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

June 18th and 19th, 2014 Meeting Minutes

Board Meetings are open to the public pursuant to the "Open Meetings Act" and notices to the public are posted in the Albuquerque Journal. Notice published May 16, 2014.

Location: 5200 Oakland Ave. NE, Albuquerque, NM

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

Wednesday June 18, 2014

1. Procedural Items:

9:00 a.m. Call to Order: The meeting of the Pharmacy Board was called to order by Chairman Cross at 9:00 a.m. on June 18, 2014.

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

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

Ms. Saavedra arrived at 3:57 p.m.

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

Approval of April 2014 Minutes: Motion to approve the April 17th & 18th, 2014 minutes as amended, Ms. Mendez-Harper, seconded by Ms. Yarbrough, 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: **6 Clinic/Home Health** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Carrier to approve applications, board voted unanimously to pass motion.

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

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

Motion: **11 Custodial/Nursing Home** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni to approve applications, board voted unanimously to pass motion.

Motion: **4 Pharmacy/Hospital** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Carrier to approve applications, board voted unanimously to pass motion.

Motion: **4 Non-Resident Pharmacy** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Carrier to approve applications, board voted unanimously to pass motion.

Motion: **16 Wholesale/Broker** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Carrier to approve applications, board voted unanimously to pass motion.

NEW MEXICO BOARD OF PHARMACY
REGULAR MEETING
APPLICATION LIST
June 18 & 19, 2014

CLINIC /HOME HEALTH	*CONSULTANTPHARMACIST*
1.Ben Archer Health Center *DBA Mayfield School Based Clinic* *1995 N Valley Drive* *Las Cruces, NM 88007*	*New* *Sarah Harrington, R.Ph.*
2.HMS-Med Square *144 W 11th Street* *Silver City, NM 88061*	*Remodel* *Steven Jones, R.Ph.*
3.Lovelace Family *1112 N Main* *Roswell, NM 88201*	*New* *Karen Snow, R.Ph.*
4.New Mexico School for the Death *1060 Cerrillos Road* *Santa Fe, NM 87501*	*Relocation* *George Gonzales, R.Ph.*
5.RMCH Home Health *1910 Red Rock* *Gallup, NM 87301*	*Relocation* *Arthur Macias, R. Ph.*
6.Valle Del Sol of New Mexico *301 Camino del Pueblo* *Bernalillo, NM 87004*	*Relocation* *Shelley Bagwell, R.Ph.*
LIMITED DRUG RESEARCHER	
1.Lovelace Respiratory Researcher Institute *Dr Weber* *Bldg 9217 – Area Y* *Kirtland Air Force Base* *Albuquerque, NM 87115*	*New*
EMERGENCY MEDICAL SERVICE	*CONSULTANT PHARMACIST*
1.Air Methods *Deming Native Air 30* *3865 Raymond Reed Blvd SE* *Deming, NM 88030*	*Relocation* *Raymond Rede, R.Ph.*
2.Tri-State Care Flight LLC *5315 Lomas Drive* *Carlsbad, NM 88220*	*New* *Charles Vandiver, R.Ph.*

CUSTODIAL/NURSING HOME	*CONSULTANT PHARMACIST*
1.Advantage Communications *9921 Cameron NW* *Albuquerque, NM 87120*	*New* *Ron Lujan, R.Ph.*
2.Anita Tapia *6442 Paseo Del Sol West* *Santa Fe, NM 87507*	*New* *Ron Lujan, R.Ph*
3.Bright Horizons *8301 Krim NE* *Albuquerque, NM 87109*	*New* *Jeff Campbell, R.Ph*
4.L.A. In-Home Care *1624 33rd St. SE* *Rio Rancho, NM 87124*	*New* *Annabel Roberts, R.Ph*
5.Landmark @ Desert Gardens *200 S Linam* *Hobbs, NM 88240*	*New* *Maureen Rogers, R.Ph.*
6.Lifehouse Santa Fe Operations LLC *DBA The Montecito* *500 Rodeo Road* *Santa Fe, NM 87505*	*New* *Ron Lujan, R.Ph.*
7.Mimbres Memorial Hospital Nursing Home *900 W Ash Street* *Deming, NM 88030*	*New* *Terrence Clark Jr., R.Ph.*
8.Retreat Gardens *4075 Jackie Road SE* *Rio Rancho, NM 87124*	*New* *Shauna Porter, R.Ph.*
9.Tohatchi Area of Opportunity & Services Inc. *1658 South 2nd Street* *Gallup, NM 87301*	*New* *Nia Harris, R.Ph*
10.Tohatchi Area of Opportunity & Services Inc. *2534 East Aztec 4-A* *Gallup, NM 87301*	*New* *Nia Harris, R.Ph*
11.Turquoise Health Wellness *1111 W Fir* *Portales, NM 88130*	*New* *Alfred Baca, R.Ph.*
PHARMACY /HOSPITAL	*PHARMACIST IN CHARGE*
1.Fort Bayard Medical Center *41 Fort Bayard* *Santa Clara, NM 88026*	*New* *Mark Bailey, R.Ph.*
2.In Your Atmosphere Holdings LLC *1676 Hospital Drive* *Santa Fe, NM 87505'*	*Change of Ownership,* *Mark Sarnowski, R.Ph.*
3.Lowe's Pharmacy *675 10th Street* *Alamogordo, NM 88310*	*Remodel* *Gail Watters, R.Ph.*

