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

August 25th and 26th, 2014 Regular Board Meeting Agenda

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 July 23, 2014.

Location: Ruidoso Convention Center, 111 Sierra Blanca Dr. Ruidoso, New Mexico

Scheduled Meeting Time: 9:00 a.m. – 5:00 p.m. Monday and Tuesday

MONDAY AUGUST 25, 2014

1. Procedural Items:

9:00 a.m. Call to Order: The meeting of the Pharmacy Board was called to order by Chairman Cross at 9:01 a.m. on August 25, 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	**A** Anise Yarbrough	**A** Allen Carrier

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

Approval of June 2014 Minutes: Motion to approve the June 18th & 19th, 2014 minutes as presented by Ms. Mendez-Harper, seconded by Ms. Saavedra, 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: **8 Clinic/Home Health** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

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

Motion: **1 Emergency Medical Service** applications is in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Harper, board voted unanimously to pass the motion.

Motion: **16 Custodial/Nursing Home** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing to approve applications, board voted unanimously to pass motion.

Motion: **7 Pharmacy/Hospital** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Buesing to approve applications, board voted unanimously to pass motion.

Motion: **32 Non-Resident Pharmacy** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Ms. Saavedra to approve applications, board voted unanimously to pass motion.

Motion: **21 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
August 25 & 26, 2014

CLINIC /HOME HEALTH	CONSULTANTPHARMACIST
1.ABQ Health Partners Rio Bravo Women's Health 200 Rio Bravo Blvd SW Albuquerque, NM 87105	Remodel Martin Martinez, R.Ph.
2.Artesia Healthcare Professionals Dr. Salgado's Clinic 612 N 13th Street Suite D Artesia, NM 88210	New Kirk Irby, R.Ph.
3.Miners Colfax Medical Center 142 S 1st Raton, NM 87740	New Cindy Johnson, R.Ph.
4.Next Care NM LLC 5504 Menaul Blvd NE Suite F Albuquerque, NM 87110	New Andrew Kurtz, R.Ph.
5.PMS 528 Clinic 3777 New Mexico Hwy 528 NE Rio Rancho, NM 87144	New Rich Gutierrez, R.Ph.
6.PMS Torreon Clinic 2500 State Hwy 197 Torreon, NM 87013	Remodel Katie Klein, R.Ph.
7.PMS Socorro Mental Health 1200 Hwy 60 West Socorro, NM 87801	New Katie Klein, R.Ph.
8.Valle del Sol of New Mexico 717 Abrahams Road Suite D Moriarty, NM 87035	Relocation Shelley Bagwell, R.Ph.
ANIMAL CONTROL	CONSULTANT PHARMACIST
Otero County Animal Shelter 601 Wright Avenue Alamogordo, NM 88310	New Hal Sims, R.Ph.

EMERGENCY MEDICAL SERVICE Santa Fe County Fire Department 1 Municipal Way Edgewood, NM 87015	CONSULTANT PHARMACIST Relocation Christine Atwell, R.Ph.
CUSTODIAL/NURSING HOME 1.Anita D'Antonio 6519 Sunview Drive NW Albuquerque, NM 87120	CONSULTANT PHARMACIST New Lori Carabajal, R.Ph.
2.Beehive Homes of Four Hills 13440 Wenonah Avenue NE Albuquerque, NM 87123	New Clover Wagner, R.Ph.
3.Casa de Esperanza Inc 3903 Shady Brook Court Las Cruces, NM 88005	New Scott Wallace, R.Ph.
4.Dungarvin New Mexico LLC 5201 Tamariz Drive NW Albuquerque, NM 87120	New Martin Salas, R.Ph.
5.Easter Seals El Mirador 10 A-Van-Nu-Po Santa Fe, NM 87508	Change of Ownership Nia Harris, R.Ph.
6.Easter Seals El Mirador County Road 40.365 Alcalde, NM 87511	Change of Ownership Nia Harris, R.Ph.
7.Hobbs Hive LLC 1928 College Lane Hobbs, NM 88242	New Clover Wagner, R.Ph.
8.Jim Wood Home 1163 W Canal Hatch, NM 87937	New Scott Wallace, R.Ph.
9.L.A. In-Home Care 1625 33rd Street SE Rio Rancho, NM 87124	New Annabel Roberts, R.Ph.
10.La Posada Assisted Living 299 E Montana Las Cruces, NM 88005	New Theodore Trujillo, R.Ph.
11.Ramah Care Services 1612 Freedom Drive Gallup, NM 87301	New Stephanie Rodriguez, R.Ph.
12.Ramah Care Services 418 Julie Drive Gallup, NM 87301	New Stephanie Rodriguez, R.Ph.
13.Ramah Care Services 915 East Logan Gallup, NM 87301	New Stephanie Rodriguez, R.Ph.

14.Ravenna Assisted Living 3051 Twin Oaks Drive NW Albuquerque, NM 87120	New Shauna Porter, R.Ph.
15.Tobosa Developmental Services 22 Bent Tree Road Roswell, NM 88203	New Paul Turner, R.Ph.
16.Woodmark at Uptown 7201 Prospect Place NE Albuquerque, NM 87110	New Ron Lujan, R.Ph.
PHARMACY /HOSPITAL	PHARMACIST IN CHARGE
1.Home Medical Equipment Specialists 10801 Golf Course Rd NW Albuquerque, NM 87113	Relocation Emily Bustos, R.Ph.
2.Rx Innovations Inc 7215 Washington Street NE Albuquerque, NM 87109	Change of Ownership Melissa Whelchel, R.Ph.
3.Smith's Pharmacy 751 Trinity Drive Suite 100 Los Alamos, NM 87544	Relocation Robert Medina, R.Ph.
4.UNM Hospital Sterile Prep-Inpatient Pharmacy 2211 Lomas Blvd Albuquerque, NM 87106	Remodel Bill Long, R.Ph.
5.Walgreens Pharmacy 201 Cedar SE Suite 102 Albuquerque, NM 87106	New Jennifer Ortega, R.Ph.
6.Walgreens Pharmacy 1509 E Santa Fe Avenue Grants, NM 87020	New Jennifer Ortega, R.Ph.
7.Walgreens Pharmacy 122 North Gold Avenue Deming, NM 88030	Relocation Jeffrey Gorbett, R.Ph.
NON-RESIDENT PHARMACY	PHARMACIST IN CHARGE
1.Advantage Pharmacy LLC 6375 US Hwy 98W Suite 50 Hattiesburg, MS 39402	New Jason May, R.Ph.
2.American Star Pharmacy 6407 S Cooper Street Suite 113B Arlington, TX 76001	New Ajeesha Abraham, R.Ph.
3.Anderson Compounding Pharmacy 310 Bluff City Highway Bristol, TN 37620	New R.C . Anderson II, R.Ph.
4.Aureus Health Services LLC DBA Aureus Pharmacy 61 Doctors Park Cape Girardeau, MO 63703	New Kelley Pipkin, R.Ph.

5.BriovaRx 1050 Patrol Road Jeffersonville, IN 47130	New Michael Zeglinski, R.Ph.
6.Central Rexall Drugs Inc 125 E Thomas Street Hammond, LA 70401	New Donald Fellows Jr., R.Ph.
7.Currant Health Florida LLC 7209 Bryan Dairy Road Largo, FL 33777	New Sokhninder Shah, R.Ph.
8.DermaTran Health Solutions 85 Technology Parkway Rome, GA 30165	Change of Ownership Lisa Harris, R.Ph.
9.DermaTran Health Solutions 1504 Market Street Redding, CA 96001	Change of Ownership Charles Hoeft, R.Ph.
10.DMR Pharmacy 433 Kings Hwy Brooklyn, NY 11223	New Dmitri Gelfand, R.Ph.
11.Executive Pharmacy 4300 N University Drive #E200 Fort Lauderdale, FL 33351	New Leonard Arteaga (not Ortega), R.Ph.
12.Express Scripts Pharmacy Inc DBA Express Scripts 2040 Route 130 North Burlington, NJ 08016	New Lynda Doremus. R.Ph.
13.Florida Pharmacy Solutions 13933 17th Street Suite 300 Dade City, FL 33525	New Craig Woodruff, R.Ph.
14.Hollywood Healthcare Corp 15851 SW 41st Suite 700 Davie, FL 33331	New Beth Kravec, R.Ph.
15.Innovative Pharmacy Solutions 9140 S State Street Suite #201 Sandy, UT 84070	New Jody Hicken, R.Ph.
16.Insight Pharmacy 700 E Township Line Road Suite LL2 Havertown, PA 19083	New Young Gim, R.Ph.
17.Inventive Infusion Solutions 18866 Stone Oak Parkway Suite 101A San Antonio, TX 78258	New Jeremy Davila, R.Ph.
18.Ken's Professional Compounding 2202 W Charleston Blvd #13 Las Vegas, NV 89102	New Kenneth Heaton, R.Ph.
19.Life-Q LLC 1838 Elm Hill Pike Suite 125 Nashville, TN 37210	New Benson Chiong, R.Ph.

