmacist-in-charge shall convene or identify a Multidisciplinary Committee, which is charged with oversight of the automated medication system.
(p) A managing pharmacy utilizing an automated medication system may distribute patient-specific drugs within the health care facility without verifying each individual drug selected or packaged by the system, if:
(i) The initial medication order has been reviewed and approved by a pharmacist; and the drug is distributed for subsequent administration by a health care professional permitted by New Mexico law to administer drugs.

F. STOCKING OR RESTOCKING OF AN AUTOMATED MEDICATION SYSTEM

(1) Responsibility for accurate stocking and restocking of an automated medication system lies with the pharmacist-in-charge and with any pharmacist tasked with supervising such functions.
(2) The stocking or restocking of an automated medication system, where performed by someone other than a pharmacist, shall follow one of the following procedures to ensure correct drug selection:
(a) A pharmacist shall conduct and document a daily audit of drugs placed or to be placed into an automated medication system by a pharmacy technician, which audit may include random sampling.
(b) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of drugs placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification process shall require an initial quality assurance validation, followed by a quarterly quality assurance review by a pharmacist. When a bar code verification, electronic verification, or similar verification process is utilized as specified in this section, stocking and restocking functions may be performed by a pharmacy technician or by a registered nurse trained and authorized by the pharmacist-in-charge.
(3) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the drug stocking, restocking or verification process.
(4) Medication Reuse. Any drug that has been removed from the automated medication system shall not be replaced into the system unless:
(a) the drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-in-charge to determine that reuse of the drug is appropriate; or
(b) specific drugs, such as multi-dose vials, have been exempted by the Multidisciplinary Committee.

G. Quality Assurance Program

The pharmacist-in-charge shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:
(1) Review of override medication utilization;
(2) Investigation of any medication error related to drugs distributed or packaged by the automated medication system;
(3) Review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated medication system;
(4) Review of the operation of the automated medication system;
(5) Integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the managing pharmacy; and
(6) Assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

H. Records

The managing pharmacy/pharmacist-in-charge shall maintain, for at least three years, the following records related to the automated medication system in a readily retrievable manner:

(1) Managing pharmacy's distribution records for all dangerous drugs, including controlled substances, transferred to each automated medication system.

(2) Perpetual inventories of controlled substances contained within each automated medication system.

(3) Transaction records: At the time of any event involving the contents of the automated device, the device shall automatically produce on demand, a written or electronic record showing:

(a) the date and time of transaction;
(b) the type of transaction;
(c) the name, strength, and quantity of medication;
(d) the name of the patient for whom the drug was ordered;
(e) the name or identification code (electronic signature) of the person making the transaction;
(f) the name of the prescribing practitioner;
(g) the name of the pharmacist conducting the drug utilization review; and
(g) the identity of the device accessed.

(4) Delivery Records: A delivery record shall be generated on demand for all drugs filled into an automated dispensing device which shall include:

(a) date;
(b) drug name;
(c) dosage form
(d) strength;
(e) quantity;
(f) identity of device; and
(g) name or initials of the person filling the automated dispensing device.

(5) Any report or analysis generated as part of the quality assurance program required by Paragraph (G) of this regulation.

I. The Multidisciplinary Committee shall:

(1) Include the pharmacist-in-charge or the pharmacist-in-charge's designee;

(2) Establish the criteria and process for determining which drug qualifies as an override medication; and

(3) Develop policies and procedures regarding the operation of the automated medication system.

Appendix J

This is an amendment to 16.19.36 NMAC, Sections 2, 6, 7, 11, 13 and 15, effective 03-22-2015.

16.19.36.2 SCOPE: All facilities as defined in Paragraph (1), (2), (5) [~~and (7)~~] through (11) and (15) of Subsection B of 61-11-14 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 preparations or services.
[16.19.36.2 NMAC - N, 06-28-14; A, 03-22-15]

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 properly compounded in accordance with all applicable USP/NF General Chapters numbered below 1000.
[16.19.36.6 NMAC - N, 6-28-14; A, 03-22-15]

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. "Batch" means more than one unit of a compounded preparation that is intended to have uniform character and quality within specified limits, prepared in a single process, and completed during the same and limited time period.

[~~**D.**~~] **E. "Beyond-use date"** (BUD) means the date, or as appropriate, date and time, after which a compounded preparation is not to be used and is determined from the date and time the preparation is compounded.