***The board may go into Executive Session to discuss these items and any other items pursuant to Section 10-15-1H(1), Section 10-15-1 H(2) or Section 10-15-1 H (3) or Section 10-15-1 H(7), of the Open Meeting Act. Agenda items may be executed at any time during the meeting to accommodate hearings.**

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

4.Presbyterian Healthcare Services — *New*
DBA Plains Regional Medical Center Pharmacy — *Amy Kelley, R.Ph.*
2401 W 21st Street
Clovis, NM 88101

NON-RESIDENT PHARMACY — *PHARMACIST IN CHARGE*

1.AllCare Plus Pharmacy Inc — *New*
12 Plymouth Street Suite 200 — *John Leighton, R.Ph.*
Worcester, MA 01608

2.Ardon Health, LLC — *New*
11835 NE Glenn Widing Drive — *Atta E-Karim Chowdhry, R.Ph*
Portland, OR 97220

3.Advanced Pharmacy, LLC — *New*
350- D Feaster Road, — *Heather Alford, R.Ph*
Greenville, SC 29615

4.American Specialty Pharmacy — *New*
2414 Babcock Road Suite 111 — *Abdul Hameed, R.Ph.*
San Antonio, TX 78229

5.ARJ Infusion Services — *New*
10049 Lakeview Ave — *Mark Allen Hoover, R.Ph*
Lenexa, KS 66219

6.Carefree Compounding & Wellness — *New*
2525 W Carefree Hwy, Ste 106 — *Paula Vogt-McGee, R.Ph*
Phoenix, AZ 85085

7.Clevis Management Corp — *New*
38656 Medical Center Drive Suite C — *Fakhor Artin, R.Ph.*
Palmdale, CA 93551

8.Dr N Vahedi Pharmacy Inc — *New*
DBA Fusion Rx Compounding Pharmacy — *Navid Vahedi, R.Ph.*
2001 Westwood Blvd Suite A
Los Angeles, CA 90025

9.Focus Rx Pharmacy Service — *New*
1361 Lincoln Avenue Unit 9 — *Richard Collins, R.Ph.*
Holbrook, NY 11741

10.Genoa Healthcare LLC — *New*
4508 Auburn Way N Suite A-104 — *Daniel Barni, R.Ph.*
Auburn, WA 98002

11.Guardian Pharmacy — *New*
1823 Commercenter West — *Bhavesh Desai, R.Ph.*
San Bernardino, CA 92408

12.K & K Pharmacy — *New*
1411 W America Blvd — *Marilyn Kay Campbell, R.Ph .*
Muleshoe, TX 79347

13.Mandell's Clinical Pharmacy — *New*
7 Cedar Grove Lane — *Teresa Malanda, , R.Ph*
Somerset, NJ 08873

14.Medical Arts Pharmacy Services Inc *10412 W Atlantic Blvd* *Coral Springs, FL 33071*	*New* *Adesioye Adesumbo, R.Ph.*
15.New Life Pharmacy, LLC *9883 S. 500 W* *Sandy, UT 84070*	*New* *Sirtaj Singh, R.Ph*
16.OmniPlus Pharmacy *4916 Main St. Suite # 100* *Houston, TX 77002*	*New* *Raghuveer Chintalapally, R.Ph*
17.One Stop Rx LLC *10106 S Sheridan Road* *Tulsa, OK 74133*	*New* *Melinda Mast, R.Ph.*
18.RARX LP *1911 Church St Suite 202* *Nashville, TN 37203*	*New* *Brantley Wescott, R.Ph.*
19.Renner Pharmacy *3005 E Renner Road Suite 120* *Richardson, TX 75082*	*New* *Stephen Thomas, R.Ph.*
20.Rx To Go Pharmacy, LLC *4371 Veronica S Shoemaker Blvd* *Fort Myers, FL 33916*	*New* *Katherine Hogan, R.Ph*
21.Synergy Pharmacy Services, Inc *31201 US Highway 19N, Suite 2* *Palm Harbor, FL 34684*	*New* *Andrew Assad, R.Ph*
22.Tropical Pharmacy Inc, *6289 W. Sunrise Blvd, Suite 118* *Sunrise, FL 33313*	*New* *Doretha Thompson Robinson, R.Ph*
23.Unlimited Home Health Center Inc *1862 W Bitters Suite 301* *San Antonio, TX 78248*	*New* *Laura Capote, R.Ph.*
24.Valu Script Pharmacy *102 E Carmel Drive* *Carmel, IN 46032*	*New* *Leonardo Alfonz, R.Ph.*
<u>WHOLESALER/BROKER</u> *1.Abbott Laboratories Inc* *3158 Martin Luther King Jr Drive* *North Chicago, IL 60064*	*New*
2.BioDelivery Services International Inc *801 Corporate Center Drive* *Raleigh, NC 27608*	*New*
3.Cascade Healthcare Product, Inc. *1826 NW 18th Avenue* *Portland, OR 97209*	*New*
4.Chiesi USA, Inc. *1255 Crescent Green Drive, Suite 250* *Cary, NC 27518*	*Change of Ownership*