20.Mark Bayou Pharmacy LLC
82 Black Bayou Loop
Santa Rosa Beach, FL 32459

New
Amy Frazier, R.Ph.

21.Mesa Pharmacy Inc
DBA Mesa Pharmacy VII
18013 Sky Park Circle Suite D
Irvine, CA 92614

New
Andrew Do, R.Ph.

22.OncoMed The Oncology Pharmacy of Buffalo NY
640 Ellicott Street
Buffalo, NY 14203

New
Eric Saul, R.Ph.

23.Praxis Rx Pharmacy
5455 W Waters Suite 214
Tampa, FL 33634

New
William Bailey, R.Ph.

24.Prime Pharmacy Solutions LLC
1346 Lindberg Drive Suite 627
Slidell, LA 70458

New
Joe Campo, R.Ph.

25.Real Time Pharmacy Services
DBA MedEnvios Healthcare
7415 Corporate Center Drive Suite B
Miami, FL 33126

New
Luis Caba, R.Ph.

26.Script Corporation
2907 W Empire Avenue
Burbank, CA 91504

New
Navid (not David) Doostan, R.Ph.

27.Solar Medical Supplies
720 Highway 75
Imperial Beach, CA 91932

New
John Williams, R.Ph.

28.Sun City Compounding
720 Arizona Avenue
El Paso, TX 79902

New
Daniel Moreno, R.Ph.

29.SunQuest Pharmaceuitcals Inc
150 Eileen Way Suite 1
Syosset, NY 11791

New
Richard Walker, R.Ph.

30.Tech-Pharmaceuticals Inc
DBA Vidascript
7432 SW 48th Street
Miami, FL 33155

New
Frank Ammirata, R.Ph.

31.Walgreens Pharmacy Services Midwest LLC
8325 South Park Circle Suite 201
Orlando, FL 32819

New
Fenicia Hutt, R.Ph.

32.Woods Pharmacy LLC
151 Texas Road
Old Bridge, NJ 08857-3904

New
Madhavi Padiagala, R.Ph.

<u>WHOLESALER/BROKER</u>

1.Abraxis BioScience LLC
86 Morris Avenue
Summit, NJ 07901

New

2.bioCSL Inc (correct spelling per company) 1020 First Avenue King of Prussia, PA 19406	New
3.Bound Tree Medical LLC 3221 E Arkansas Lane Suite 145 Arlington, TX 76010	New
4.Cadence Pharmaceuticals Inc 12481 High Bluff Drive #200 San Diego, CA 92130	Change of Ownership
5.D & H Wholesale Medical Inc DBA D & H Medical Supply 609 Willow Glen Ruston, LA 71270	New
6.Diamondback Drugs 7631 E Indian School Road Scottsdale, AZ 85251	New
7.InterMune Inc 3280 Bayshore Blvd Brisbane, CA 94005	New
8.JCB Laboratories 7335 W 33rd Street North Wichita, KS 67205	New
9.Marlex Pharmaceuticals Inc 50 McCullough Drive New Castle, DE 19720	New
10.MediNatura Inc 10421 Research Road SE Albuquerque, NM 87123	New
11.Omeros Corporation 201 Elliott Avenue West Seattle, WA 98119	New
12.Pragma Pharmaceuticals LLC 134 Birch Hill Roa Locust Valley, NY 11560	New
13.Retrophin Inc 777 3rd Avenue 22nd Floor New York, NY 10017	New
14.Rockwell Medical Inc 30142 S Wixom Road Wixom, MI 48393	New
15.SCA Pharmaceuticals LLC 8821 Knoedl Court Little Rock , AR 72205	New

16.Sebela Pharmaceuticals Inc — New
645 Hembree Parkway Suite I
Roswell, GA 30076

17.Theravance Biopharma US Inc — New
901 Gateway Blvd
San Francisco, CA 94080

18.Teva API Inc — New
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

19.Tolmar Pharmaceuticals Inc — New
1201 Cornerstone Drive
Windsor, CO 80550

20.Tolmar Pharmaceuticals Inc — New
701 Centre Avenue
Fort Collins, CO 80526

21.WellGistics LLC — New
480 Eagles Landing Drive
Lakeland, FL 33810

b) Pharmacist Clinicians:

Motion: Change the meeting date on the pharmacists clinician committee report to reflect the actual meeting date from April 10, 2014 to August 13, 2014, 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 including controlled substances for Mikiko Yamada, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: Approve the new protocol for existing license with prescriptive authority, no controlled substances for John Togami, motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: Approve the new protocol for existing license with prescriptive authority including controlled substances for Richard Levine, 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 Ms. Buesing, 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. Mazzoni to go into closed session at 9:15 a.m., to discuss the MTP report. Mr. Cross, Mr. Woodul, Mr. Mazzoni, Ms. Mendez-Harper, Ms. Buesing, Mr. Anderson and Ms. Saavedra voted unanimously to pass the motion.

The board went back into open session at 9:21 a.m. and the only issue discussed was the MTP report.

4. 10:00 a.m. Carl Flansbaum – PMP report, delinquent reporting pharmacies: See Appendix A

Mr. Flansbaum stated that a letter was sent out by his department informing PMP registrants of potential disciplinary action for non-reporting, which prompted a huge surge in registrants reporting and becoming in compliance. He also stated that he is working with the IT department to rectify the problem of passwords expiring for FTP accounts, he would like to develop passwords that do not

expire.

Mr. Flansbaum stated that corrections made by registrants to the PMP *must be done within the same 7-day reporting period* that the error was made in, which when not done correctly accounts for 80% of the technical problems addressed by the PMP department.

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

The Chairman Danny Cross opened the rule hearing at 10:35 and took roll call. Present were Mr. Woodul, Mr. Mazzoni, Ms. Mendez-Harper, Ms. Buesing, Mr. Anderson, Ms. Saavedra, and Chairman Cross. Absent were Ms. Yarbrough and Mr. Carrier. Also present were board counsel Mary Smith, Executive Director, Larry Loring, and Administrative Secretary, Debra Wilhite.

The Chairman entered the notice of hearing as exhibit #1, exhibit #2 proposed language for 16.19.10.11 NMAC, no written comments; exhibit #3 proposed language for 16.19.4.11 NMAC, exhibit #4 written comments; exhibit #5 proposed language for 16.19.12 NMAC, no written comments; exhibit #6 proposed language for 16.19.20.8 NMAC, no written comments; exhibit #7 proposed language for 16.19.29.7 NMAC, exhibit #8 written comments; exhibit #9 proposed language for 16.19.11.8 NMAC, no written comments; and the sign in sheet as exhibit #10.

a) 16.19.4.11 Consultant pharmacist – Add Class D clinic review schedule: See Appendix B

Motion: Adopt language as amended in 16.19.4.11 NMAC. Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper, board voted unanimously to pass the motion.

b) 16.19.10.11 Clinic – Add Class D public school emergency medications: See Appendix C

Motion: Adopt language as amended in 16.19.10.11 NMAC. Motion made by Mr. Mazzoni, seconded by Ms. Buesing, board voted unanimously to pass the motion.

c) 16.19.12 Fees – Add Class D clinic/$30 license fee; change refund provision: See Appendix D

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

d) 16.19.20.8 Registration Requirements – exclude veterinarians from PMP registration: See Appendix E

Motion: Adopt language as amended in 16.19.20.8 NMAC. Motion made by Mr. Woodul, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

e) 16.19.29.7 Definitions – exclude veterinarians from dispenser; remove "animal" from patient definition: See Appendix F

Motion: Adopt language as amended in today's discussion for 16.19.29.7 NMAC. Motion made by Mr. Mazzoni, seconded by Mr. Woodul, board voted unanimously to pass the motion.

f) 16.19.11.8 Nursing Home Drug Control – Update nursing home stock drug list: See Appendix G

Motion: Adopt language as amended in 16.19.11.8 NMAC. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

6. Committee Reports and Board Actions:
(30 minutes will be allotted for committee's discussion for 2015 plan of action)

Rich Mazzoni - Rules Committee: 16.19.6.7 Definitions and 16.19.6.27 Automated Filling Systems: See Appendix H