[~~**E.**~~] **F. "Biological safety cabinet"** (BSC) means a ventilated cabinet that provides ISO Class 5 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.**~~] **G. "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.**~~] **H. "Certification"** means independent third party documentation declaring that the specific requirements of USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* have been met.

[~~**H.**~~] **I. "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.**~~] **J. "Closed system vial-transfer device"** means a vial-transfer system that allows no venting or exposure of substances to the environment.

[~~**J.**~~] **K. "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.**~~] **L. "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.~~] **M. "Compounding aseptic isolator"** (CAI) means an enclosed ISO Class 5 environments 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.~~] **N. "Critical area"** means an ISO Class 5 environment.

[~~N.~~] **O. "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 ampules, 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.~~] 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.

[~~P.~~] **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.

[~~Q.~~] 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).

[~~R.~~] 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.

[~~S.~~] T. "Immediate use" means administration begins not later than one hour following the start of the compounding procedure. For those events in which delay in preparation would subject patient to additional risk and meeting USP/NF <797> (*Immediate-Use CSP Provision*) criteria.

[~~T.~~] 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).

[~~U.~~] 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).

[~~V.~~] **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).

[~~W.~~] **X. "Laminar airflow"** means a non-turbulent, non-mixing streamline flow of air in parallel layers.

[~~X.~~] 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.

[~~Y.~~] **Z. "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 preparation 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.

[~~Z.~~] 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.

[~~AA.~~] **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.

[~~BB.~~] **CC. "Parenteral product"** means any preparation administered by injection through one or more layers of skin tissue.

[~~CC.~~] 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.

[~~DD.~~] 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.

[**~~EE.~~] 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.

[~~FF.~~] 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.

[~~GG.~~] **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.

[~~HH.~~] **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).

[~~II.~~] **JJ. "Process validation"** means documented evidence providing a high degree of assurance that a specific process will consistently produce a preparation meeting its predetermined specifications and quality attributes.

[~~JJ.~~] **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.

[~~KK.~~] **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.

[~~LL.~~] **MM. "Quality control"** means a system for verifying and maintaining a desired level of quality in a preparations or process, as by planning, continued inspection, and corrective action as required.

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

[~~NN.~~] 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.

[~~OO.~~] 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. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

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

[~~QQ.~~] RR. "Sterile" means free from bacteria or other living microorganisms.

[~~RR.~~] SS. "Sterilization by filtration" means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

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

[~~TT.~~] **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.

[~~UU.~~] **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.

[~~VV.~~] WW. "USP" means United States pharmacopeia.

[**~~WW. "USP/NF standards"~~** ~~means United States pharmacopeia/national formulary~~ *~~USP General Chapters <797> Pharmaceutical Compounding–Sterile Preparations.~~*]

[16.19.36.7 NMAC - N, 06-28-14; A, 03-22-15]

16.19.36.11 DOCUMENTATION REQUIRED:

A. Written policies, procedures and SOPs consistent with USP/NF <797> *(General Chapter <797> Pharmaceutical Compounding-Sterile Preparations)* standards as well as those required below, must be established, implemented, followed by facility personnel, and 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 proper 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, and drug interactions;

(9) error prevention and incident reporting policies and procedure as per 16.19.25 NMAC.

C. All records required by this part shall be kept by the facility for at least three years and shall be readily available for inspection by the board or boards' agent.

[16.19.36.11 NMAC - N, 06-28-14; A, 03-22-15]

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/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* and as outlined by the pharmacist-in-charge and described in the site policy and procedures or training manual, prior to compounding sterile preparations.

A. Instructional topics shall include:

(1) aseptic technique;

(2) critical area contamination factors;

(3) environmental monitoring;

(4) facilities;

(5) equipment and supplies;

(6) sterile pharmaceutical calculations and terminology;

(7) sterile pharmaceutical compounding documentation;

(8) quality assurance procedures;

(9) proper gowning and gloving technique;

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

(11) general conduct in the controlled area.

B. Training shall be obtained through [~~the following:~~] completion of a site-specific, structured on-the-job didactic and experiential training program (not transferable to another practice site).

[~~**(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. Pharmacy technicians shall complete 100 hours of documented experiential training in compounded sterile preparations in accordance with Section 61-11-11.1 of the Pharmacy Act NMSA 1978 prior to compounding sterile preparations. Documentation of experiential training as defined in Subsection A of this section is transferrable to another practice site.

