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

October 16th and 17th, 2014 Draft Meeting Minutes

Board Meetings are open to the public pursuant to the "Open Meetings Act" and notices to the public are posted in the Albuquerque Journal. Notice published September 15, 2014.

Location: 5200 Oakland Ave. NE, Albuquerque, NM

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

Thursday October 16, 2014

1. Procedural Items:

9:00 a.m. Call to Order: The meeting of the Pharmacy Board was called to order by Chairman Cross at 9:03 a.m. on October 16, 2014.

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

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

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

Approval of August 2014 Minutes: Motion to approve the August 25th and 26th, 2014 minutes as presented by Ms. Mendez-Harper, seconded by Ms. Buesing, 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: **5 Clinic/Home Health** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion.

Motion: **2 Limited Controlled Substances** applications all are in order. Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson, board voted unanimously to pass the motion./

Motion: **12 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. Mr. Cross recused himself from the vote for #6.

Motion: **4 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: **37 Non-Resident Pharmacy** applications all are in order. Motion made by Ms. Harper-Mendez, seconded by Mr. Anderson 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 Anderson to approve applications, board voted unanimously to pass motion.

NEW MEXICO BOARD OF PHARMACY
REGULAR MEETING
APPLICATION LIST
October 16 & 17, 2014

CLINIC /HOME HEALTH	CONSULTANT PHARMACIST
1.Christus St Vincent Medicine Sports Medicine Los Alamos 2237 Trinity Drive Suite D Los Alamos, NM 87544	New Terri Stanford, R.Ph.
2.Concentra Medical Centers 5700 Harper Drive NE Albuquerque, NM 87109	Change of Ownership Larry Cato, R.Ph.
3.PHC Las Cruces DBA Imaging Center of Las Cruces 160 N Roadrunner Pkwy Las Cruces, NM 88011	New Janet Pate, R.Ph.
4.Sandia Surgery Center 5302 Juan Tabo NE Suite 1D & E Albuquerque, NM 87111	New Tuesday Horner, R.Ph.
5.United Shockwave Services 1720 Wyoming Blvd Albuquerque, NM 87112	New Monica Martinez, R.Ph.

LIMITED CONTROLLED SUBSTANCES	CONSULTANT PHARMACIST
1.Lovelace Respiratory Research Institute Dr. Waylen Weber 2425 Ridgecrest Drive SE Albuquerque, NM 87108	New Bill Weast, R.Ph.
2.Lovelace Respiratory Research Institute Dr. David Revelli 2425 Ridgecrest Drive SE Albuquerque, NM 87108	New Bill Weast, R.Ph.

CUSTODIAL/NURSING HOME	CONSULTANT PHARMACIST
1.Ability First DBA Mesadura House 4205 Mesadura NW Albuquerque, NM 87120	New Annabel Roberts, R.Ph.

2.Angeles de Vida 8701 Odin Road SW Albuquerque, NM 87121	New Bill Harvey, R.Ph.
3.Artesia Health Facilities LP DBA San Pedro Nursing and Rehabilitation Center 1402 West Gilchrist Artesia, NM 88210	Change of Ownership Terence Clark Jr., R.Ph.
4.Alta Mira 3412 Del Aqua Court Albuquerque, NM 87111	New Reynaldo Saenz, R.Ph.
5.Buena Vista Senior Care 8505 Rancho Santa Fe Place NE Albuquerque, NM 87113	New Reynaldo Saenz, R.Ph.
6.CARC Inc 902 W Cherry Lane Carlsbad, NM 88220	New Joseph Cross, R.Ph.
7.Citizens for the Development Disabled 221 Moreno Street Las Vegas, NM 87701	New Rudy Nolasco, R.Ph.
8.Curry County Detention Center-Amex 801 Mitchell Street Clovis, NM 88101	New Patricia Cantwell, R.Ph.
9.Elizabeth Maestas 522 Lagunitas Road SW Albuquerque, NM 87105	New Richard Garcia, R.Ph.
11.Jennifer Madrid 10505 Box Canyon Place Albuquerque, NM 87114	New Lori Carabajal, R.Ph.
12.Jennifer Madrid 4549 Allsup Circle Los Lunas, NM 87031	New Lori Carabajal, R.Ph.
<u>PHARMACY /HOSPITAL</u>	<u>PHARMACIST IN CHARGE</u>
1.CVS Pharmacy 610 Silver Heights Blvd Silver City, NM 88061	New Pamela Natharivs, R.Ph.
2.Walgreens 2625 San Pedro Drive NE Albuquerque, NM 87110	Remodel Cynthia McRae, R.Ph.