Motion: Notice 16.19.6.7 NMAC for the October 2014 board meeting. Motion made by Ms. Buesing, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Danny Cross - Clinic Committee: Proposed language for public health offices/waivers, create new types of health clinics, school based clinics with and without drugs, dispensing modernization. See Appendix I
Chris Woodul - Wholesale Committee: Outsourcing facilities, compounding pharmacies, look at NY state rules regarding outsourcing.
Buffie Saavedra - Tele-Pharmacy Committee: Discuss and propose language to address automated dispensing and utilization/nursing homes, hospice and long-term facilities; will ask the board for direction, we have new members on the committee; Mr. Harvey will bring proposed language to the October 2014 meeting.
Joe Anderson - Pharmacist CE Committee: CPE/50 participants – will no longer house the program; focus groups documentation/experiential program used from COP; app's being created to simplify and record CPE development through receiving grants; peer review process/focus group.
Amy Buesing - Sterile Products Committee: Look at regulations changes to reflect USP <797> to present at the October 2014 board meeting. See Appendix J
LuGina Mendez-Harper - Pharmacist Practice Committee: See Appendix K
Greg D'Amour - Pharmacist Clinician Committee: Address the overlapping of pharmacist practice and pharmacist clinician issues.
Danny Cross - Pharmacy Technician Committee: Plan of action at this time pending.
Allen Carrier - Emergency Preparedness Committee: Plan of action at this time pending.
Substance Abuse Harm Reduction Committee: Plan of action at this time pending.
Joe Anderson - Board of Pharmacy/BAOM Education Committee: The BAOM/Chiropractic boards lost their lawsuit regarding the formulary; they may be starting the process over again.
Joe Anderson - Board of Pharmacy/Chiropractic Formulary Committee: Plan of action at this time pending.

7. Recess for the day: The Pharmacy Board meeting was recessed at 4:36 p.m. and will reconvene at 9:00 a.m. tomorrow, Tuesday August 26, 2014.

TUESDAY AUGUST 26, 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 August 26, 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	**A** Anise Yarbrough	**A** Allen Carrier

2. 9:05 a.m. Cindy McCormick – Personnel Issues*: No presentation was made at this time.

3. 10:00 a.m. – 11:30 a.m. Public/Professional Requests/Waiver Petitions*:

Ed Scott – prescription transfer between pharmacies: Mr. Scott presented information regarding problems he has experienced with transfers of original prescription order information and/or the lack there of from a pharmacy that has closed; to his pharmacy. Mr. Scott provided language from the Texas pharmacy rules to be considered by the boards' rules committee to develop proposed language regarding transfers of prescriptions between pharmacies which is not currently in our rules.

The board discussed the requirements that are listed on the *Pharmacy Closure form* as stated in 16.19.6.13 NMAC.

The board asked that Mr. Loring do an audit of pharmacy closures to be presented at the October 2014 board meeting.

Ken Corazza – verifying CS licenses to determine if active or expired: Mr. Corazza presented information regarding the filling of prescriptions by a pharmacist that have been written by a practitioner during the time that the practitioners CS license may have been expired, and what repercussions to the pharmacist/pharmacies that may result from this issue.

No action was taken at this time but the rules committee will address the definition of corresponding responsibility in 16.19.20.41 A(1) and bring back to the board.

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

a) 61-11-29 agency termination statute:

Executive Director, Larry Loring explained to the board that the board/agency must justify its existence by providing a Sunset report as referenced in statute 61-11-29. Mr. Loring has provided the Sunset report as required to the LFC.

b) Open Meetings Resolution Adoption: See Appendix L

Motion made by Mr. Mazzoni, seconded by Mr. Anderson to approve the 2015 Open Meetings resolution, board voted unanimously to pass the motion.

c) 2015 Board Meeting Dates:

Motion made by Mr. Mazzoni, seconded by Mr. Anderson to approve the 2015 board meeting dates as listed; January 22nd & 23rd - April 16th & 17th - June 24th starting @ 1:00pm/June 25th starting @ 9:00am and June 26th starting @ 9:00am if necessary – August 20th & 21st – October 15th & 16th, board voted unanimously to pass the motion.

d) District 6-7-8 Meeting Sept 21-24 Whitefish, Montana:

Mr. Mazzoni and Ms. Mendez-Harper will attend the NABP district meeting.

e) Board of Pharmacy Strategic Plan 2015:

Mr. Loring stated that he developed the Pharmacy board strategic plan for the 2014-2015 year, and has started working on developing the strategic plan for 2015-2016. Due to his retirement in December 2014, he would like to ask the board members for their help in completing the plan.

Ms. Buesing stated that she will help develop the strategic plan for 2015-2016 year, and bring to the board at the April board meeting for discussion.

f) LFC Sunset hearing Sept. 23 in Santa Fe:

Mr. Loring stated that the Legislative Finance Committee will have a hearing September 23, 2015 to address the Sunset report.

Mr. Mazzoni will attend the hearing in Santa Fe to represent the board.

g) 16.19.7 Sterile Products: See Appendix H

Motion made during committee reports to notice for hearing at the October 2014 board meeting.

h) 16.10.16 NMAC PA's prescribing, distributing drugs: See Appendix M

Mr. Loring stated that he would like feedback from the board regarding physician's assistants prescribing and distributing drugs to be discussed at the October board meeting.

i) Executive Director's position:

Mr. Loring stated that SPO should be posting the opening in this month in August.

j) 50-year Pharmacists update:

Mr. Loring stated that the board will present each year, recognition certificates to pharmacists that have 50 years of active service with the board.

k) Tom Ortega "Thank You Card":

Mr. Loring stated that Mr. Tom Ortega's sister sent a thank you card to the board stating her appreciation of the recognition letter and certificate from the NABP.

l) Committee assignments 2015 plan of action– Danny Cross: Discussed on Monday under committee reports.

5. Case Presentations:

Inspector Mossberg: 2014-029/close

Inspector McCracken: 2013-061/VS 2014-025/close 2014-034/NCA 2014-037/close

Inspector Kesner: 2014-020/close

Inspector B. Padilla: 2014-030/close

Inspector A. Padilla: 2014-016/close 2014-028/VS 2014-031/VS 2014-033/close

Motion: **Close cases:** 2014-016, 2014-020, 2014-025, 2014-030, 2014-033, 2014-037. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

Motion: **Close case:** 2014-029. Motion made by Mr. Mazzoni, seconded by Mr. Woodul, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself from the vote.

Motion: **Issue voluntary surrende**r for case 2013-061. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Motion: **Issue NCA to revoke** for case 2014-034. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

VS = Voluntary Surrender

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

2012-100 – New Life Assisted Living CU10677 – Stipulated Agreement

Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper to approve the stipulated agreement for 2012-100, board voted unanimously to pass the motion.

2014-028 – Judy Manzanares PT9267 – Voluntary Surrender
2014-031 – Janet Lovato PT8486 – Voluntary Surrender

Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper to accept the voluntary surrender for 2014-028 and 2014-031, board voted unanimously to pass the motion.

2014-033 – Andrea Bowra PT7247 – Voluntary Surrender: Closed during case presentations.

2013-054 – Fitz Glasgow RP7612 – Stipulated Agreement

Motion made by Mr. Mazzoni, seconded by Ms. Mendez-Harper to approve the stipulated agreement for 2013-054, board voted unanimously to pass the motion.

7. Election of Officers:

Motion made by Ms. Saavedra, seconded by Mr. Anderson to elect Mr. Danny Cross as the Chairman, elect Ms. Amy Buesing as the Vice-Chair and elect Ms. LuGina Mendez-Harper as Secretary, board voted unanimously to pass the motion.

8. Adjournment: With no further business, Ms. Saavedra made a motion to adjourn the Pharmacy Board meeting at 12:05 p.m., seconded by Mr. Anderson, board voted unanimously to pass the motion.

Appendix A

Delinquent Reporters to the PMP for consideration of action by the Board of Pharmacy

Submitted: 25.August.2014

Carl Flansbaum, RPh. Director, PMP

The following dispensers have had both a recent as well as multiple instances of delinquency since the beginning of the year. I request for a consideration of action, possibly by either issuing a NCA or pursing a pre-NCA settlement.

Attached is the reminder letter sent to all dispensers on July 16, 2014

All the below reporters did upload the day after receiving the delinquent notice on 8/19

Dispenser #1 (Non-Resident)

NM Pharmacy License# PH0000XXX

NM CS Licenses# CS00XXXXXX

Dates of Delinquency

8/19/2014 7/1/2014 6/3/2014 1/21/2014 1/7/2014

Dispenser #2

NM Pharmacy License# PH0000XXXX

NM CS Licenses# CS00XXXXXX

Dates of Delinquency

8/19/2014 7/1/2014 3/4/2014

Dispenser #3 (Non-Resident)

NM Pharmacy License# PH0000XXXX

NM CS Licenses# CS00XXXXXX

Dates of Delinquency

8/19/2014 7/15/2014 6/17/2014 5/20/2014 5/6/2014

Dispenser #4 (Non-Resident)

NM Pharmacy License# PH0000XXXX

NM CS Licenses# CS00XXXXXX

Dates of Delinquency

8/19/2014 5/6/2014 1/21/2014

Dispenser #5

NM Pharmacy License# PH0000XXXX

NM CS Licenses# CS00XXXXXX

Dates of Delinquency

8/19/2014 7/29/2014 6/3/2014 4/15/2014 4/1/2014 3/18/2014

2/18/2014

Dispenser #6 (Non-Resident)

NM Pharmacy License# PH0000XXXX

NM CS Licenses# CS00XXXXXX

Dates of Delinquency

8/19/2014 6/3/2014 1/21/2014

To: New Mexico Controlled Substance Pharmacy Licensee
Re: Notice to Dispensers Regarding PMP Reporting Requirements and Potential Disciplinary

Action for Delinquency by the New Mexico Board of Pharmacy (Board)

You have been notified at least once this calendar year regarding delinquent reporting of required prescription data to the New Mexico Prescription Monitoring Program. You must read this notice and maintain compliance with the PMP reporting requirements in order to avoid disciplinary action being taken against you and your license by the New Mexico Board of Pharmacy.