[~~**C.**~~] **D.** Experiential training shall include those areas of training as outlined in USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* with appropriate observational assessment and testing of performance as outlined in USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* including glove fingertip and media fill tests.

[~~D.~~] **E.** All personnel, including pharmacists compounding sterile [~~chemotherapy~~] hazardous drugs, pharmacists supervising compounding personnel, pharmacy interns compounding sterile [~~chemotherapy~~] hazardous drugs, and pharmacy technicians compounding sterile [~~chemotherapy~~] hazardous drugs, shall have completed [~~a board approved course in chemotherapy drug preparation as well as training in compounding sterile preparations as listed in H1 above , prior to compounding sterile chemotherapy preparations.~~] didactic and experiential training with competency evaluation through demonstration and written or practical testing as required by USP/NF in addition to training in sterile non-hazardous preparations as listed above. Training will be conducted as outlined by the pharmacist-in-charge and described in the site policy and procedures or training manual and shall be completed prior to compounding sterile hazardous preparations.

[~~E.~~] **F.** 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.~~] **G.** 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.

[16.19.36.13 NMAC - N, 06-28-14; A, 03-22-15]

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 non-sterile to sterile bulk compounding of more than 25 units of compounded sterile preparations is performed using non-sterile chemicals, containers, or devices, and the results of 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 batch label of each sterile compounded product shall contain:

(a) [~~patient name;~~] drug product name(s), diluent names(s), and amount(s) of each;

(b) [~~if batch filling,~~] batch lot or control number;

(c) [~~solution, ingredient names, amounts;~~] final concentration(s), and volume when appropriate, solution ingredient names and amounts;

(d) [~~expiration date and time, when applicable;~~] beyond use date, and time when applicable;

(e) route of administration when applicable;

(f) [~~directions for use including infusion rates, specific times scheduled, when appropriate and applicable~~] date of preparation;

(g) facility identifier; 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;

(h) when appropriate, ancillary instructions such as storage instructions or cautionary systems, including hazardous material warning labels and containment bags; and

(i) device instructions when needed.

(5) the patient specific label of a CSP shall contain:

(a) patient name;

(b) solution, ingredient names, amounts;

(c) beyond use date, and time when applicable;

(d) route of administration;

(e) directions for use, including infusion rates, specific times scheduled, when appropriate and applicable;

(f) identifier of person preparing the product and, if prepared by supportive personnel (i.e., pharmacist intern or pharmacy technician), the identifier of the pharmacist that completed the final check;

(g) when appropriate, ancillary instructions such as storage instructions or cautionary systems, including hazardous material warning labels and containment bags; and

(h) device instructions when needed;

(i) if dispensed for other than inpatient use, the label shall include all other required information.

B. There shall be a mechanism for tracking and retrieving products which have been recalled. [~~When~~] If batch preparation of compounded sterile [~~products~~] preparations is being performed, a [~~worksheet (log)~~] record 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.~~]

(1) A formulation record shall provide a consistent source document (recipe) for CSP preparation and shall include the following:

(a) name, strength, dosage form, and final volume of the compounded preparation;

(b) all ingredients and their quantities;

(c) equipment needed to prepare the CSP, when appropriate, and mixing instructions;

(d) other environmental controls, such as the duration of mixing and other factors pertinent to consistent preparation of the CSP;

(e) beyond use dating, the container for dispensing, storage requirements, and quality control procedures; and

(f) information need for proper labeling (e.g. sample label).

(2) The compounding record for each CSP batch shall verify accurate compounding in accordance with the formulation record and shall include:

(a) reference to the formulation record for the CSP;

(b) name, strength, volume, manufacturer, and manufacturer's lot number for each component;

(c) name, strength, and volume of the finished CSP;

(d) reconciliation of actual yield with anticipated yield, and total number of CSP units produced;

(e) identifier of person preparing the product and, if prepared by support personnel (i.e., pharmacist intern or pharmacy technician), the identifier of the pharmacist that completed the final check;

(f) date of preparation;

(g) batch lot or control number assigned;

(h) assigned beyond use date, and time when appropriate;

(i) results of applicable quality control procedures.