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

5.C.O. Truxton, Inc. — *New*
136 Harding Ave
Bellmawr, NJ 08031

6.FFF Enterprises Inc — *New*
1601 Old Greensboro Road
Kernersville, NC 27284

7.J. Knipper and Company Inc. — *Change of Ownership*
350 Starke Rd
Carlstadt, NJ 07072

8.Kenco Bracco — *New*
4320 Executive Dr. Suite 100
Southaven, MS 38672

9.Neogen Corporation — *New*
944 Nandino Blvd
Lexington, KY 40511

10.Par Sterile Products, LLC — *Change of Ownership*
870 Parkdale Road
Rochester, MI 48307

11.Precious Arrows LLC — *New*
2800 Sumner Blvd Suite 136
Raleigh, NC 27616

12.Purelife LLC — *New*
1908 E Dominguez
Carson, CA 90810

13.Ozburn-Hessey Logistics, LLC — *New*
DBA OHL
2780 McDonough St
Joliet, IL 60436

14.Specialty Therapeutic Care LP — *New*
6610 W Sam Houston Pkwy N Suite 300
Houston, TX 77041

15.Vensun Pharmaceuticals, Inc. — *New*
790 Township Line Road, Suite 250
Morrisville, PA 19067

16.Walgreens Specialty Pharmacy #15443 — *New*
10530 John W. Elliott Dr. Suite 100
Frisco, TX 75033

b) Pharmacist Clinicians:

Motion: Approve registration as pharmacist clinician without prescriptive authority for Lauren Davis, Stephanie Knecht and Jackson Kelly, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: Approve registration as pharmacist clinician with prescriptive authority, no controlled substances for Amy Nguyen and Carolyn Castillo-Ashford, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

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

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

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

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

Motion made by Ms. Harper, seconded by Mr. Mazzoni to go into closed session at 9:30 a.m., to discuss the MTP report. Mr. Carrier, Mr. Anderson, Mr. Mazzoni, Ms. Buesing, Ms. Mendez-Harper, Ms. Yarbrough and Mr. Cross voted unanimously to pass the motion.

The board went back into open session at 9:41 a.m. and the only issue discussed was the MTP report.

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

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

The Chairman entered the notice of hearing as exhibit #1, proposed language for 16.19.4.15 NMAC as exhibit #2, proposed language for 16.19.20.68 NMAC as exhibit #3, and sign in sheet as exhibit #4. There were not any written comments.

a) 16.19.4.15 (new section) - Expedited Pharmacist Licensure by Reciprocity for Military and Spouses Licensed In Another Jurisdiction: See Appendix A

Motion: Adopt language as amended in 16.19.4.15 NMAC. Motion made by Mr. Anderson, seconded by Ms. Buesing, board voted unanimously to pass the motion.

b) 16.19.20.68. A. - Place Alfaxalone into schedule IV: See Appendix B

Motion: Adopt language as amended in 16.19.20.68 NMAC. Motion made by Mr. Mazzoni, seconded by Mr. Anderson, board voted unanimously to pass the motion.

5. Disciplinary Hearing:

10:30 a.m. Order to Show Cause Hearing: 2010-069 – Kenneth Sanchez PT4852:

The Chairman opened the hearing at 10:35 a.m. and took roll call. Present were Mr. Carrier, Mr. Anderson, Mr. Mazzoni, Ms. Buesing, Ms. Mendez-Harper, Ms. Yarbrough and Chairman Danny Cross. Absent were Mr. Woodul and Ms. Saavedra.

Present was board counsel, Ms. Mary Smith. Also present were Mr. Larry Loring, Debra Wilhite and Inspector, Ben Kesner.

Respondent, Kenneth Sanchez was not present.

Testimony was heard by the parties present and discussion and deliberation was held by the board regarding the reinstatement of the February 8, 2011 revocation order for Mr. Kenneth Sanchez. The Chairman closed the hearing at 10:45 a.m.

Motion: A motion was made by Mr. Mazzoni to reinstate the February 8, 2011 revocation order and increase the revocation for a period of10 years to commence on 6/18/14 for Kenneth Sanchez, case 2010-069, seconded by Ms. Buesing, board voted unanimously to pass the motion.

Mary Smith will prepare the revocation order for Mr. Sanchez.