3.Walgreens 3100 N Main Street Las Cruces, NM 88001	Remodel Ariane Luna, R.Ph.
4.Walmart Pharmacy 1115 NM Highway 528 SE Rio Rancho, NM 87124	New Timothy Cornell, R.Ph.
NON-RESIDENT PHARMACY	PHARMACIST IN CHARGE
1.Ability Pharmacy Inc 558 Hemphill Street Fort Worth, TX 76104	New Mahtab Abghari, R.Ph.
2.Atlantic Medical LLC 1068 Thousand Oaks Drive Suite B Hernando, MS 38632-7742	New Mary Skinner, R.Ph.
3.Amber Enterprises Inc DBA Amber Pharmacy 10004 South 152nd Street Suite A Omaha, NE 68138	Change of Ownership Susan Allen, R.Ph.
4.America Homecare Federation 31 Moody Road Enfield, CT 06082	Change of Ownership Jeffrey Lagasee, R.Ph.
5.Avita Drugs LLC DBA Avita Drugs 5551 Corporate Blvd Suite 102 Baton Rouge, LA 70808	New Kristy Loupe, R.Ph.
6.Cardiac Infusion Specialists 5442 La Sierra #200 Dallas, TX 75231	New Lilia Luss, R.Ph.
7.Care Direct Rx LLC 112-A Celtic Drive Madison, AL 35758	New Cydney Estes, R.Ph.
8.Coast Quality Pharmacy LLC DBA AnazaHealth 5710 Hoover Blvd Tampa, FL 33634	Change of Ownership Jacob Beckel, R.Ph.
9.Custom Care Pharmacy 7007 W North Avenue Oak Park, IL 60302	New Vishali Patel, R.Ph.

10.El Dorado Pharmacy LLC
1300 E Arapaho Road
Richardson, TX 75081

New
Austin Keyser, R.Ph.

11.Empower Pharmacy
12123 Jones Road
Houston, TX 77070

New
Souchinda Nanthavongdouangsy, R.Ph.

12.Enclara Health LLC
1480 Imperial Way
West Deptford, NJ 08066

Change of Ownership
Walter Valentine, R.Ph.

13.ExcelleRx Inc
2525 Horizon Lake Drive
Memphis, TN 38133

Change of Ownership
Deborah Kelly, R.Ph.

14.ExcelleRx Inc
1601 Cherry Street Suite 1700
Philadelphia, PA 19102

Change of Ownership
Michael Cinger, R.Ph.

15.ExcelleRx
DBA Hospia Pharmacia
512 Elmwood Avenue
Sharon Hill, PA 19079

Change of Ownership
Kimberly Hunter, R.Ph.

16.Factor Support Network Pharmacy Inc
900 Avenida Acaso Suite A
Camarillo, CA 93012

Change of Ownership
Jacqueline Nguyen, R.Ph.

17.Gentry Health Services Inc
1090 Enterprise Drive
Medina, OH 44256

New
Nimesh Patel, R.Ph.

18.Highland Specialty Pharmacy LLC
23 Town Center Square
Hattiesburg, MS 39402

New
Brooke Ogdesby, R.Ph.

19.Independence Holding Company LLC
DBA Complete Care Pharmacy
201 N 5th Street
Springfield, IL 62701

New
Jeffrey Denney, R.Ph.

20.Independence Holding Company LLC
DBA Complete Care Pharmacy
101 E Plummer
Chatham, IL 62629

New
Michelle Gwinn-Mackey, R.Ph.

21.Irvine Wellness Pharmacy
113 Waterworks Way #160A
Irvine, CA 9618

New
Haleh Sadig, R.Ph.

22.Jack P Herick Inc DBA Glades Drugs 109 South Lake Avenue Pahokee, FL 33476	New Alan Kruger, R.Ph.
23.Lehigh Pharmacy & Supplies Inc DBA Cape Pharmacy & Supplies 307 Del Prado Blvd North #3 Cape Coral, FL 33909	New Mark Walker, R.Ph.
24.Longevity Drugs 101 N Federal Highway Lake Worth, FL 33460	New Ryan Goodkin, R.Ph.
25.Marian Respiratory Care Inc 28691 US Hwy 98 Suite D1 Daphne, AL 36526	New Jolie Darby, R.Ph.
26.Med Worx Compounding LLC 950 E County Line Road Suite A Ridgeland, MS 39157	New Laura Cialone, R.Ph.
27.MedArbor Pharmacy 150 Monument Road Suite 408 Bala Cynwyd, PA 19004	New Hajira Ebady, R.Ph.
28.North Beaches Pharmacy Inc 1510 Penman Road Jacksonville Beach, FL 32250	New Robert Poland, R.Ph.
29.Omnicare of Northern Illinois 2313 S Mount Prospect Des Plaines, IL 60018	New Amanda Pruden, R.Ph.
30.Omni-One-Med Pharmacy Services LLC 17310 W Grand Parkway South Suite E Sugar Land, TX 77479	New Hemlata Kataria, R.Ph.
31.Paramount Pharmacy 7200 South 180th Street Suite 103 Tukwila, WA 98188	New Sangmin Lee, R.Ph.
32.Philidor Rx Services LLC 330 S Warminster Road Suite 350 Hatboro, PA 19040	New Sylvan Richter, R.Ph.
33.Primerose Pharmacy LLC 4733 W Atlantic Avenue Suite C-5 Delray Beach, FL 33445	New Gerson Greenbarg, R.Ph.

34.TCS Labs
DBA The Compounding Shop
4000 Park Street North
St Petersburg, FL 33709

Change of Ownership
Michael Haulsee, R.Ph.

35.Triangle Compounding Pharmacy
3700 Regency Parkway Suite 140
Cary, NC 27518

New
Wendy Hagwood, R.Ph.

36.Twin Lakes Pharmacy LLC
16462 FM 529
Houston, TX 77095

New
Sheeba Thomas, R.Ph.

37.Your RX Pharmacy Inc
2637 Ira E Woods Avenue #200
Grapeville, TX 76051

New
Praful Patel, R.Ph.