[16.19.36.15 NMAC - N, 09-07-14; A, 03-22-15]

Appendix K

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Turquoise lodge Hospital Waiver Request

Reason for Waiver Request:

Turquoise Lodge is currently teamed up with the National Institute of Drug Addiction (NIDA) in order to compare two medications; extended· release naltrexone (XR·NTX, Vivitrol) and buprenorphine/naloxone (BUP-NX, Suboxone). Both medications are approved by the US FDA {United States Food and Drug Administration) for this purpose. Vivitrol is the newer of the two drugs, and we are interested in comparing it to Suboxone over 6 months (24 weeks) of treatment. The Vivitrol will be given on site at Turquoise Lodge Hospital; however Suboxone would be dispensed to patient's on an outpatient basis, which would require a Retail License. We are requesting a waiver to dispense this medication to individuals in this study as outpatients. Turquoise Lodge does not intend to accept no more than 20 patients in the suboxone arm of this study and the study would end early *2016*.

Expected Public Benefit As A Result of the Waiver:

Treatment for opioid dependence often involves medication, either to help with shorHerm detoxification, or to help prevent relapse over a longer period. Many people relapse after short-term treatment, so it is often recommended that people remain on medication for long periods, several months to many years.

The study is a NIDA Clinical Trials Network (CTN) multi-site trial comparing the effectiveness of the two drugs (Vivitrol and Suboxone) to prevent relapse to opioid use and addiction. Participants who qualify for participation and are consented to participate and will be randomized into either of the two groups and receive 6 months of treatment, that include frequent Medical Management (MM) and research follow up visits (weekly for 24 weeks) during the treatment phase. They will continue to be followed up for two additional research follow-up visits after that (at weeks 28 and 36 from baseline). Participants will also have the opportunity to attend weekly group counseling sessions, if they so choose and will be compensated for their time and effort in the participation of the research study visits. All study-related visits are conducted in a highly confidential and private in an effort to protect the participant's privacy. After the six-month {24 weeks) treatment phase of the study, we will help participants seek similar treatment in the community. Related purposes of the study are to understand whether there are genetic or hereditary differences in how individuals respond to these medications and the economic costs and benefits of the two treatments.

Appendix L

16.19.6.27 OUTSOURCING FACILITIES:

A. LICENSING, REGISTRATION:

Any outsourcing facility that is engaged in the compounding of sterile drugs in this state shall be registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act and be licensed as an outsourcing facility in this state. Any outsourcing facility located in another state that intends to deliver compounded sterile drugs into New Mexico shall be registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act and be licensed as an outsourcing facility in this state.

B. PRESCRIPTIONS:

No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also licensed as a pharmacy in this state and meets all other applicable requirements of federal and state law.

C. RESTRICTIONS:

Any drugs compounded in an outsourcing facility licensed pursuant to this rule shall be compounded in accordance with all applicable federal and state laws.

D. LABELING:

The label of any drug compounded by an outsourcing facility shall include, but not be limited to the following:

(1) a statement that the drug is a compounded drug or a reasonable comparable alternative statement that prominently identifies the drug as a compounded drug;

(2) the name, address, and phone number of the applicable outsourcing facility; and

(3) with respect to the drug:

- (a) the lot or batch number;
- (b) the established name of the drug;
- (c) the dosage form and strength;
- (d) the statement of quantity or volume, as appropriate;
- (e) the date that the drug was compounded;
- (f) the expiration date;
- (g) storage and handling instructions;
- (h) the National Drug Code number, if available;
- (i) the statement that the drug is not for resale, and the statement "Office Use Only"; and
- (j) a list of the active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient.

E. CONTAINER:

The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include:

(1) a list of active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient; and

(2) any other information required by regulations promulgated by the commissioner to facilitate adverse event reporting in accordance with the requirements established in section 310.305 of title 21 of the code of federal regulations.

F. BULK DRUGS:

A drug may only be compounded in an outsourcing facility that does not compound using bulk drug substances as defined in section 207.3(a)(4) of title 21 of the code of federal regulations or any successor regulation unless:

(1) the bulk drug substance appears on a list established by the secretary of health and human services identifying bulk drug substances for which there is a clinical need;

(2) the drug is compounded from a bulk drug substance that appears on the federal drug shortage list in effect at the time of compounding, distributing, and dispensing;

(3) if an applicable monograph exists under the USP-NF, or another compendium or pharmacopeia recognized by the secretary of health and human services and the bulk drug substances each comply with the monograph, and;

(4) the bulk drug substances are each manufactured by an establishment that is registered with the federal government.