Douglas Krell CS10164 - 2006-145 Order to Show Cause Hearing is re-scheduled for October 2014.

6. 11:00 a.m. – 11:30 a.m. Public/Professional Requests/Waiver Petitions*:

The Retreat – Renew waiver 2013-004 for CS's in emergency kit: Shauna Porter and Lena Smith presented a request for an extension of waiver to house controlled substances in the emergency kits used within the custodial facility.

Motion made by Mr. Mazzoni, seconded by Mr. Carrier to extend the waiver for two years as requested, board voted unanimously to pass the motion.

Winona Stoltzfus, Michele Disco – Medications in schools - 16.19.10.11 Clinic – add category "D" school and 16.19.4.11 Consultant Pharmacist – add "D" clinic requirement: See Appendix C

Winona Stoltzfus and Michele Disco presented proposed language regarding creating a new class of clinic for school based clinics (class D) that would stock drugs, epi-pens and albuterol. Discussion regarding all protocols, training, standing orders to schools/rural health offices and the consulting requirements of consultant pharmacists for the class "D" clinics were addressed.

Executive Director Larry Loring discussed the $75.00 biennial fee that will be required for licensing a class "D" clinic.

Motion: Notice 16.19.4.11 NMAC, 16.19.10.11 NMAC and 16.19.12 NMAC for the August 2014 board meeting. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

7. 1:00 p.m. Committee/PMP Reports and Board Actions:

Amy Buesing - Sterile Products Committee: See Appendix D

Ms. Buesing discussed proposed changes to 16.19.36 NMAC sections13, 14 and 15 regarding training requirements for technicians compounding sterile preparations as outlined by statute.

Ms. Buesing asked if section 15 of 16.19.36 NMAC would be filed as it was not included when filed and Mr. Loring stated that it would be filed as soon as possible.

Carl Flansbaum – PMP report and proposed rule changes: See Appendix E & F

Mr. Flansbaum reported dispensers in violation of 16.19.29.8 NMAC for delinquent reporting. The board discussed sending notification via written correspondence informing the licensees that delinquent reporting will result in the board taking action by issuing NCA's to these licensees.

Mr. Mazzoni and Ms. Mendez-Harper will work with Mr. Flansbaum to develop the correspondence to be sent out by the board.

Change 16:19.20.8 (REGISTRATION REQUIREMENTS) to exclude Veterinarians from the requirement of registering with the New Mexico prescription monitoring program in conjunction with their controlled substance registration.

Motion: Notice 16.19.20.8 NMAC for the August 2014 board meeting. Motion made by Mr. Mazzoni, seconded by Ms. Harper-Mendez, board voted unanimously to pass the motion.

Change 16.19.29.7 (CONTROLLED SUBSTANCE PRESCRIPTION MONITORING PROGRAM) DEFINITIONS) to (1.) exclude an animal as a "Patient" and (2.) exclude veterinarians or veterinary clinics as "Dispensers" as it relates to the Controlled Substance Prescription Monitoring Program.

Motion: Notice 16.19.29.7 NMAC for the August 2014 board meeting. Motion made by Mr. Mazzoni, seconded by Ms. Harper-Mendez, board voted unanimously to pass the motion.

Chris Woodul - Wholesale Committee discussion of 16.19.8.7 P & JJ, pharmacy drug sales to wholesalers:

Mr. Woodul was not present, no action taken at this time.

Rich Mazzoni - Rules Committee: See Appendix G

Mr. Mazzoni presented proposed language for 16.19.11. 8(B)(6)(a) regarding facility drug stock.

Motion: Notice 16.19.11.8 NMAC for the August 2014 board meeting. Motion made by Mr. Mazzoni, seconded by Ms. Harper-Mendez, board voted unanimously to pass the motion.

8. Case Presentations*:

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

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

Inspector Kesner:	2014-011/close	2014-020/table	2014-024/close-DA
Inspector A. Padilla:	2012-075/close-DA 2013-011/close	2012-076/close-DA 2013-069/DA	2012-077/close-DA
Inspector B. Padilla:	2013-059/table 2014-019/DR	2014-009/VS	2014-015/table
Inspector Mossberg:	2014-021/close	2014-023/AL	
Inspector McCracken:	2014-022/close	2014-026/close-DA	

Motion: **Close case:** 2014-021. Motion made by Ms. Buesing, seconded by Mr. Carrier, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself from the vote.

Motion: **Close cases:** 2012-075, 2012-076, 2012-077, 2013-011, 2013-069, 2014-011, 2014-022, 2014-024, and 2014-026. Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough, board voted unanimously to pass the motion.

Motion: **Table cases:** 2013-059, 2014-015 and 2014-020. Motion made by Ms. Mendez-Harper, seconded by Mr. Carrier, board voted unanimously to pass the motion.

Motion: **Issue advisory letter** case 2014-023. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing, board voted unanimously to pass the motion.