<u>WHOLESALER/BROKER</u>

1.Attain Med Inc
5825 Glenridge Drive NE Bldg 4 Suite 106
Atlanta, GA 30319

New

2.CLS Behring LLC
1020 1st Avenue
King of Prussia, PA 19406

New

3.Cubist Pharmaceuticals Inc
65 Hayden Avenue
Lexington, MA 02421

New

4.Direct Rx LLC
1111 Aldermand Drive Suite 450
Alpharetta, GA 3005

New

5.DV Medical Supply Inc
2000 W 135th Street
Gardena, CA 90249

New

6.Exela Pharma Services
1245 Blowing Rock Blvd
Lenoir, NC 28645

New

7.H.D. Smith LLC
1101 West Vickery Blvd
Fort Worth, TX 76104

Change of Ownership

8.Independent Pharmaceutical
854 E Crescentville Road
West Chester, OH 45246

New

9.Jurox Inc — New
4520 Main Street
Kansas City, MO 64111

10.Keryx Biopharmaceuticals Inc — New
750 Lexington Avenue 20th Floor
New York, NY 10022

11.Marquet Cardiovascular US Sales LLC — New
1 Industrial Road Suite 20
Dayton, NJ 08810

12.Medical Specialties Distributors LLC — New
26350 Broadway Avenue
Oakwood Village, OH 44246

13.Medical Specialties Distributors LLC — New
1240 Forest Parkway Suite 400
West Deptford, NJ 08066

14.Neos Therapeutics LP — New
2940 North Hwy 360 Suite 400
Grand Prairie, TX 75050

15.Owen Laboratories Inc — New
2929 Texas Longhorn Way
Fort Worth, TX 76177

16.PARI Respiratory Equipment Inc — New
2412 PARI Way
Midlothian, VA 23112

17.Professional Hospital Supply Inc — New
2601 South 37th
Phoenix, AZ 85034

18.Resource Optimization & Innovation — New
2909 N Neergard Avenue
Springfield, MO 65803

19.Smiths Medical ASD Inc — New
9124 Polk Lane Suite 101
Olive Branch, MS 38654

20.Smith Medical Partners LLC — New
950 Lively Blvd
Wood Dale, IL 60191

21.Vertical Pharmaceuticals LLC — Change of Ownership
2500 Main Street Suite 6
Sayreville, NJ 08872

b) Pharmacist Clinicians:

Motion: Approve registration as pharmacist clinician for Davena Norris, motion made by Ms. Mendez-Harper, seconded by Woodul, board voted unanimously to pass the motion.

Motion: Approve the new protocol for existing license with prescriptive authority including controlled substances for Kassie Kotter, motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion.

The board will table a motion for Victoria Aragon's protocol until the licensing manager, Sarah Trujillo verifies the information with the clinician credentialing committee chairman Greg D'Amour, this afternoon.

Ms. Trujillo returned with a modified report regarding the protocols for Ms. Aragon and Ms. Kassie Kotter.

Motion: Amend the motion for Kassie Kotter from "approve the new protocol for existing license with prescriptive authority including controlled substances" to approve new protocol for existing license, also to approve new protocol for existing license for Victoria Aragon, 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. Anderson to go into closed session at 9:23 a.m., to discuss the MTP report. Mr. Cross, Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni and Mr. Anderson voted unanimously to pass the motion. Absent were Ms. Saavedra and Mr. Carrier.

The board went back into open session at 9:46 a.m. and the only issue discussed was the MTP report.

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

The Chairman Danny Cross opened the rule hearing at10:03 a.m. and took roll call. Present were Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni, Mr. Anderson and Chairman Cross. Absent were Ms. Saavedra 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 16.19.6.7 NMAC; no written comments, exhibit #3 proposed language for 16.19.6.27 NMAC; no written comments, and the sign in sheet as exhibit #4.

a) 16.19.6.7 Definitions – additions: See Appendix A

b) 16.19.6.27 Automated Filling System – proposed new section: See Appendix B

Motion: Take language 16.19.6.7 NMAC and 16.19.6.27 back to committee for further review. Motion made by Ms. Buesing, seconded by Mr. Anderson, board voted unanimously to pass the motion.

5. Committee Reports and Board Actions:

Buffie Saavedra - Remote Tele-Pharmacy Committee: 16.19.6 NMAC new section 27, automation proposed language: See Appendix C

Motion: Notice 16.19.6 NMAC, new section 27, at the January 2015 board meeting. Motion made by Ms. Buesing, seconded by Mr. Mazzoni board voted unanimously to pass the motion.

Rich Mazzoni - Rules Committee: New Section 16.19.6.23 D (5) - Amend transfer rule: See Appendix D

Motion: Notice 16.19.6.23 D(5) NMAC at the January 2015 board meeting. Motion made by Mr. Mazzoni, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Amy Buesing – Sterile Products Committee: 16.19.36 proposed revisions: See Appendix E

Motion: Notice 16.19.36 NMAC at the January 2015 board meeting. Motion made by Ms. Buesing, seconded by Mr. Woodul, board voted unanimously to pass the motion.

Joe Anderson – BAOM committee report with discussion and board action on the issue of the BOP's statutory duties regarding the BAOM expanded practice training: See Appendix F

Mr. Anderson stated that the BAOM is in violation of their statute which references that the NMBOP and the BAOM work in conjunction regarding approval of formularies. Initial training cannot be developed since the IV therapy is in the works and no rules exist to support regulation and enforcement.

Mr. Loring will send a letter to the BAOM informing them of the statutes and enforcement and regulation of rules.