G. INGREDIENTS:

If an outsourcing facility uses ingredients, other than bulk drug substances, such ingredients must comply with the standards of the applicable USP-NF monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the secretary of health and human services for purposes of this subdivision, if any.

H. UNSAFE OR INEFFECTIVE DRUGS:

No outsourcing facility may compound a drug that appears on a list published by the secretary of health and human services that has been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

I. PROHIBITION ON WHOLESALING:

No compounded drug will be sold or transferred by any entity other than the outsourcing facility that compounded such drug. This does not prohibit the administration of a drug in a health care setting or dispensing a drug pursuant to a properly executed prescription.

J. PROHIBITION AGAINST COPYING AN APPROVED DRUG:

No outsourcing facility may compound a drug that is essentially a copy of one or more approved drugs.

K. PROHIBITION AGAINST COMPOUNDING DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES:

No outsourcing facility may compound a drug:

(1) that is identified, directly or as part of a category of drugs, on a list published by the secretary of health and human services that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(2) that is compounded in accordance with all applicable conditions identified on the drug list as conditions that are necessary to prevent the drug or category of drugs from presenting demonstrable difficulties.

L. ADVERSE DRUG REPORTS:

Outsourcing facilities shall submit a copy of all adverse event reports submitted to the secretary of health and human services in accordance with the content and format requirements established in section 310.305 of title 21 of the code of federal regulations, or any successor regulation, to the executive secretary for the state board of pharmacy.

M. RECORD KEEPING:

Outsourcing facility distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of compounded sterile drugs. These records shall include the following information:

(1) the identity and quantity of the drugs received and distributed or disposed of; and

(2) the dates of receipt and distribution or other disposition of the drugs;

(3) the name, location and license number of the business, health care practitioner or other entity appropriately licensed to possess, dispense, distribute, administer or destroy prescription drugs.

N. INSPECTION OF RECORDS:

Inventories and records shall be made available for inspection and photocopying by authorized inspectors employed by the board and authorized federal, state or local law enforcement agency officials for a retention period of three (3) years following disposition of the compounded sterile drugs.

16.19.8 NMAC Outsourcing proposed language

Appendix M

16.19.11.8 MINIMUM STANDARDS:

A. MINIMUM STANDARDS FOR THE DISTRIBUTION, STORAGE, HANDLING AND RECORD KEEPING OF DRUGS:

(1) The pharmaceutical service shall be organized and maintained primarily for the benefit and safety of the patient.

(2) All medications administered to patients shall be by direct order of a physician, or other licensed practitioner, as defined in the Pharmacy Act, 61-11-2P.

(3) The pharmaceutical service shall be under the direction of a registered pharmacist, who may be on a part-time or consultant basis.

(4) Policies relating to the control, distribution and administration of medications shall be developed by the pharmacist. Preparation of a written procedures manual shall be the responsibility of the pharmacist.

(5) An automatic stop-order policy shall be adopted to provide guidance in these instances where medications ordered are not specifically limited as to time or number of doses.

(6) Adequate facilities to be provided for storage of medications. Proper labeling is required on each patient's medication container.

(7) Complete records - In addition to those records specifically required by federal and state laws, records shall be maintained of the receipt, use, or disposition of medications. The receipt and destruction journal shall show:

(a) date;
(b) patient's name;
(c) pharmacy's name;
(d) name of drug;
(e) strength and dosage form;
(f) prescription number;
(g) quantity;
(h) initials of person accepting delivery; and
(i) inventory of drugs to be destroyed.

(8) Appropriate current drug reference sources shall be provided at the facility.

(9) In licensed nursing homes an emergency drug supply shall be maintained to be used in a medical emergency situation, contents and quantity to be determined by a physician, nursing director and the pharmacist of each institution. In licensed custodial care facilities an emergency drug supply may be used. This emergency drug supply shall be assessed only when licensed personnel are on duty. In licensed custodial care facilities, <u>without a 24-hour/365 day on-site nurse</u> ~~only~~, the emergency drug tray shall not contain any controlled substances. <u>Licensed custodial care facilities, with a 24-hour/365 day on-site nurse may use an emergency drug tray containing controlled substances.</u> A list of the contents of the emergency drug supply shall be attached to the outside of the tray.

(10) Medication errors and drug reactions should be documented and a method of reporting shall be addressed in the pharmacy procedure manual.