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

VS = Voluntary Surrender
DA = Submitted to District Attorney
DR = Default Revocation
AL = Advisory Letter

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

2014-009 - Jennifer Kobyljanec RP6539 – Voluntary Surrender

Motion made by Ms. Mendez-Harper, seconded by Ms. Yarbrough to accept the voluntary surrender for case 2014-009, board voted unanimously to pass the motion.

2013-007 – Anthony Fliss PT8039 – Default Revocation
2013-074 - Gregory Chavez PT7587 – Default Revocation
2014-019 – Gregory Looper PT9094 – Default Revocation

Motion made by Ms. Mendez-Harper, seconded by Ms. Saavedra to approve the default revocations for cases 2013-007, 2013-074 and 2014-019, board voted unanimously to pass the motion.

10. Recess for the day: The Pharmacy Board meeting was recessed at 4:02 p.m. and will reconvene at 10:00 a.m. tomorrow, Friday June 19, 2014.

Thursday June 19, 2014

1. Procedural Items:

9:00 a.m. Reconvene: The meeting of the Pharmacy Board was reconvened by Chairman Danny Cross at approximately 10:10 a.m. on June 19, 2014.

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

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

Ms. Buesing arrived at 10:45 a.m.

2. Disciplinary Hearing:

9:30 a.m. Order to Show Cause Hearing: 2013-044 – Harriet James – CS207595:

Executive Larry Loring informed the board that he received a fax from Ms. Harriet James' attorney, Frederick Jones, requesting that the hearing be vacated and that Ms. James' application for licensure be withdrawn.

Motion made by Mr. Mazzoni, seconded by Ms. Buesing to accept the request to vacate the hearing and withdraw Ms. James' application for licensure, the board voted unanimously to pass the motion.

3. 10:30 a.m. Brian Sallee – NMMSIS update:

Mr. Brian Sallee reported:

- Jimmie Jones is a full-time partner working with him.
- NMMSIS servers in Las Cruces are up and running since September 2013 with IT specialists working at that location and later to come will be the hiring of another IT person to partner with Tennessee IT to determine if and how to expand our program.
- Information from the system has been helpful in investigations.
- Cross-commissioned -training was held for 10 new agents with Bill Harvey, Ben Kesner and Larry Loring.
- Meth lab numbers are substantially down.

4. Litigation/Board Counsel Issues*:

a) Stephen Ellwood – Motion to Dismiss Appeal:

Counsel for the board, Ms. Mary Smith stated that the motion to dismiss should be granted some-time soon.

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

a) NABP Topics:

1) Annual Meeting: Meeting was May 17 – 20, in Phoenix, AZ, in attendance were Mr. Loring, Mr. Cross, Mr. Mazzoni and Ms. Mendez-Harper.

2) Richard Mazzoni elected to NABP executive committee: Mr. Mazzoni has been elected to the executive committee and will be in attendance for the District 8 meeting on September 21-24, 2014 to be held at Grouse Mountain Lodge in Whitefish, Montana.

3) Resolution Committee Report – Ms. Mendez-Harper: Due to, former board member Tom Ortega's passing a memorandum and certificate in recognition of his participation and contributions made to the board will be sent from the NABP to his family.

4) NABP Red Flag Video – Ms. Mendez-Harper: The board viewed the video regarding red flags/potential signs of drug diversion pharmacists should watch for that may be occurring at pharmacies. The board suggested adding the video to the law updates presented by the board inspectors. The link will be added to the boards' website and NMPhA indicated they would also include the link.

https://www.youtube.com/watch?v=WY9BDgcdxaM&feature=youtu.be

b) 16.19.12 Fees – add nonrefundable to applications:

Mr. Loring stated that rule 16.19.12 NMAC and the applications will be updated to include that" fees paid are non-refundable". Rule 16.19.12 NMAC will be noticed for the August board meeting.

c) 16.19.36 NMAC - training requirements for technicians compounding sterile preparations as outlined by statute:

Training requirements for technicians as they relate to rule 16.19.36 NMAC were discussed under committee reports by Ms. Buesing.

d) Sunset review:

Mr. Loring stated that he has completed and submitted the Sunset report and a future Sunset date will be determined at the 2015 Legislature, thus enabling the board to exist and therefor serving a useful purpose to the public. Mr. Loring also stated that the LFC (Legislative Finance Committee) will hold a meeting September 23, 2014 and may need 1 or 2 board members to be in attendance.

e) Executive Director's position update:

Mr. Loring met with HR and stated that the Executive Directors position will be posted in August 2014, and suggested that any inspectors interested may apply.

f) Pharmacist survey:

Mr. Loring stated that approximately 350 pharmacists of the 1500 licensed pharmacists have completed the survey to date. Board will send e-alert, add to pharmacy law update, and work with NMPhA to promote completion of survey.

g) Controlled substance prescription security paper – request from Ken Corazza:

Mr. Loring stated that the board would have to adopt rules to *require* the use of security paper for writing scripts for controlled substances. Mr. Loring also stated that the current use of tamper-proof

paper has not decreased the forgeries in New Mexico. Ms. Buesing stated that they use tamper-proof paper and faxing these scripts cannot be transmitted.