6. PMP Report – Carl Flansbaum: See Appendix G

a) Delinquent PMP report: See Appendix H

b) Proposed language changes for 16.19.29 NMAC: See Appendix I

Motion: Notice 16.19.20 NMAC at the January 2015 board meeting. Motion made by Ms. Buesing, seconded by Mr. Mazzoni to board voted unanimously to pass the motion.

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

Friday October 17, 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 October 17, 2014.

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

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

2. 9:30 a.m. – 11:00 a.m. Public/Professional Requests/Waiver Petitions*:

Kelly Dillon – consider dismissal of remaining probation: Mr. Kelly Dillon was present and asked the board to consider early release from the probation ending date of August 29, 2016 from case 2010-043, due to wanting to reciprocate to Georgia.

Mr. Cross left the board meeting at 9:45 a.m.

Motion made by Mr. Mazzoni, seconded by Mr. Woodul to go into closed session at 9:57 a.m., to discuss the request of Kelly Dillon. Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni and Mr. Anderson voted unanimously to pass the motion. Absent were Ms. Saavedra and Mr. Carrier and Mr. Cross.

The board went back into open session at 10:22 a.m. and the only issue discussed was the Kelly Dillon request.

Motion made by Mr. Mazzoni, seconded by Mr. Anderson to deny the request for early dismissal from probation, a roll call vote was taken; Mr. Woodul voted no, Ms. Yarbrough yes, Ms. Mendez-Harper voted yes, Ms. Buesing voted yes, Mr. Mazzoni voted yes, and Mr. Anderson voted yes, to deny request.

Christine M-Vigil – waiver extension for Carlos Vigil Middle School, Espanola Valley High School, Penasco schools, Taos Middle School Wellness and Maxwell Wellness Center: Ms. Vigil requested that the board extend the waivers for the school clinics and wellness centers regarding the 48sq. ft. requirement in 16.19.10.11 K.1 (b) and (c).

Motion made by Mr. Woodul, seconded by Mr. Anderson to approve the waivers for four years, a roll call vote was taken; Mr. Woodul voted yes, Ms. Yarbrough voted no, Ms. Mendez-Harper voted yes, Ms. Buesing voted yes, Mr. Mazzoni voted yes, and Mr. Anderson voted yes, to approve the waivers extensions for four years.

Chad Tewksbury – ALT Recovery Group pharmacy license: Mr. Ray Stewart and Ms. Deborah Cullen were present to request a waiver of the required square footage for ALT Recovery. They will be storing methadone and suboxone. The board requested that they would need to submit for a dual licensure thus the need to apply for a custodial license along with his existing clinic license due to the future dispensing of suboxone and the need to directly observe that type of therapy for patients.

Jennifer Rogers-Kobyljanec requesting reinstatement of license RP6539: Ms. Jennifer Kobyljanec was present and asked the board to consider reinstating her license. She informed the board of her ongoing group and individual therapy, enrollment to the Monitored Treatment Program and has completed an outpatient treatment for her chemical dependency. Ms. Kobyljanec stated that she has been unable to gain employment due to the voluntary surrender of her license on May 30, 2014.

Motion made by Mr. Mazzoni, seconded by Ms. Buesing to go into closed session to discuss the request of Jennifer Kobyljanec, Mr. Woodul, Ms. Yarbrough, Ms. Mendez-Harper, Ms. Buesing, Mr. Mazzoni and Mr. Anderson voted unanimously to pass the motion. Absent were Ms. Saavedra and Mr. Carrier and Mr. Cross.

The board went back into open session and the only issue discussed was the Jennifer Kobyljanec request.

Motion made by Ms. Mendez-Harper, seconded by Mr. Anderson to grant the request to reinstate Jennifer Kobyljanec's license, the board voted unanimously to pass the motion.

Melissa Heinz Bennett, DOH - Endorsement of a naloxone standing order protocol- Approve online training for pharmacist naloxone prescriptive authority: Mr. Loring stated that the NM Department of Health has requested the board's endorsement of certain naloxone storage and distribution policies in order to more effectively combat overdose deaths in New Mexico. DOH would like the endorsement of the standing order regarding naloxone storage and distribution to be effective immediately so that they may begin the distribution and storage policies as soon as possible.

Upon discussion the board would like the DOH to research more options with Mr. Loring to present at the January 2015 board meeting and possibly present to the legislature. Also, discussion was held regarding the modification of the training to meet the requirements of New Mexico. No action was taken.

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

a) Pharmacy closure report: See Appendix J

b) 16.19.20.67 Remove hydrocodone from schedule III : See Appendix K

Motion: Notice 16.19.29 NMAC at the January 2015 board meeting. Motion made by Ms. Buesing, seconded by Mr. Mazzoni to board voted unanimously to pass the motion.

c) Executive director position:

Two candidates will be interviewed in closed session pursuant to Section 10-15-1H(2) on 10/17/14 from 8:00 am – 9:00 am.

d) BJA Harold Rogers Prescription Drug Monitoring Program Grant:

Carl Flansbaum stated that the Harold Rogers Grant was approved and received by the NMBOP for the PMP.

e) Sunset review Oct 28th:

Mr. Loring and Mr. Mazzoni will be attending the Sunset Review in Santa Fe.

f) Hydrocodone refills after October 6, 2014:

The board inspectors will inform inquiries regarding hydrocodone refills to follow the DEA rule up till April 8, 2015.