This notice is a reminder that pursuant to the Controlled Substances Act and the Board's rules, a dispenser shall report to the New Mexico Prescription Monitoring Program (PMP) all controlled substance prescription data as mandated by the Board within 7 days of a prescription being filled. See 16.19.29.7(D) NMAC ("dispenser" defined); 16.19.29.8 NMAC (required controlled substance prescription data).

Due to the importance of timeliness of prescription data reporting to provide accurate information about a person's use of controlled substances, reporting compliance to the PMP is being more closely monitored. While the Board understands that there are occasionally unforeseen problems with reporting as required, it is the responsibility of the dispenser to monitor their reporting of prescription data and immediately communicate with the PMP Staff regarding any possible reporting issues.

Therefore, the Board is proving this reminder that a dispenser who *knowingly* (1) fails to timely report prescription data or (2) submits incorrect prescription data violates 16.19.29 NMAC. A dispenser who does not report as required is considered "delinquent" and shall be subject to disciplinary action by the Board. Concurrently, a dispenser who does not respond to notices of delinquency shall have its PMP account(s) deactivated.

Beginning with the August 2014 Board meeting, the PMP Director will report all delinquencies to the Board. A dispenser who is not proactively addressing and resolving its delinquent reporting issues, or a dispenser with repeated delinquencies, will be reported to the Board for its consideration and possible disciplinary action. This disciplinary action could include suspension or revocation of a dispenser's Controlled Substance registration or licensure, a fine and costs, termination of access to PMP, and/or a formal complaint to the dispenser's licensing authority.

The Board has seen widespread interest and support for more frequent reporting of data to the New Mexico PMP (e.g., daily reporting). Because of this interest and the fact that many states already require daily reporting, the Board is expected to consider more frequent reporting in the near future. Therefore, it is in a dispenser's best interest to have their PMP reporting processes running as seamlessly as possible and in strict compliance with the Board's rules, 16.19.29 NMAC.

Thank you for your prompt attention to this matter. Additional information on the PMP can be found at http://nmpmp.org.

Sincerely;
Larry Loring, RPh.
Executive Director, NM Board of Pharmacy
Carl A. Flansbaum, RPh.
PMP Director, NM Board of Pharmacy
Attachment: Referenced sections of NMAC 16.19.29 and NMSA 61-11-20

Appendix B

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 reviewed at least once yearly during school session.

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 administration 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 inhaler and epinephrine auto-injector.

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

Appendix D

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 refundable.
[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 biennialy
B.	Intermediate Clinic	$300.00 biennialy
C.	Major Clinic	$300.00 biennialy
D.	School clinic	~~$75.00 biennially~~ **change to $30.00 bi-ennially**
~~D~~E.	Duplicate License	$10.00
~~E~~F..	Animal Control Clinics	$100.00 biennialy

[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 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;

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.

Appendix G

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 [~~a~~] 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 only, the emergency drug tray shall not contain any controlled substances. A list of the contents of the emergency drug supply shall be attached [~~tot~~] 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 [~~a~~] 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 [~~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 (CDC) and prevention's advisory committee on immunization practices and appropriate for the facility population served;

(v) [~~Flu vaccine.;~~] 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.

(7) DRUG CONTROL

(a) All state and federal laws relating to storage, administration and disposal of controlled substances and dangerous drugs shall be complied with.

(b) Separate sheets shall be maintained for controlled substances records indicating the following information for each type and strength of controlled substances: date, time administered, name of patient, dose, physician's name, signature of person administering dose, and balance of controlled substance in the container.

(c) All drugs shall be stored in locked cabinets, locked drug rooms, or state of the art locked medication carts.

(d) Medication requiring refrigeration shall be kept in a secure locked area of the refrigerator or in the locked drug room.

(e) All refrigerated medications will be kept in separate refrigerator or compartment from food items.

(f) Medications for each patient shall be kept and stored in their originally received containers, and stored in separate compartments. Transfer between containers is forbidden, waiver shall be allowed for oversize containers and controlled substances at the discretion of the drug inspector.

(g) Prescription medications for external use shall be kept in a locked cabinet separate from other medications.

(h) No drug samples shall be stocked in the licensed facility.

(i) All drugs shall be properly labeled with the following information:

(i) Patient's full name;

(ii) Physician's name;

(iii) Name, address and phone number of pharmacy;

(iv) Prescription number;

(v) Name of the drug and quantity;

(vi) Strength of drug and quantity;

(vii) Directions for use, route of administration;

(viii) Date of prescription (date of refill in case of a prescription renewal);

(ix) Expiration date where applicable: The dispenser shall place on the label a suitable beyond-use date to limit the patient's use of the medication. Such beyond-use date shall be not later than (a) the expiration date on the manufacturer's container, or (b) one year from the date the drug is dispensed, whichever is earlier;

(x) Auxiliary labels where applicable;

(xi) The Manufacturer's name;

(xii) State of the art drug delivery systems using unit of use packaging require items i and ii above, provided that any additional information is readily available at the nursing station.

(j) Customized Patient Medication Packages: In lieu of dispensing one, two, or more prescribed drug products in separate containers or standard vial containers, a pharmacist may, with the consent of the patient, the patient's care-giver, the prescriber, or the institution caring for the patient, provide a customized patient medication package. The pharmacist preparing a patient medication package must abide by the guidelines as set forth in the current edition of the U. S. Pharmacopoeia for labeling, packaging and record keeping.

(k) Repackaging of Patient Medication Packages: In the event a drug is added to or discontinued from a patient's drug regimen, when a container within the patient medication package has more than one drug within it, the pharmacist may repackage the patient's patient medication package and either add to or remove from the patient medication packaged as ordered by the physician. The same drugs returned by the patient for repackaging must be reused by the pharmacist in the design of the new patient medication package for the new regimen, and any drug removed must either be destroyed, returned to the DEA or

returned to the patient properly labeled. Under no circumstances may a drug within a container of a patient medication package which contains more than one drug be returned to the pharmacy stock.

(l) Return of Patient Medication Package Drugs: Patient medication packages with more than one drug within a container may not under any circumstances be returned to a pharmacy stock.

(m) Patient Medication Packages with only one drug within a container:

(i) Non-Institutional: A patient medication package stored in a non-institutional setting where there is no assurance of storage standards may not be returned to pharmacy stock;

(ii) Institutional: A patient medication package stored in an institutional setting where the storage and handling of the drugs are assured and are consistent with the compendia standards may be returned to the pharmacy stock provided the following guidelines are followed: (1) the drug is to be kept within the patient medication package and is to remain sealed and labeled until dispensed; (2) the expiration date of drug shall become 50% of the time left of the expiration for the drug; (3) no Schedule II drugs may be returned to inventory; and (4) proper record keeping for the addition of other scheduled drugs into inventory must be done.

(8) DRUG INFORMATION

(a) The pharmacist shall be accessible for providing drug information.

(b) A current reference books shall be located in each nursing station.

(c) Each nursing station shall have poison control information and phone number and a conversion chart for pharmaceutical weights and measures, and as a part of the drug procedures manual.

(9) EMERGENCY DRUG SUPPLY

(a) There shall be an accountability record indicating the following:

(i) Name of drug, strength, and amount of medication used;

(ii) Date used;

(iii) Time;

(iv) Patient's name;

(v) Physician's name;

(vi) Nurse administering drug;

(vii) Nature of emergency.

(b) Pharmacist shall make notation of date and time medication replacement is made on the line following that line containing withdrawal information and sign his name, unless the pharmacy chooses to change out the complete emergency box each time it is used. The pharmacy shall keep a record of each time the box is changed and a list of all drugs that were replaced in the box.

(10) Destruction of dispensed drugs for patients in health care facilities or institutions:

(a) The drugs are inventoried and such inventory is verified by the consultant pharmacist. The following information shall be included on this inventory:

(i) name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist;

(iii) date of drug destruction;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength, and quantity of drug;

(viii) signature of consultant pharmacist destroying drugs;

(ix) signature of witness(es); and

(x) method of destruction.