No action was taken at this time.

h) BOP 50 year pharmacist recognition:

Ms. Mendez-Harper asked that the board recognize 50 year active pharmacists by posting their names in the NABP newsletter and sending them a certificate. Mr. Loring presented the current list of 33 pharmacists to be recognized. The board will continue to recognize 50 year active pharmacists on a yearly basis.

i) Any issues/complaints related to modified pharmacist to technician ratio regulations:

Mr. Loring stated that the board has not received any complaints related to the ratio change. There have been a few incidents of technicians counseling, as observed during inspections, and those have been addressed.

j) Personnel matters – Cynthia McCormick:

Ms. Cindy McCormick was present to discuss personnel issues.

Motion made by Ms. Harper, seconded by Mr. Woodul to go into closed session at 11:30 a.m., to discuss personnel issues. Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni, Mr. Anderson, Ms. Saavedra, and Mr. Carrier voted unanimously to pass the motion.

The board went back into open session at 12:10 p.m. and the only issue discussed was personnel issues.

Executive Director, Larry Loring submitted his retirement letter to the board. The board expressed their gratitude for his service, hard work and dedication to the Board of Pharmacy, the licensees and to the citizens of New Mexico.

Mr. Loring will retire at the end of the year.

6. **Adjournment:** With no further business, Ms. Buesing made a motion to adjourn the Pharmacy Board meeting at 12:15 p.m., seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Appendix A

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

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

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

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

16.19.4.15~~6~~ INACTIVE STATUS:

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

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

Appendix B

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

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

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

Appendix C

16.19.10.11 PUBLIC HEALTH CLINICS:

A. CLINIC LICENSURE

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

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

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

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

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

(i) administered to patients of the clinic; and

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

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

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

B. FORMULARIES

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

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

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

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

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16.19.4.11 CONSULTANT PHARMACIST:

C. CONSULTANT PHARMACIST - CLINIC FACILITY:

(1) The consultant pharmacist providing services to a clinic shall.

(a) Assume overall responsibility for clinic pharmacy services, for clinic pharmacy supportive personnel, and for procedures as outlined in the procedures manual, including all records of drugs procured, administered, transferred, distributed, repackaged or dispensed from the clinic.

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

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TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 12 FEES

16.19.12.8 FEES: All fees shall be paid in advance of the issuance of any license, permit, certificate or replacement of a certificate and shall not be returndable.
[03-07-80...08-27-90; 16.19.12.8 NMAC - Rn, 16 NMAC 19.12.8, 03-30-02]

16.19.12.15 CLINIC LICENSE FEES: Clinic license fees shall be:
A. Limited Clinic $300.00 bi-ennialy
B. Intermediate Clinic $300.00 bi-ennialy
C. Major Clinic $300.00 bi-ennialy
D. School clinic $75.00 bi-ennially
~~D~~E. Duplicate License $10.00
~~E~~F.. Animal Control Clinics $100.00 bi-ennialy
[03-07-80...08-06-94; 12-15-99; 16.19.12.15 NMAC - Rn, 16 NMAC 19.12.15, 03-30-02; A, 09-30-03]

Appendix D

Meeting Minutes

Sterile Compounding Committee

Advisory to the NM Board of Pharmacy

Wednesday May 14, 2014 3:00- 4:30 PM

Telephone Conference Call

Members present: Amy Buesing, Board Member and Co-Chair, Kristina Wittstrom, Co-Chair; Catherine Cone, Kris Mossberg (for Adela Padilla), Phil Saucedo, Christina Kim, Scott Roach

ABuesing reported on the hearing for new sterile preparations regulations (16.19.36) during the April Board meeting. While the proposed changes were adopted after comments from both the Committee and members of the public, two sections were marked for additional review by the Committee: 16.19.36.13 Requirements for Training and 16.19.36.15 Quality Assurance of CSP.

Summary of the section discussions is presented here.

I. Requirements for Training

a. Proposed section A.2 Pharmacist Interns

- Change to Training for Pharmacists and Interns
- Remove a(ii) completion of a board approved course *[There are none. Training from commercially available programs are part of item a(i)]*
- Change a(iii) to read certification by UNM College of Pharmacy <u>for pharmacist interns</u>

b. Proposed section A.3 Certified Pharmacy Technician

- Item (a): There was extensive discussion concerning NMSA 61.11.11.1 and stipulation of 100 additional hours of training in sterile preparations. Neither members of the Committee or public attending the April Board meeting were aware of this requirement, expressing concern over its source and its intent.

61-11-11.1. Pharmacy technician; qualifications; duties. (Repealed effective July 1, 2016.) A. The classification of pharmacy technician is established. An applicant for registration as a pharmacy technician shall: (1) be at least eighteen years of age and not addicted to drugs or alcohol; (2)

complete initial training as required by regulations of the board that includes on-the-job and related education commensurate with the tasks to be performed by the pharmacy technician; and (3) if the potential duties of the pharmacy technician will include the preparation of sterile products, complete an additional one hundred hours of experiential training as required by regulations of the board.