g) Disposal of controlled substances October 9, 2014:

Federal law took effect for pharmacies to destroy/dispose of drugs *through incineration ONLY*.

h) Cory McGuinn-Parks letter:

No action taken at this time.

i) Class D clinic self-assessment questions:

Inspector, Ben Kesner has developed a form that he will present for review by the board regarding medications kept on site, drug storage, authorized personnel, records, policy and procedure manual and compliancy with DOH.

j) Intern fee is $25.00 amend 16.19.12 NMAC: See Appendix L

Motion: Notice 16.19.12 NMAC at the January 2015 board meeting. Motion made by Mr. Mazzoni, seconded by Ms. Buesing to board voted unanimously to pass the motion.

k) Intern training period: See Appendix M

Motion: Notice 16.19.5.7 NMAC at the January 2015 board meeting. Motion made by Mr. Anderson, seconded by Mr. Mazzoni to board voted unanimously to pass the motion.

l) AFD letter to the board:

Mr. Timothy Woodard thanked Inspector, McCracken, Inspector A. Padilla and Phong Trinh (NMBOP intern) for providing such prompt, knowledgeable and professional level of service to our students and our department.

m) NABP topics:

1) Interactive Board Member forum, Dec 2-3: NABP will pay for one board member to attend; Ms. Mendez-Harper will attend.

2) LuGina: **District 6, 7, and 8 Meeting:** Mr. Mazzoni and Ms. Mendez-Harper attended.
District 8 resolutions: See Appendix N
Drug Supply Chain Security Act: See Appendix N

4. Case Presentations:

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

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

Inspector McCracken:	2014-018/NCA	2014-040/NCA	2014-044/close
Inspector Mossberg:	2014-032/AL	2014-035/close	
Inspector B. Padilla:	2014-048/close-DA		
Inspector A. Padilla:	2014-042/NCA	2014-045/NCA	
Inspector Kesner:	2014-038/NCA`	2014-039/close	2014-043/NCA

Motion: **Close cases:** 2014-044, 2014-035, 2014-048 and 2014-039. Motion made by Ms. Mendez-Harper, seconded by Ms. Buesing, board voted unanimously to pass the motion. Mr. Anderson abstained from voting.

Motion: **Issue an advisory letter:** 2014-032. Motion made by Ms. Buesing, seconded by Mr. Mazzoni, board voted unanimously to pass the motion. Ms. Mendez-Harper recused herself from the vote. Mr. Anderson abstained from the vote.

Motion: **Issue NCA to revoke:** 2014-045. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion. Mr. Anderson abstained from the vote.

Motion: **Issue NCA to revoke:** 2014-018 and 2014-040. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion. Mr. Anderson abstained from the vote.

Motion: **Issue an NCA to deny**: 2014-038 and 2014-043. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion. Mr. Anderson abstained from the vote.

Motion: **Issue an NCA to deny**: 2014-042. Motion made by Ms. Mendez-Harper, seconded by Mr. Mazzoni, board voted unanimously to pass the motion. Mr. Anderson abstained from the vote.

Motion: **Issue NCA w/pre-nca settlement agreement for PMP cases**: A, B, C, D, E, F, G, H, I and N, O, P. Motion made by Ms. Mendez-Harper, seconded by Mr. Woodul, board voted unanimously to pass the motion.

NCA = Notice of Contemplated Action
AL – Advisory Letter
DA = District Attorney

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

2013-061 – Specialty Compounding LLC, PH3131 & CS214887 – Stipulated Agreement:

Motion made by Mr. Mazzoni, seconded by Mr. Woodul to approve the stipulated agreement for 2013-061, board voted unanimously to pass the motion.

2012-097 – Ashley Primrose PT8194 – Default Revocation:

Motion made by Mr. Mazzoni, seconded by Mr. Anderson to approve the stipulated agreement for 2012-097, board voted unanimously to pass the motion.

6. Adjournment: With no further business, Mr. Mazzoni made a motion to adjourn the Pharmacy Board meeting at 12:22 p.m., seconded by Mr. Woodul, board voted unanimously to pass the motion.

Appendix A

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]

Appendix B

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]

Scott R. Huhn PharmD
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879 Second Street
Santa Rosa, CA 95404
707-486-7801

October 9, 2013

Larry Loring RPh
Executive Director
New Mexico State Board of Pharmacy
5200 Oakland Ave NE
Albuquerque, NM 87113

Sent via Fax (505) 222-9845 and email pharmacy.board@state.nm.us

RE: Request to present to the New Mexico Board of Pharmacy regarding the New Mexico Title 16 Occupational and Professional Licensing Chapter 19, Part 6, proposed regulation 27 Automated Drug Distribution Systems in Licensed Health Care Facilities.

Omnicare writes to request an opportunity to speak to the Board on October 16, 2014 regarding the following points of discussion:

16.19.6.27 B (1) Definitions

"Automated drug distribution system, …related to the storage, packaging, or dispensing of drugs":

1. Will this include both continuous dispensing of maintenance medications as well as first dose/emergency supply?
2. Does Section B (6) "Override medication" refer to first dose/emergency supply?