B. POLICY AND PROCEDURES MANUAL:

(1) The pharmacist shall be responsible for the preparation of a written procedures manual, the aim of which shall be:

(a) To improve communications with the facility;
(b) To improve patient care;
(c) To aid in personnel training;
(d) To increase legal protection;
(e) To aid in evaluating performance;
(f) To promote consistency and continuity.

(2) There shall be a copy of the policy and procedure manual at each facility location. This copy must be read and initialed by all personnel responsible for the procurement, administration or control of the patient's medication.

(3) The consultant pharmacist shall make an annual review of the procedures manual. Findings of which shall be reported to the facility administration.

(4) Guidelines for developing a pharmaceutical procedures manual;

(a) Drug Policy: A written policy concerning methods and procedures for the pharmaceutical services stating the appropriate methods and procedures for obtaining, dispensing and administering drugs and biologicals.

(b) Prescription Drug Orders: The designated agent of the facility may transcribe prescription drug orders from a licensed practitioner and transmit those orders via telephone or facsimile to the pharmacy.

(c) Licensed practitioners will identify the designated agents of a facility by written authorization according to the facility's policy and procedures manual.

(d) The facility shall have a Medication Administration Record (MAR) documenting medications administered to residents, including over-the-counter medications. This documentation shall include:

(i) Name of resident;
(ii) Date given;
(iii) Drug product name;
(iv) Dosage and form;
(v) Strength of drug;
(vi) Route of administration;
(vii) How often medication is to be taken;
(viii) Time taken and staff initials;
(ix) Dates when the medication is discontinued or changed;
(x) The name and initials of all staff administering medications.

(e) Any medications removed from the pharmacy container or blister pack must be given immediately and documented by the person assisting.

(f) All PRN medications shall have complete detail instructions regarding the administering of the medication. This shall include:

(i) Symptoms that indicate the use of the medication;
(ii) Exact dosage to be used;
(iii) The exact amount to be used in a 24 hour period.

(g) Describe medication storage, procedures, and function at the nursing stations.

(h) Describe the medication administration system used with means of verifying accuracy of delivered dosage. Describe the procedure for recording missed or refused doses and the procedure followed for missed or refused doses.

(i) State that medications prescribed for one patient shall not be administered to any other patient.

(j) Describe policy concerning self-administration of medications by patients. A physician's order shall be required before any resident is allowed to self-administer medications.

(k) State procedures for documenting medication errors and drug reactions:

(i) Should a staff member of the facility notice an error, possible overdose, or any discrepancy in any of the prescriptions filled by the pharmacy, they will immediately contact the pharmacy. If necessary, the pharmacy will contact the physician.

(ii) In the event of an adverse drug reaction the facility will immediately contact the physician.

(l) List labeling and storage requirements of medications in conformity with the official compendium (USP/NF).

(5) OTHER INFORMATION

(a) Emergency Drug Tray - use, inventory control, replacement of drugs, security when licensed staff is not on duty.
(b) Location of Emergency Drug Tray.
(c) 24-hour emergency pharmaceutical services.
(d) Part-time or consultant pharmacist hours on premises.
(e) In-service training.
(f) Drug information service.
(g) Automatic stop orders.
(h) Controlled substances - inventory, security and control.
(i) Renewal of physician's orders.
(j) A policy concerning "PASS" medications.
(k) Discontinued medication.

(l) Records and standards of storage of over-the-counter drugs.

(m) Drug receipt and disposition records.

(6) DRUG DISTRIBUTION

(a) All dangerous drugs shall be obtained from a properly licensed facility. Stock dangerous drugs acquired, maintained and administered by or at the nursing home, or licensed custodial care facility with a 24-hour/365 day on-site nurse, shall be listed in the ~~nursing home~~ policy and procedure manual. 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) Vaccines as recommended by the centers for disease control (CDC) and prevention's advisory committee on immunization practices and appropriate for the facility population served;

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

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

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

Appendix N

SCHOOL BASED CLINIC SELF-ASSESSMENT FORM

Clinic Name: _____ Date: _____
Clinic Address: _____City: _____Zip: _____
Clinic Phone: _____Clinic Fax: _____Clinic Email: _____
Clinic Responsible Party: _____
NMBOP License Number: _____Expiration Date: _____