(b) The drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(c) The actual destruction of the drug is witnessed by the consultant pharmacist and one of the following:

(i) An agent of the New Mexico board of pharmacy;

(ii) Facility administrator;

(iii) The director of nursing.

(11) A consultant pharmacist may utilize a waste disposal service or reverse distributor to destroy dangerous drugs and controlled substances in health care facilities, boarding homes or institutions provided the following conditions are met:

(a) The inventory of drugs is verified by the consultant pharmacist. The following information must be included on this inventory:

(i) Name and address of the facility or institution;

(ii) Name and pharmacist license number of the consultant pharmacist;

(iii) Date of packaging and sealing of the container;
(iv) Date the prescription was dispensed;
(v) Unique identification number assigned to the prescription by the pharmacy;
(vi) Name of dispensing pharmacy;
(vii) Name, strength and quantity of drug;
(viii) Signature of consultant pharmacist packaging and sealing container; and
(ix) Signature of the witness.

(b) The consultant pharmacist seals the container or drugs in the presence of the facility administrator, the director of nurses or an agent of the board of pharmacy.

(c) The sealed container is maintained in a secure area at the facility or pharmacy until transferred to the waste disposal service or the reverse distributor by the consultant pharmacist, facility administrator, director of nursing or agent of the board of pharmacy.

(d) A record of the transfer [~~tot he~~] to the waste disposal service or reverse distributor is maintained and attached [~~tot he~~] to the inventory of drugs. Such records shall contain the following information:

(i) Date of the transfer;
(ii) Signature of the person who transferred the drugs to the waste disposal service or reverse distributor;
(iii) Name and address of the waste disposal service or reverse distributor;
(iv) Signature of the employee of the waste disposal service or the reverse distributor who receives the container; and
(v) The waste disposal service or reverse distributor shall provide the facility with proof of destruction of the sealed container.

(12) Record Retention: All records required above shall be maintained by the consultant pharmacist and the health care facility or institution for three years from the date of destruction.

[16.19.11.8 NMAC - Rp 16.19.11.8, 12-15-02; A, 10-24-14]

Appendix H

New Mexico Board of Pharmacy
Rules Committee
Richard Mazzoni, Committee Chair
August Board Meeting Committee Report

Committee Members:
Richard Mazzoni, NMBOP
Lynette Berggren, Albertsons
Henna Griego, Express Scripts
Leslie Wiedlocker, CVS Caremark
Lugina Mendez-Harper, NMBOP
Chris Woodul, NMBOP
Cheranne McCracken, NMBOP Staff
Dale Tinker, NM Pharmacists Association

- Committee mission and purpose: review existing rules for amendment or deletion; consider promulgation of new rules as practice modalities change and evolve.
- Important issue(s): evaluation of rules that have significant number of requests for waivers.
- 2014-2015 goals and objectives: continue review of those rules frequently waived; consideration of new or amended rules to address innovative practice methodologies

Next rule for discussion (agenda item): 16.19.6.7 Definitions and 16.19.6.27 Automated Filling Systems. Proposed for discussion at October meeting if Board approves.

For reference:

(NMAC) 16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

B. Only a pharmacist shall perform the following duties:

(1) final check on all aspects of the completed prescription including sterile products and cytotoxic preparations, and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;

(NMSA) 61-11-11.1 C. The supervising pharmacist shall observe and direct the pharmacy technician to a sufficient degree to assure the accurate completion of the activities of the pharmacy technician and shall provide a final check of all aspects of the prepared product and document the final check before dispensing.

16.19.10.11 F. REPACKAGING:

(1) Repackaging from bulk containers to dispensing units for distribution at locations other than the site of repackaging requires FDA registration, whether or not the repackaged drugs enter interstate commerce. (See FDA Regulations Title 21, Sections 207, 210 and 211).

(2) Repackaging of drug from bulk containers into multiple dispensing units for future distribution to clinic patients at the site of repackaging may be done by a physician, dentist, pharmacist, or by a pharmacy technician under the supervision of the pharmacist as defined in Subsection B of 16.19.22.7 NMAC. All drugs repackaged into multiple dispensing units by a pharmacy technician must undergo a final check by the pharmacist.

(3) A record of drugs repackaged must be maintained, to include the following.

(a) Date of repackaging.
(b) Name and strength of drug.
(c) Lot number or control number.
(d) Name of drug manufacturer.
(e) Expiration date (per USP requirements).
(f) Total number of dosage units (tabs, caps) repackaged (for each drug).
(g) Quantity per each repackaged unit container.
(h) Number of dosage units (tabs, caps) wasted.
(i) Initials of repackager.
(j) Initials of person performing final check.

(4) All dispensing units of repackaged medication must be labeled with the following information.
(a) Name, strength, and quantity of the drug.
(b) Lot number or control number.
(c) Name of manufacturer.
(d) Expiration date.
(e) Date drug was repackaged.
(f) Name or initials of repackager.
(g) Federal caution label, if applicable.
(5) Repackaged units must be stored with the manufacturer's package insert until relabeled for dispensing. as specified under Subsection G of 16.19.10.11 NMAC.

16.19.6.7 DEFINITIONS:

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

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

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

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

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

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

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

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

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

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

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

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

M. "Repacked" means any drug that has been removed from the original packaging of the manufacturer or a repackager's packaging and is placed in a container for use in an automated filling system.
[16.19.6.7 NMAC - Rp, 16 NMAC 19.6.7, 03-30-02; A, 06-30-06; A, 12-15-08]

16.19.6.27 AUTOMATED FILLING SYSTEMS:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) All drugs repackaged by a pharmacist intern or pharmacy technician must undergo a final check by the pharmacist. [16.19.6.27 NMAC]

Questions:
Is a repackaging allowance needed?
Should we require a repackaging log?

Appendix I

Clinic Committee Minutes for August 2014.

Members:

Danny Cross
Bill Harvey (abscent) written comments
Bill Lord (abscent)
George Gonzales (abscent) (Leo Duran substitute)
Charlie Vandiver
Katie Klein
James Brown
Christy Martinez-Vigil (abscent) written comments
Ben Kessner
Cheranne McCracken
Wes Langner

1. School based clinics for Epinephrine and Albuterol

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 reviewed at least once yearly during school session.

(h) Class D clinics shall be reviewed by the consultant pharmacist annually to ensure :

(i) that clinic is in compliance with training and protocols required by the Department of Health (DOH).

(ii) DOH designated staff completes Board of Pharmacy self-inspection form and is approved by the consultant pharmacist and submitted to the board upon initial licensure and at each renewal.

Before committee meeting:

B. PROPOSED LANGUAGE CHANGE:

(iii) Class C clinics shall be visited by the consultant pharmacist at least every three months.
~~(iv) Class D clinics shall be reviewed at least once yearly during school session.~~
(h) Class D clinics shall be reviewed by the consultant pharmacist at least once yearly to ensure that clinic is following set policies and procedures. Self inspection form is to be completed annually by clinic staff , approved by the consultant pharmacist and submitted to the board upon initial licensure and at each renewal.

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 refundable.
[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:…		$300.00 biennialy
D.	School clinic	~~$75.00~~ $30.00 biennially	
~~D~~E.	Duplicate License	$10.00	
~~E~~F.	Animal Control Clinics	$100.00 biennialy	

2. Designating new clinic categorie dealing with differences of a Health Office vs Clinic

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 administration to students of the school.

(e) Class E permit for Public Health Office

Discussion: to differentiate the day to day activities of public health. The new category could accommodate the special requirements that have been the subject of the waivers we have granted. There are substantial differences in operations at a public health clinic and a public health office.

1. PHOs do not provide primary care services.

2. DOH/PHD has (5) regions in NM. Each region has one Regional Health Officer (RHO: MD) that covers the region. Each region has anywhere from (4) to (12) PHOs.

3. PHOs are not always be staffed with an MD or mid-level. Most PHOs operate with nurses providing non-primary clinical services under DOH/PHD protocol.

4. DOH/PHD currently operates under a waiver for bi-annual clinic visitations. Audits are conducted electronically from Santa Fe.

5. Regulations specific to PHOs need to reflect the services provided by DOH and PHD protocols.

6. DOH follows CDC treatment recommendations in each protocol.

7. DOH follows CDC VFC (vaccines for children) vaccination recommendations for all patients. Please note that this is a federal program with federal oversight.

8. DOH follows Title X treatment recommendations for the Family Planning protocols. Please note that this is a federal program with federal oversight.

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 reviewed at least once yearly during school session.