16.19.6.27 C Authorization

"The managing pharmacy must also submit and maintain a separate registration with the Drug Enforcement Administration":

1. While there is a registration requirement under 21 Code of Federal Regulations (CFR) 1301.17 and 1301.27, it only applies to those pharmacies which install or operate an automated system at a long term care facility (LTCF) for the regular dispensing of controlled substances. (See attached guidance letter from the DEA April 30, 2007).
2. If the system is utilized for continuous dispensing, as outlined in Section E (p), then Omnicare would maintain a separate DEA 223 registration for the "system".

Thank you for your consideration. Please confirm an opportunity for me to present during the Rule Hearings portion of your agenda. I can be reached via phone or email, (707-486-7801; scott.huhn@omnicare.com)

Sincerely,

Scott R. Huhn PharmD
Regional Compliance Officer
Omnicare, Inc.

Appendix C

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

16.19.6.27 Automated Drug Distribution Systems in Licensed Health Care Facilities

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

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

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

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

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

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

(5) "Override medication" means:

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

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

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

C. Authorization.

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

D. Notification.

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

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

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

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

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

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

E. Operation of automated drug distribution systems.

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

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

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

(b) Controlling access to the automated medication system;

(c) Maintaining policies and procedures for:

(d) Operating the automated medication system;

(e) Training personnel who use the automated medication system;

(f) Maintaining patient services whenever the automated medication system is not operating; and

(g) Defining a procedure for a pharmacist to grant access to the drugs in the automated medication system or to deny access to the drugs in the automated medication system.

(h) Securing the automated medication system;
(i) Assuring that a patient receives the pharmacy services necessary for appropriate pharmaceutical care;
(j) Assuring that the automated medication system maintains the integrity of the information in the system and protects patient confidentiality;
(k) Establishing a procedure for stocking or restocking the automated medication system; and
(l) Insuring compliance with all requirements for packaging and labeling.
(m) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a drug except an override medication or a practitioner controlled medication.
(n) A pharmacist shall perform retrospective drug use review for an override medication.
(o) The pharmacist-in-charge shall convene or identify a Multidisciplinary Committee, which is charged with oversight of the automated medication system.
(p) A managing pharmacy utilizing an automated medication system may distribute patient-specific drugs within the health care facility without verifying each individual drug selected or packaged by the system, if:
(i) The initial medication order has been reviewed and approved by a pharmacist; and the drug is distributed for subsequent administration by a health care professional permitted by New Mexico law to administer drugs.

F. STOCKING OR RESTOCKING OF AN AUTOMATED MEDICATION SYSTEM

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

G. Quality Assurance Program

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

H. Records

The managing pharmacy/pharmacist-in-charge shall maintain, for at least three years, the following records related to the automated medication system in a readily retrievable manner:
(1) Managing pharmacy's distribution records for all dangerous drugs, including controlled substances, transferred to each automated medication system.

(2) Perpetual inventories of controlled substances contained within each automated medication system.
(3) Transaction records: At the time of any event involving the contents of the automated device, the device shall automatically produce on demand, a written or electronic record showing:

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

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

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

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

I. The Multidisciplinary Committee shall:

(1) Include the pharmacist-in-charge or the pharmacist-in-charge's designee;
(2) Establish the criteria and process for determining which drug qualifies as an override medication; and
(3) Develop policies and procedures regarding the operation of the automated medication system.

Appendix D

16.19.6.23 PRESCRIPTIONS:

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

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

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

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

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

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

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

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

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

Appendix E

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

16.19.36.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.36.1 NMAC - N, 06-28-14]

16.19.36.2 SCOPE: All facilities as defined in Paragraph (1), (2), (5-11) and (~~7~~15) of Subsection B of 61-11-14 NMSA 1978, and all persons or entities that own or operate, or are employed by a facility for the purpose of providing pharmaceutical compounded sterile preparations or services.
[16.19.36.2 NMAC - N, 06-28-14]

1-Retail pharmacy, 2 – nonresident pharmacy, 5 – hospital pharmacy, 6- industrial health clinic, 7 – community health clinic, 8 – dept of health public health offices, 9- custodial care facility, 10 – home care services, 11 – emergency medical services, 15 – research drug facilities.
Adds additional facilities to which USP compliance applies.

16.19.36.3 STATUTORY AUTHORITY: Paragraph (6) of Subsection A of Section 61-11-6 NMSA 1978 authorizes the board of pharmacy to provide for the licensing of all places where dangerous drugs are stored, dispensed, distributed or administered and for the inspection of their facilities and activities. Paragraph (7) of Subsection A of 61-11-6 NMSA 1978 authorizes the board to enforce the provisions of all laws of the state pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs and their standards of strength and purity.
[16.19.36.3 NMAC - N, 06-28-14]

16.19.36.4 DURATION: Permanent.
[16.19.36.4 NMAC - N, 06-28-14]

16.19.36.5 EFFECTIVE DATE: June 28, 2014, unless a different date is cited at the end of a section.
[16.19.36.5 NMAC - N, 06-28-14]

16.19.36.6 OBJECTIVE: The objective of Part 36 of Chapter 19 is to establish standards to ensure that the citizens of New Mexico receive ~~properly compounded~~ contaminant-free sterile preparations properly compounded in accordance with all applicable USP-NF General Chapters numbered below 1000.

Added to specify that proper compounding must be in accordance with USP-NF Chapters. Not so stated elsewhere in this regulation. Includes all enforceable chapters as other chapters are referenced in 797. (e.g., Antimicrobial Effectiveness Testing <51>; Injections <1>, Sterility Testing <71>, Bacterial Endotoxins Test <85> and eventually <800>.