- The language 'as required by regulations of the board" needs to be explained before moving forward on this issue. **Action Item: ABuesing will investigate with Board legal counsel and Board Executive Director for clarification**.
- Item (b): board approved course was also discussed. While some technician training programs provide sound instruction in sterile preps, not all are approved by the Board. CPT trained in sterile preps receive modified instruction prior to beginning job duties in licensed pharmacies. It is not clear if this language is needed, but Committee would like comments from members of the public before deciding.

c. Proposed section B Hazardous CSP Training

- This section was proposed in anticipation of USP <800>. As the new chapter is not finalized, it may be more appropriate to wait until the final version is released.
- The proposed chapter may have significant impact on many aspects of preparing hazardous CSP and will require additional review before recommendations can be made.
- The proposed chapter needs to be reviewed before proceeding. **Action Item: CKim will review with the UNM SPOT team and provide feedback. Committee members will review the proposed chapter.**

II. Quality Assurance of CSP

a. Item A (4) Batch labels

- The definition of 'batch' should be removed and placed in definitions.
- (d) BUD should include stipulation of date or time, as applicable.
- (g) facility identifier should be retained.

b. Item (6) Batch records

- Use of "worksheet" in this section is not consistent.

- In 6 replace 'worksheet' with 'record' – or other language to improve clarity of expectations.
- Item 6 (A): Change to "A master reference [or formulation] document for product preparation shall be available and include:" Term for master document to be added to defintions.
- Item 6(A) (6) 'sample label' should be changed to "information for appropriate labeling". *[use of a sample label is not necessary if the formulation document contains all needed information]*
- Item 6(B)(1) The reference name should match language used in A
- Item 6(B)(9): change to read: "results of applicable quality control procedures" *[QC is not required on <u>all</u> CSP]*

c. Item A (2) Final prep testing results prior to release of high risk CSP's

- Is this section referring to high risk CSP's
- What is patient care will be compromised by waiting for test results?
- Need to delineate between bulk compounding and preparing multiple individualized doses for a specific patient
- Action item: CKim and CCone to research and come back to committee with information and recommendations.

d. New section C. Quality Control Measures

- This section added to specifically call out areas of deficiencies noted by pharmacy inspectors. Inspectors feel that specific statements within the regulations would facilitate enforcement.
- Committee may have addressed these issues elsewhere as it is noted that topics have been discussed before.
- Additional research and investigation of current language and interface with USP <797> is needed before additional discussion. **Action Item: ABuesing and KWittstrom will review current regulations and provide more information.**
- Item 4. Statement is currently listed in Food Drug & Cosmetic Act as well as Drug Quality and Safety Act. There are allowances/permissions in which the proposed prohibited compounding is allowed. More information is needed before making recommendations. **Action Item: KMossberg will research and provide feedback.**

III. Proposed addition: 16.19.36.16 Records

- The duration and availability of records is thought to be addressed elsewhere in the regulations. Location of such needs to be identified.

- **Action Item: ABuesing and KWittstrom will research and provide feedback.**

IV. Volunteers that have expressed an opportunity to review/comment before presenting to NMBOP

a. Doug Scribner

b. Krista McCoy

c. Vanessa Conley

d. Cheranne McCracken

Next Meeting: TBD (end of May)
Submitted by KWittstrom May 15th 2014

Meeting Minutes
Sterile Compounding Committee
Advisory to the NM Board of Pharmacy

Wednesday May 30, 2014 3:00- 4:30 PM
Telephone Conference Call

Members present: Amy Buesing, Board Member and Co-Chair, Kristina Wittstrom, Co-Chair; Kris Mossberg, Adela Padilla, Phil Saucedo, Christina Kim, Scott Roach, Teri Rolan

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The action/ discussion items from last meeting were presented, reviewed and discussed as outlined below.

1. **16.19.36.15 A (2) Final prep testing results prior to release of high risk CSP's**

Suggested rewording: If non-sterile to sterile bulk compounding of more than 25 units of compounded sterile products is performed using non-sterile chemicals, appropriate…..

2. **16.19.36.13: proposed new item specific to Certified Pharmacy Technicians. The statute 61-11-11.1 specifies 100 hours of experiential training for CPhT preparing CSP. There is no alternative to this at this time.**

Concerns for lack of general awareness of this statute requirement and a process by which CPhT with substantial prior experience can be documented.
ABuesing will bring this to BoP for discussion and approach.

3. **16.19.36.13 Proposed section B Hazardous CSP Training [Tabled to next meeting]**
Action Item: CKim will review with the UNM SPOT team and provide feedback. Committee members will review the proposed chapter.