(v) Class E Public Health Office shall be visited by the consultant pharmacist biennially

(h) Class D clinics shall be reviewed by the consultant pharmacist annually to ensure :

(i) that clinic is in compliance with training and protocols required by the Department of Health (DOH).

(ii) DOH designated staff completes Board of Pharmacy self-inspection form and is approved by the consultant pharmacist and submitted to the board upon initial licensure and at each renewal.

ACTION:

Department of Health representatives George and Leo to review requirements for other clinic classifications and bring back to the committtee recomendations for what is appropriate for a Health Office licensee.

3. Role of clerical help vs Pharmacy Technicians in a clinic setting

A registered pharmacy technician must be under the supervision of a pharmacist. The statutes require this. Our rule in 16.19.10.11.D (5) allows for supportive personnel to input data and produce label. The committee has concerns that practitioners may not have a clear understanding of the responsibilities of the final check. We feel that clinic medical directors and consultant pharmacist need to develop and maintain QA procedures for clinics, including practitioner initial on the final label. The statute would have to be changed to allow certified pharmacy technicians to work in clinics without a pharmacist supervision.

16.19.10.11 PUBLIC HEALTH CLINICS:

D. PHARMACY TECHNICIANS AND SUPPORT PERSONNEL:

(1) Pharmacy technicians, working in a clinic under the supervision of the pharmacist, may perform activities associated with the preparation and distribution of medications, including prepackaging medications and the filling of a prescription or medication order. These activities may include counting, pouring, labeling and reconstituting medications.

(2) The pharmacist shall ensure that the pharmacy technician has completed the initial training required in Subsection A of 16.19.22.9 NMAC.

(3) A written record of the initial training and education will be maintained by the clinic pursuant to requirements of Subsection C of 16.19.22.9 NMAC.

(4) The permissible ratio of pharmacy technicians to pharmacists on duty is to be determined by the pharmacist in charge or consultant pharmacist.

(5) Support personnel may perform clerical duties associated with clinic pharmacy operations, including computer data entry, typing of labels, processing of orders for stock, duties associated with maintenance of inventory and dispensing records.

(6) The pharmacist is responsible for the actions of personnel; allowing actions outside the limits of the regulations shall constitute unprofessional conduct on the part of the pharmacist.

(7) Name tags including job title, shall be required of all personnel while on duty in the clinic.

Here at xx xxxxxx xxxxxx xxxxxx, our policy & procedure, which has been in existence since 1999, states that "nursing personnel and pharmacy assistants prepare the label with the following information……" Our medical providers must review & initial the label and affix it to the properly ordered medication.

At XXX our nursing staff/MAs prepare the label for dispensing. We have an electronic dispensing software, where they input the data and in turn a label is printed. The provider then verifies the label and counts the Rx. Then labels the dispensing container. I have never been told that nursing staff/MAs cannot prepare the label for dispensing. We have 30+ clinic that dispense.

G. CLINIC DISPENSING OR DISTRIBUTING:

(1) Drugs shall be dispensed or distributed only to clinic patients on the order of a licensed practitioner of the clinic.

(2) The clinic practitioner shall record the prescribed drug therapy on the patient medical record indicating the name, strength, quantity and directions for use of the prescribed drug. This information shall be initialed or signed by the practitioner. A separate prescription form in addition to the medical record may be used.

(3) The prescription order may then be prepared by the practitioner, pharmacist or technician under the supervision of the pharmacist and a dispensing label affixed to the dispensing unit of each drug. The following information shall appear on the label affixed to the dispensing unit.

(a) Name of patient.
(b) Name of prescriber.
(c) Date of dispensing.
(d) Directions for use.
(e) Name, strength, and quantity of the drug.
(f) Expiration date.
(g) Name, address and phone number of the clinic.
(h) Prescription number, if applicable.

(4) The pharmacist or practitioner must then provide a final check of the dispensing unit and sign or initial the prescription or dispensing record.

(a) The consultant pharmacist is responsible for implement a quality assurance program with the medical director to ensure a proper final check by the practitioner is completed. The quality assurance program will be included in the policy and procedure manual and quality assurance activities will be documented by the pharmacist.

(5) Refill prescription orders must also be entered on the patient's medical record and the dispensing

All in all a very productive discussion. Additional issue to be considered in the future in conjunction with the remote tele pharmacy committee is Automated Dispensing Machines in the clinic setting.

Appendix J

Meeting Minutes

Sterile Compounding Committee
Advisory to the NM Board of Pharmacy

Friday June 27, 2014 2:00- 3:30 PM
Telephone Conference Call

Members present: Amy Buesing, Board Member and Co-Chair, Kristina Wittstrom, Co-Chair; Phil Saucedo, Christina Kim, Catherine Cone

Guests: Frank and Liz Latino (invited) and James Brown (uninvited)

James Brown joined the conference call out of curiosity and was allowed to listen through the first agenda item.

A. The Latinos had submitted a list of concerns with the language of 16.19.36 to be addressed by the committee. (See attached document). Each item was reviewed and explained. It is noted that the concerns address language transferred directly from 16.19.11 and for the most part do not represent new language or requirements.

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

1. 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.

ABuesing presented committee concerns regarding the lack of general awareness of this statute requirement to the Board for discussion. The requirement is written in the state statute and cannot be reversed or modified by the Board. Facilities using technicians to compound sterile preparations must provide documentation of this additional experiential requirement to be compliant.

It was suggested that broad notification of this statute be made through NMPhA and NMSHP to increase awareness of this statute.

2. 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**.**

3. 16.19.36.15 Proposed New section C. Quality Control Measures
It was determined that sufficient language exists in current regulations and no additional language is needed.

4. A copy of the language in 16.19.36 has been obtained. KWittstrom will add the most recent proposed changes to the copy and distribute for review and edit.

Next Meeting: To be determined

Submitted by KWittstrom July 1 2014

This list of concerns was submitted to the committee by Frank and Liz Latino. The explanations of individual items are listed after each item. June 27 2014

Concerns:

A) **Quality Assurance of Compounded Sterile Preparations-This is stricter than USP 797!**
2)16.19.36.15NMC-if bulk compounding of compound sterile preparations is performed using non-sterile chemicals, appropriate end product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;
Response: This section is verbatim from prior 16.19.6.11 C -4(a)(ii) and is NOT a change from old regulations. New wording has been proposed to address this specific issue.

USP 797 states-All high-risk level CSP's that are prepared in groups of more than 25 identical individual single-dose packages or in multiple-dose vials (MDV's) for administration to multiple patients or that are exposed longer than 12 hours at 2-8 degrees and longer than 6 hours at warmer than 8 degrees before they are sterilized shall meet the sterility test before they are dispensed or administered.

(4) **the label of each sterile coumpounded product shall contain: patient name; if batch filling, lot or control number;solution, ingredient names, amounts, etc**. Shouldn't your log sheets have all this and your label only have the main ingredients/preparation name along with the obvious patient name, date, directions, & providers name, pharmacy name, date

Response: This wording is verbatim from prior 16.19.6.11.C-4(a)(iv) and is NOT a change from old regulations. Formatting was changed to bullet the label requirements rather than sentence structure. No changes proposed.

FF. "Plan of Care"-a plan specifying proactive objective and subjective monitoring (eg. Vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and noncompliance) and the frequency with which monitoring is to occur.-

a)in a small retail compounding pharmacy we deal with preventative CSP's not with critical intra-venous antibiotics, intravenous solutions, or emergent CSP's .We provide a small amount of injectable sub-q, IM or ophthalmic solutions. It is unrealistic and usually not accessible for us to obtain vital signs, & laboratory tests like in a hospital type setting. We try to obtain subjective data.

Response: FF is from definitions. This is verbatim from prior definitions found in 16.19.6.11 B (s)(iv) with no changes made. "Plan of care" is referenced in 16.19.36.12 B (3) as verbatim from 16.19.6.11 B (6)(c) with no changes made. The section reads:

> patients receiving parenteral products in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;

16.19.36.8 NMAC Pharmacist In Charge
B. (2)-Responsible for providing a pharmacist who is available for twenty-four hour seven-day-a week services-

Response: From 16.19.6.11 B (3)(c): "pharmacist on staff who is available for twenty-four hour seven day-a-week-services. Changed to language above " Responsible for providing….

and 16.19.36.14 NMAC Patient or caregiver training for home use of Compounded Sterile Preparations.

B. The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy.
We provide preventative type CSP's and not intra-venous, or emergent medications. We have a 24 hour phone service/number available which will be checked the next business day.

Response: From 16.19.6.11 (3)(c): "pharmacist on staff who is available for twenty-four hour seven day-a-week-services. Changed to language above " Responsible for providing….

16.19.36.12 NMAC Record Keeping And Patient Profile-what do we do if patients interruptions in therapy due to hospitalization and they don't notify us. We are in a retail setting and this would be difficult to catch.