[16.19.36.6 NMAC - N, 6-28-14]

16.19.36.7 DEFINITIONS:

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

B. **"Ante-area"** means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities are performed. It is also a transition area that:

(1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and

(2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

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

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

Definition of 'batch' added for clarity – as written in USP <795>.

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

F~~E~~. **"Biological safety cabinet"** (BSC) means a ventilated cabinet that provides ISO Class 5 environment for CSP's, provides personnel, preparation, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for preparation protection, and HEPA-filtered exhausted air for environmental protection.

G~~F~~. **"Buffer area"** means an area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the staging of components and supplies used when compounding CSP's.

H~~G~~. **"Certification"** means independent third party documentation declaring that the specific requirements of USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* have been met.

I~~H~~. **"Cleanroom"** means a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

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

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

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

L~~K~~. **"Compounding aseptic containment isolator"** (CACI) means an enclosed ISO Class 5 environment workspace for compounding of hazardous sterile preparations, provides personnel protection with negative pressure and appropriate ventilation and provides preparation protection by isolation from the environment and high-efficiency particulate air (HEPA)-filtered laminar airflow. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter

(HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

M~~L~~. **"Compounding aseptic isolator"** (CAI) means an enclosed ISO Class 5 environments for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).

N~~M~~. **"Critical area"** means an ISO Class 5 environment.

O~~N~~. **"Critical site"** means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

P~~O~~. "Direct compounding area" (DCA) means a critical area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

Q~~P~~. **"Disinfectant"** means an agent that frees from infection and destroys disease-causing pathogens or other harmful microorganisms, but may not kill bacterial and fungal spores. It refers to substances applied to inanimate agents, usually a chemical agent, but sometimes a physical one.

R~~Q~~. "Hazardous drugs" means drugs classified as hazardous if studies in animals or humans indicate exposures to them have a potential for causing cancer, development or reproductive toxicity or harm to organs. (Reference current NIOSH publications).

S~~R~~. "Home care" means health care provided in the patient's home (not a hospital or skilled nursing facility) by either licensed health professionals or trained caregivers. May include hospice care.

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

U~~T~~. "ISO 5" means air containing no more than 100 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3520 particles per cubic meter).

V~~U~~. "ISO 7" means air containing no more than 10,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (352,000 particles per cubic meter).

W~~V~~. **"ISO 8"** means air containing no more than 100,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3,520,000 particles per cubic meter).

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

Y~~X~~. "Laminar airflow workbench" (LAFW) means a ventilated cabinet for compounding of sterile preparations. Provides preparation protection with high-efficiency particulate air (HEPA) filtered laminar airflow, ISO Class 5. Airflow may be horizontal (back to front) or vertical (top to bottom) in direction.

Z~~Y~~. **"Media-fill test"** means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as soybean-casein digest medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time, and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

AA~~Z~~. "Multiple-dose container" means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. Once opened or entered,

a multiple dose container with antimicrobial preservative has a BUD of 28 days unless otherwise specified by the manufacturer.

BB~~AA~~. **"Negative pressure room"** means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is *into* the room.

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

DD~~CC~~. **"Personal protective equipment"** (PPE) means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

EE~~DD~~. **"Pharmacy bulk packages"** means a container of a sterile preparation for parenteral use that contains many single doses. Contents are intended for use in a pharmacy admixture program and are restricted to use in a suitable ISO Class 5 environment.

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

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

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

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

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

GG~~FF~~. **"Positive pressure room"** means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out* of the room.

HH~~GG~~. **"Preparation"** means a CSP that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

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

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

KK~~JJ~~. **"Product"** means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

LL~~KK~~. **"Quality assurance"** means a program for the systematic monitoring and evaluation of the various aspects of a service or facility to ensure that standards of quality are being met.

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

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

OO~~NN~~. **"Segregated compounding area"** means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSP's with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSP's and shall be void of activities and materials that are extraneous to sterile compounding.

PP~~OO~~. **"Single-dose container"** means a single-dose, or a single-unit, container for articles or preparations intended for parenteral administration only. It is intended for a single use. Examples of single-

dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

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

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

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

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

UU~~TT~~. **"Terminal sterilization"** means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a non-sterile unit.

VV~~UU~~. **"Unidirectional flow"** means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

WW~~VV~~. **"USP"** means United States pharmacopeia.

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

[16.19.36.7 NMAC - N, 06-28-14]

16.19.36.8 PHARMACIST IN CHARGE:

A. All facilities compounding sterile preparations must designate a pharmacist in charge of operations who is licensed as a pharmacist in the state of residence of the facility.

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

(1) the development, implementation and continuing review and maintenance of written policies, procedures and SOP's which comply with USP/NF standards;

(2) providing a pharmacist who is available for 24 hour seven-day-a-week services;

(3) establishing a system to ensure that the CSP's prepared by compounding personnel are administered by licensed personnel or properly trained and instructed patients;

(4) establishing a system to ensure that CSP's prepared by compounding personnel are prepared in compliance with USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*standards;

(5) ensuring facility personnel comply with written policies, procedures, and SOP's; and

(6) developing an appropriate and individualized plan of care in collaboration with patient or caregiver and other healthcare providers for each patient receiving parenteral preparations in a home setting.