4. **16.19.3615 Proposed New section C. Quality Control Measures**
    a. **Examination for visible particulate matter:**
    Discussion included: currently listed in USP < 797> ; inspector feedback suggests that this is area difficult to enforce and that specific language "would make things easier" [Amy: I have no notes on what was decided here.]
    b. **Double checking compounding accuracy: There was no consensus on what was intended with this item. APadilla will investigate further for next meeting**
    c. **Compounding facility responsibility: APadilla explained a need to hold owner/management accountable for activities in pharmacies. Need language similar to that found in 27-Dishoonorable Conduct; 10 Clinics, and 11 Nursing Homes. KWittstrom will research appropriate language for this item.**
    d. **Prohibition of drugs withdrawn for safety. Inspectors stated that similar language can be found in 27 and 30 and should be added here. Some discussion of need to include in SCP section. Consider combining as part of an operation/management sections.**

5. **Proposed addition: 16.19.36.16 Records**
    Add as item C to 16.19.36.11 Documentation Requirements

6. **There is a need to obtain the language approved by the Board before preparing any redline for proposed changes. ABuesing to obtain.**

Next Meeting: June 27th 2014 2:00 PM

7. **Submitted by KWittstrom May 31st 2014**

Next Meeting: June 27th 2014 2:00 PM

Submitted by KWittstrom May 31st 2014

Appendix E

16.19.20.8 REGISTRATION REQUIREMENTS: Persons required to register:

A. manufacture - term includes repackagers;

B. distributors - term includes wholesale drug distributors;

C. dispensers - pharmacies, hospital pharmacies, clinics (both health and veterinarian);

D. practitioners - includes a physician, doctor of oriental medicine, dentist, physician assistant, certified nurse practitioner, clinical nurse specialist, certified nurse-midwife, veterinarian, pharmacist, pharmacist clinician, certified registered nurse anesthetists, psychologists, chiropractic examiner, euthanasia technicians or other person licensed or certified to prescribe and administer drugs that are subject to the Controlled Substances Act. Practitioners (excluding Veterinarians) must register with the New Mexico prescription monitoring program in conjunction with their controlled substance registration.

E. scientific investigators or researchers;

F. analytical laboratories and chemical analysis laboratories;

G. teaching institutes;

H. special projects and demonstrations which bear directly on misuse or abuse of controlled substances - may include public agencies, institutions of higher education and private organizations;

I. registration waiver: an individual licensed practitioner (e.g., intern, resident, staff physician, mid-level practitioner) who is an agent or employee of a hospital or clinic, licensed by the board, may, when acting in the usual course of employment or business, order controlled substances, for administration to the patients of the facility, under controlled substance registration of the hospital or clinic in which he or she is employed provided that:

(1) the ordering of controlled substances for administration, to the patients of the hospital or clinic, is in the usual course of professional practice and the hospital or clinic authorizes the practitioner to order controlled substances for the administration to its patients under its state controlled substance registration;

(2) the hospital or clinic has verified with the practitioner's licensing board that the practitioner is permitted to order controlled substances within the state;

(3) the practitioner acts only within their scope of employment in that hospital or clinic;

(4) the hospital or clinic maintains a current list of practitioners given such authorization and includes the practitioner's full name, date of birth, professional classification and license number, and home and business addresses and phone numbers;

(5) the list is available at all times to board inspectors, the D.E.A., law enforcement and health professional licensing boards; and

(6) the hospital or clinic shall submit a current list of authorized practitioners with each hospital or clinic controlled substance renewal application.

[16.19.20.8 NMAC - Rp 16 NMAC 19.20.8, 07-15-02; A, 12-15-02; A, 07-15-04; A, 05-14-10; A, 08-31-12]

Appendix F

16.19.29.7 DEFINITIONS:

A. "Controlled substance" has the meaning given such term in 30-31-2 NMSA.

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

C. "Patient" means the person ~~or animal~~ who is the ultimate user of a drug for whom a prescription is issued and for whom a drug is dispensed.

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

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

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

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

(4) clinics, urgent care or emergency departments dispensing no more than 12 dosage units to an individual patient within a 72 hour period

(5) veterinarians or veterinary clinics dispensing to non-human patients

E. "Prescription monitoring program" (PMP) means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners, of which the data is to be used to support efforts in education, research, enforcement and abuse prevention.

F. "Schedule II, III, IV and V controlled substance" means substances that are listed in Schedules II, III, IV, and V of the schedules provided under 30-31-5 to 30-31-10 of NMSA or the federal controlled substances regulation (21 U.S.C. 812).

G. "Report" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance.

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

Appendix G

16.19.11.8 MINIMUM STANDARDS:

B. POLICY AND PROCEDURES MANUAL:

(6) DRUG DISTRIBUTION

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

(i) Sterile normal saline and water - injectable;

(ii) Sterile normal saline and water - irrigation;

(iii) Tuberculin testing solution;

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

(v) ~~Flu vaccine.;~~

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

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

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

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

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

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

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

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

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

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

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

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