Response: Assume that this refers to B(2) a verbatim from 16.19.6.11 B(6)(a). No changes were made or are proposed.

Meeting Minutes

Sterile Compounding Committee
Advisory to the NM Board of Pharmacy

Friday August 1, 2014 2:00- 3:45 PM
Telephone Conference Call

Members present: Amy Buesing, Board Member and Co-Chair, Kristina Wittstrom, Co-Chair; Phil Saucedo, Christina Kim, Adela Padilla

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The agenda consisted solely of a review of the proposed changes to the recently posted 16.19.36. Text of the regulation with track changes was provided for purposes of discussion.

16.19.36.2: Scope. Additional facilities added to the regulation to better encompass all who might be compounding sterile preparations.

16.19.36.6: Objective: Addition of language to specify compliance with USP-NF

16.19.36.7 Definitions: Addition of definition of "batch"

16.19.36.11 Documentation Required: Addition of statement of retention time.

16.19.36.13 Requirement for Training: This was the time consuming topic, particularly in addressing the issue of "board approved" programs and the statement about UNM CoP training. The committee feels that each site must state in their training program the specifics of what is acceptable training. The didactic training of a given site-specific program may involve a wide range of activities: ASHP & Critical Point courses, vocational programs etc. .For example, a didactic program may include the ASHP course but will still require specific OJT for that particular site and the job duties to be performed by the compounder. A tech from a vocational

program may have extensive didactic training, but will still require job specific training before beginning job duties. The UNM student program for preparation of institutional rotations may or may not be acceptable to a given site. Each institution must decide what is acceptable to their operations and note such in the SOP.

None of the practitioners on the committee would allow any "trained" individual to assume compounding duties based solely on credentials provided by a third party. While the prior training may reduce the amount of additional training needed, there would still be a requirement for site-specific training before beginning duties. Accordingly the language was minimized.

Addition of the statute requirement for 100 hours of experiential training for technicians was made.

In F – chemotherapy was changed to hazardous preparations and the training requirements modified to match those for non-hazardous sterile preparations.

The meeting concluded due to time.

Action Items: The language needs to be reviewed by the committee and then forwarded to those who have expressed interest in any proposed changes for comment. The committee will reconvene in early September to review the comments provided and make final changes.

Note that 16.19.36.15 QA was not discussed. The changes proposed have not yet been reviewed by the committee.
Submitted by Wittstrom August 4, 2014.

Appendix K

New Mexico Board of Pharmacy
Pharmacy Practice Committee

Charge:

- The pharmacy practice committee is tasked with the development of rules governing new areas of practice including the provision of pharmaceutical care and the maintenance of records when the pharmacist is not working for or through a registered pharmacy.
- Areas may include: clinical laboratories, consultants, health fairs, vaccination clinics, pharmaceutical counseling, and pharmaceutical care as a practice setting.
- Items may overlap between pharmacist practice issues and pharmacist clinician practice issues

Activity Recap:

- Brown Bag Events: Updated 16.19.4.16.A.8 presented, passed, noticed and active
- Pharmacist Clinician Ordering Lab Data: Updated 16.19.4.17.D.4.b.ii presented, passed, noticed and active
- Definition of Pharmacy Practice 16.19.4.7.X presented, passed, noticed, and active
- Active Status 16.19.4.14 presented, passed, noticed, and active
- Pharmacist Clinician Self-Treatment or Treatment of Immediate Family Members 16.19.4.17.D.5 presented, passed and active

Outstanding Business

- Pharmacist Clinician Documentation Requirement 16.19.4.17
  - Issue: Need for documentation requirements for pharmacist clinicians
  - Note: Statutes require prescription files maintained for 3 years but no specifics of pharmacist record requirements. Should apply to all pharmacists including PhC, clarify whom maintains, what is maintained and retention term
  - Next Steps: Consult with Board Counsel to discuss assistance in creating document regarding record retention
- Pharmacist Clinician-Patient Relationship Definition 16.19.4.17.E.3
  - Issue: Need for documentation requirements for pharmacist clinicians
  - Tabled along documentation requirement
- Pharmacist Practicing Independent of Licensed Pharmacy
  - Issue: What rules should apply to pharmacist practicing outside registered pharmacy (excluding brown bag events, consultant pharmacist practicing under 16.19.4.11 & 16.19.10 and PhC practicing under 16.19.4.17)?
  - Next Steps: Subcommittee to work to expand language to include responsibilities when no drug product is involved.
- Sterile Compounding Performed Independent of Licensed Pharmacy
  - Issue: What rules should pertain to pharmacists who perform sterile compounding independent of registered pharmacy?
  - No action taken due to work being conducted by Sterile Products Committee
- Pharmacist medication administration
  - Proposed language reviewed; questions posed for additional research.
  - Next steps: Further delve into questions raised by committee and revisit.

Potential New Business

- Pharmacist Medication Administration
- Scope of practice for pharmacist interns
- Clinic classes/space requirements, types of medicines dispensed – Exemption committee has addressed

Appendix L

New Mexico Board of Pharmacy

RESOLUTION NO. 2014-001

WHEREAS, the New Mexico Board of Pharmacy met in regular session at the Ruidoso Convention Center, 111 Sierra Blanca Drive, Ruidoso, NM, on August 25, 2014, as required by law; and

WHEREAS, Section 10-15-1(B) of the Open Meetings Act (NMSA 1978, Sections 10-15-1 to -4) states that, except as may be otherwise provided in the Constitution or the provisions of the Open Meetings Act, all meetings of a quorum of members of any board, council, commission, administrative adjudicatory body or other policymaking body of any state or local public agency held for the purpose of formulating public policy, discussing public business or for the purpose of taking any action within the authority of or the delegated authority of such body, are declared to be public meetings open to the public at all times; and

WHEREAS, any meetings subject to the Open Meetings Act at which the discussion or adoption of any proposed resolution, rule, regulation or formal action occurs shall be held only after reasonable notice to the public; and

WHEREAS, Section 10-15-1(D) of the Open Meetings Act requires the New Mexico Board of Pharmacy to determine annually what constitutes reasonable notice of its public meetings;

NOW, THEREFORE, BE IT RESOLVED by the New Mexico Board of Pharmacy that:

1. *All meetings shall be held at the RLD Conference Room, 5200 Oakland NE, Albuquerque, NM beginning at 9:00 a.m. or as indicated in the meeting notice.*
2. *Unless otherwise specified, regular meetings shall be* at least once every three months. *The agenda will be available at least seventy-two (72) hours prior to the meeting from the executive director of the Board, whose office is located at 5200 Oakland NE, in Albuquerque, New Mexico. Notice of any other regular meetings will be given ten (10) days in advance of the meeting date. The notice shall indicate how a copy of the agenda may be obtained.*
3. *Special meetings may be called by the chairman and shall be called upon the written request of two or more members of the Board upon three (3) days notice. The notice shall include an agenda for the meeting or information on how members of the public may obtain a copy of the agenda. The agenda shall be available to the public at least twenty-four hours before any special meeting.*
4. *Emergency meetings will be called only under unforeseen circumstances that demand immediate action to protect the health, safety and property of citizens or to protect the public body from substantial financial loss. The New Mexico Board of Pharmacy will avoid emergency meetings whenever possible. Emergency meetings may be called by the Chairman or a majority of the members upon twenty-four (24) hours' notice, unless threat of personal injury or property damage requires less notice. The notice for all emergency meetings shall include an agenda for the meeting or information on how the public may obtain a copy of the agenda.*
5. *For the purposes of regular meetings described in paragraph 2 of this resolution, notice requirements are met if notice of the date, time, place and agenda is placed in the Albuquerque Journal and/or posted in the following locations: on the Board's web site* www.rld.state.nm.us/pharmacy *and the Board's office 5200 Oakland NE Suite A, Albuquerque, NM. Copies of the written notice shall also be mailed to those broadcast stations licensed by the Federal Communications Commission and newspapers of general circulation that have made a written request for notice of public meetings.*
6. *For the purposes of special meetings and emergency meetings described in paragraphs 3 and 4 of this resolution, notice requirements are met if notice of the date, time, place and agenda is provided by telephone to newspapers of general circulation in the state and posted in the office of the Board of*

Pharmacy. Telephone notice also shall be given to those broadcast stations licensed by the Federal Communications Commission and newspapers of general circulation that have made a written request for notice of public meetings.