Consultant Pharmacist Name and Contact Information:
_____
_____

1. Medications kept on site		
a. Epinephrine	Yes	No
b. Albuterol	Yes	No
2. Current medication expiration dates	Yes	No
3. Receipt records kept	Yes	No
4. Administration records	Yes	No
5. Removal records	Yes	No
6. Current Policy and Procedures Manual	Yes	No
a. Approved by consultant pharmacist annually	Yes	No
7. Drug storage area clean and orderly	Yes	No
8. Drug source registered with NMBOP	Yes	No
9. Drug storage temperature monitored	Yes	No
10. Medication access restricted to authorized personnel	Yes	No
11. List Personnel Name, Job Title, DOH Training Date	Yes	No

I CERTIFY THE INFORMATION PROVIDED ON THIS FORM IS TRUE AND ACCURATE

_____ _____ _____
Print name and title of clinic representative Signature Date

_____ _____ _____
Print name of Consultant R.Ph Consultant R.Ph signature Date

***The board may go into Executive Session to discuss these items and any other items pursuant to Section 10-15-1H(1), Section 10-15-1H(2) or Section 10-15-1H(7) of the Open Meeting Act. Agenda items may be executed at any time during the meeting to accommodate hearings.**
H(1) are licensing matters, H(2) is limited to personnel matters, H(7) is pending or threatened litigation.

Appendix O

SENATE BILL 21

52ND LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2015

INTRODUCED BY

Michael Padilla

AN ACT

RELATING TO HEALTH CARE; ENACTING A NEW SECTION OF THE PHARMACY ACT TO PROVIDE FOR THE COLLECTION AND DISPOSAL OF UNUSED DANGEROUS DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the Pharmacy Act is enacted to read:

"[NEW MATERIAL] DANGEROUS DRUG TAKE-BACK PROGRAM--RULEMAKING.--

A. In consultation with the environmental improvement board and the federal drug enforcement administration, the board of pharmacy shall adopt and promulgate rules to establish a dangerous drug take-back program that will:

(1) require each retail pharmacy in the state

.197788.2

to collect unused dangerous drugs;

(2) provide for the safe disposal of the dangerous drugs in accordance with state and federal law; and

(3) indemnify and hold harmless wholesale drug distributors for actions taken in compliance with the dangerous drug take-back program that the board of pharmacy establishes pursuant to this section.

B. The board of pharmacy shall establish a means of funding, and may impose a reasonable fee, to cover costs of executing the provisions of this section."

- 2 -

.197788.2

** ** ** ** ** ** **

SENATE BILL 22

52ND LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2015

INTRODUCED BY

Michael Padilla

AN ACT

RELATING TO HEALTH; ENACTING A NEW SECTION OF THE NEW MEXICO DRUG, DEVICE AND COSMETICS ACT TO REQUIRE THE BOARD OF PHARMACY TO ESTABLISH AND OPERATE AN OVERPRESCRIBING HOTLINE FOR REPORTS OF CONTROLLED SUBSTANCES PRESCRIBING PRACTICES SUSPECTED TO BE EXCESSIVE OR OTHERWISE IN VIOLATION OF ESTABLISHED PRESCRIBING STANDARDS; MAKING AN APPROPRIATION.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the New Mexico Drug, Device and Cosmetics Act is enacted to read:
"[NEW MATERIAL] OVERPRESCRIBING HOTLINE--ESTABLISHMENT--DUTIES.--The board shall establish a program to address prescribing of controlled substances that is suspected to be excessive or otherwise in violation of established prescribing standards. The program shall include:
.197560.1

A. a twenty-four-hour telephonic hotline and publicly accessible internet web site to provide the public with a venue through which to report controlled substance prescribing practices that are suspected to be in excess of therapeutically indicated prescribing practices; and
B. rules and procedures for investigation of prescribing reported as suspected to be in excess of therapeutically indicated prescribing practices and for working in conjunction with practitioner licensing boards to discipline practitioners for prescribing practices in violation of established standards."
SECTION 2. APPROPRIATION.--Two hundred fifty thousand dollars ($250,000) is appropriated from the general fund to the board of pharmacy for expenditure in fiscal year 2016 to establish and operate an overprescribing hotline pursuant to Section 1 of this act for the recording and investigation of excessive prescribing of pain medication by medical practitioners. Any unexpended or unencumbered balance remaining at the end of fiscal year 2016 shall revert to the general fund.