7. *Teleconference Participation: When it is difficult or impossible for a Board member to attend a Board meeting in person, the member may participate by means of a conference telephone or similar communications equipment as authorized by Section 10-15-1(C) NMSA 1978, and as provided by the Board's rules and regulations.*
8. *In addition to the information specified above, all notices shall include the following language:*
   If you are an individual with a disability who is in need of a reader, amplifier, qualified sign language interpreter, or any other form of auxiliary aid or service to attend or participate in the hearing or meeting, please contact the Board of Pharmacy at 505-222-9830 at least one week prior to the meeting or as soon as possible. Public documents, including the agenda and minutes, can be provided in various accessible formats. Please contact the executive director of the board at 505-222-9830 if a summary or other type of accessible format is needed.
9. *The Board of Pharmacy may close a meeting to the public only if the subject matter of such discussion or action is accepted from the open meeting requirement under Section 10-15-1(H) of the Open Meetings Act.*
   (a) If any meeting is closed during an open meeting, such closure shall be approved by a majority vote of a quorum of the Board of Pharmacy taken during the open meeting. The authority for the closed meeting and the subjects to be discussed shall be stated with reasonable specificity in the motion to close and the vote of each individual member on the motion to close shall be recorded in the minutes. Only those subjects specified in the motion may be discussed in the closed meeting.
   (b) If a closed meeting is conducted when the Board of Pharmacy is not in an open meeting, the closed meeting shall not be held until public notice, appropriate under the circumstances, stating the specific provision of law authorizing the closed meeting and the subjects to be discussed with reasonable specificity, is given to the members and to the general public.
   (c) Following completion of any closed meeting, the minutes of the open meeting that was closed, or the minutes of the next open meeting if the closed meeting was separately scheduled, shall state whether the matters discussed in the closed meeting were limited only to those specified in the motion or notice for closure.
   (d) Except as provided in Section 10-15-1(H) of the Open Meetings Act, any action taken as a result of discussions in a closed meeting shall be made by vote of the Board of Pharmacy in an open public meeting.

Passed by the Board of Pharmacy this day of August 25, 2014.

Appendix M

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 10 MEDICINE AND SURGERY PRACTITIONERS
PART 16 ADMINISTERING, PRESCRIBING AND DISTRIBUTION OF MEDICATION
16.10.16.1 ISSUING AGENCY: New Mexico Medical Board, hereafter called the board.
[16.10.16.1 NMAC - Rp 16 NMAC 10.16.1, 7/15/01; A, 7/22/08]
16.10.16.2 SCOPE: This part applies to physician assistants and their supervising physicians.
[16.10.16.2 NMAC - Rp 16 NMAC 10.16.2, 7/15/01]
16.10.16.3 STATUTORY AUTHORITY: This part is promulgated pursuant to the Medical Practice Act, sections 61-6-1 through 61-6-35 NMSA 1978.
[16.10.16.3 NMAC - Rp 16 NMAC 10.16.3, 7/15/01]
16.10.16.4 DURATION: Permanent
[16.10.16.4 NMAC - Rp 16 NMAC 10.16.4, 7/15/01]
16.10.16.5 EFFECTIVE DATE: July 15, 2001 unless a later date is cited at the end of a section.
[16.10.16.5 NMAC - Rp 16 NMAC 10.16.5, 7/15/01]
16.10.16.6 OBJECTIVE: This part sets forth the manner in which a physician assistant may administer, pre-scribe and distribute dangerous drugs.
[16.10.16.6 NMAC - Rp 16 NMAC 10.16.6, 7/15/01]
16.10.16.7 DEFINITIONS:
A. "**Prescribe"** means to issue an order individually for the person for whom prescribed, either di-rectly from the prescriber to the pharmacist or indirectly by means of a written order signed by the prescriber, bear-ing the name and address of the prescriber, license classification, the name and address of the patient, the name of the drug prescribed, direction for use and the date of issue.
B. "**Administer"** means to apply a prepackaged drug directly to the body of a patient by any means.
C. **"Dispense"** means to deliver a drug directly to a patient and includes the compounding, labeling and repackaging of a drug from a bulk or original container.
D. "**Distribute"** means to administer or supply to a patient under the direct care of the distributing physician assistant one or more doses of drugs prepackaged by a licensed pharmacist and excludes the compounding or repackaging from a bulk or original container.
E. "Formulary" means any dangerous drugs; including Schedule II-V controlled substances, physi-cian assistants may use in the care of patients where there is an established physician- or physician assistant-patient relationship.
F. "Established physician- or physician assistant-patient relationship" means a relationship be-tween a physician or physician assistant and a patient that is for the purpose of maintaining the patient's well-being. At a minimum, this relationship is established by an interactive encounter between patient and physician or physi-cian assistant involving an appropriate history and physical or mental status examination sufficient to make a diag-nosis and to provide, prescribe or recommend treatment, with the informed consent from the patient and availability of the physician or physician assistant or coverage for the patient for appropriate follow-up care. A medical record must be generated by the encounter.
G. "Licensed physician" means a medical doctor licensed under the Medical Practice Act to practice medicine in New Mexico.
H. "Physician assistant" means a health professional who is licensed by the board to practice as a physician assistant and who provides services to patients under the supervision and direction of a licensed physician.
[16.10.16.7 NMAC - Rp 16 NMAC 10.16.7, 7/15/01; A, 7/22/08; A, 1/1/09]
16.10.16.8 ADMINISTERING AND PRESCRIBING DANGEROUS DRUGS
A. Physician assistants may administer formulary drugs; including Schedule II-V controlled sub-stances, where there is an established physician- or physician assistant-patient relationship, under the direction of the supervising physician. Physician assistants must comply with all other state and federal laws regulating the admini-

stration and prescribing of controlled substances.
B. Physician assistants may prescribe formulary drugs; including Schedule II-V controlled sub-stances, where there is an established physician- or physician assistant-patient relationship, under the direction of the supervising physician, and may telephone prescriptions to pharmacies for any drug they are authorized to prescribe.
C. Physician assistants may prescribe on a prescription pad that shall contain the following:
(1) the name, business address and telephone number of the supervising physician;
(2) the name, title and New Mexico license number of the physician assistant;
(3) if the signature line is without MD, PA, or PA-C printed after it, the PA or PA-C must add the designation "PA" or "PA-C" at the end of the signature line when signing a prescription; if the PA or PA-C must of necessity use a prescription pre-printed with "MD" at the end of the line, the designation "MD" must be clearly crossed out and "PA" or "PA-C" must be added;
(4) when the physician assistant leaves the supervision or employ of the supervising physician, or there is a change in the supervising or alternate physicians, the supervising physician shall immediately notify the board.
[16.10.16.8 NMAC - Rp 16 NMAC 10.16.8, 7/15/01; A, 7/22/08; A, 1/1/09]

16.10.16.9 DISTRIBUTION OF MEDICATIONS

A. It must be clear to the physician and to the physician assistant that the intent of the legislature and of the board is that a physician assistant is not to function as a pharmacist in the general sense of that licensee's du-ties. Dispensing, as defined by statute and this document, is not a physician assistant's job and is prohibited. Distri-bution of a limited supply of medication to facilitate the medical needs of a patient may be done by a physician assis-tant under the direction of the supervising physician. Physician assistants may distribute dangerous drugs where there is an established physician- or physician assistant-patient relationship; including Schedule II-V controlled sub-stances.
B. Distribution of a medication shall be restricted to medications repackaged by a licensed pharmacist or a pharmaceutical manufacturer or re-packager. Physician assistants may request, receive and sign for professional sample medications and may distribute sample medications to patients. A log must be kept of distributed medica-tions in accordance with board of pharmacy regulations. Samples requested/received would be appropriate to the scope of the supervising physician's practice and would be consistent with board of pharmacy regulations.
C. Any medication distributed to a patient will be properly labeled with the following: patient name, date of issue, drug name and strength, instructions for use, drug expiration date, number distributed, name of pre-scriber, address and phone number of prescriber, and pharmacist or manufacturer/repackager identification,
D. Labeling may be via hand-written or pre-printed fill-in labels. The above information shall also be properly documented in the patient's medical record, including the amount of medication provided.
[16.10.16.9 NMAC - Rp 16 NMAC 10.16.9, 7/15/01; A, 7/22/08; A, 1/1/09]

HISTORY OF 16.10.16 NMAC:
Pre-NMAC History: Material in this part was derived from that previously filed with the Commission of Public Records - State Records Center and Archives:
NMBME Rule 79-15, Rules and Regulations Pertaining to Physicians' Assistants, filed 10/4/79
86-2, Physicians Assistants, filed, 2/5/86
89-PA7, Physician Assistant-Administering and Prescribing Dangerous Drugs Other Than Controlled Substances, 6/16/89
89-PA 8, Physician Assistant- Distribution of Medications, filed 6/16/89.
PA Rule 7, Physician Assistant-Administering and Prescribing Dangerous Drugs, filed 10/27/94
PA Rule 8, Physician Assistants - Distribution of Medications, filed 10/27/94
NMAC History:
16 NMAC 10.16, Administering, Prescribing and Distribution of Medications, filed 3/5/97
History of the Repealed Material:
16 NMAC 10.16, Administering, Prescribing and Distribution of Medications - Repealed, 7/15/01