[16.19.36.8 NMAC - N, 06-28-14]

16.19.36.9 FACILITIES:

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

(1) must be physically designed and environmentally controlled to meet standards of compliance as required by USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*;

(2) must be periodically monitored, evaluated, tested, and certified by environmental sampling testing as required by USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* with documentation retained for three years;

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

(a) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet with 100 square feet exclusive to compounding sterile preparations;

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

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

(5) must minimize particle generating activities.

B. Addition of a compounding sterile preparations area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure.

C. A new CSP facility must comply with 16.19.6.8 NMAC through 16.19.6.11 NMAC of the regulations.

[16.19.36.9 NMAC - N, 06-28-14]

16.19.36.10 EQUIPMENT: Each facility compounding sterile preparations shall have sufficient equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparation of compounded sterile preparations drugs and parenteral preparations appropriate to the scope of pharmaceutical services provided and as specified in USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations).*

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

B. Primary engineering controls used to provide an aseptic environment shall be tested in the course of normal operation by an independent qualified contractor and certified as meeting the requirements presented in USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* at least every six months and when relocated, certification records will be maintained for three years.

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

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

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

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

D. Automated compounding devices shall:

(1) have accuracy verified on a routine basis at least every 30 days per manufacturer's specifications;

(2) be observed every 30 days by the operator during the mixing process to ensure the device is working properly;

(3) have data entry verified by a pharmacist prior to compounding or have accurate final documentation of compounded preparations to allow for verification of ingredients by a pharmacist prior to dispensing; and

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

[16.19.36.10 NMAC - N, 06-28-14]

16.19.36.11 DOCUMENTATION REQUIRED:

A. Written policies, procedures and SOPs consistent with USP/NF <797> *(General Chapter <797> Pharmaceutical Compounding-Sterile Preparations)* standards as well as those required below, must be established, implemented, followed by facility personnel, and available for inspection and review by authorized agents of the board of pharmacy.

B. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These records must include but are not limited to:

(1) cleaning, disinfection, evaluation, validation, testing, certification, and maintenance of the sterile compounding area;

(2) personnel qualifications, training, assessment and performance validation;

(3) operation, maintenance, validation, testing, and certification of facility and equipment;

(4) SOP's for compounding, storing, handling, and dispensing of all components used and all compounded sterile preparations;

(5) SOP's for proper disposal of physical, chemical, and infectious waste;

(6) quality control guidelines and standards;

(7) quality assurance guidelines and standards;

(8) SOP's for determination of stability, incompatibilities, and drug interactions;

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

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

Requirement for retention of records is not included elsewhere in this regulation.

[16.19.36.11 NMAC - N, 06-28-14]

16.19.36.12 RECORD KEEPING AND PATIENT PROFILE: The compounded sterile preparations facility is required to maintain patient's records which include but are not limited to the following.

A. Prescription records or provider orders including the original prescription or original provider order, refill authorization, alterations in the original prescription or original provider order, and interruptions in therapy due to hospitalization.

B. Patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patient.

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

D. Documentation that the patient receiving parenteral preparations in a home setting or the agent has received a written copy of the plan of care and training in the safe administration of the medication.

[16.19.36.12 NMAC - N, 06-28-14]

16.19.36.13 REQUIREMENTS FOR TRAINING: All personnel, including pharmacists, pharmacists who supervise compounding personnel, pharmacists interns and pharmacy technicians , shall have completed didactic and experiential training with competency evaluation through demonstration and testing (written or practical) as required by USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*and as outlined by the pharmacist-in-charge and described in the site policy and procedures or training manual, prior to compounding sterile preparations.

A. Instructional topics shall include:

(1) aseptic technique;

(2) critical area contamination factors;

(3) environmental monitoring;

(4) facilities;

(5) equipment and supplies;

(6) sterile pharmaceutical calculations and terminology;

(7) sterile pharmaceutical compounding documentation;

(8) quality assurance procedures;
(9) proper gowning and gloving technique;
(10) the handling of cytotoxic and hazardous drugs; and
(11) general conduct in the controlled area.

~~**B.** Training shall be obtained through the following:~~

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

~~**(2)** completion of a board approved course; or~~

~~**(3)** certification by university of New Mexico college of pharmacy.~~

The didactic training of a given site-specific program may involve a wide range of activities: ASHP & Critical Point courses, vocational programs etc. The committee feels that each site must state in their training program the specifics of what is acceptable training. 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.

C. Pharmacy technicians shall complete 100 hours of experiential training in compounded sterile preparations in accordance with New Mexico statute 61-11-11.1 prior to compounding sterile preparations.

This is requirement is contained within the New Mexico statute but is not widely known. Addition to regulations calls out need for compliance with this requirement. Documentation of such additional training might include vocational school transcript/record, prior experience, or on site-specific training activities. The details of acceptable documentation should be included in the institutional training program.

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

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

To define training requirements for compounding sterile hazardous preparations. Note that there are no board approved program. Wording intended to compensate for release of <800> without specification to the yet published chapter. Places responsibility with the institution to provide adequate training and oversight whatever the requirement s may be.

F~~E~~. Frequency of training and assessment shall be conducted as required by USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* to assure continuing competency and include:

(1) initial training before compounding sterile preparations;

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

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

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

G~~F~~. Documentation of training: Written documentation of initial and in-service training, the results of written or practical testing, and process validation of compounding, personnel shall be retained for three years and
contain the following information:

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

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

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

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

(5) signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

[16.19.36.13 NMAC - N, 06-28-14]

16.19.36.14 PATIENT OR CAREGIVER TRAINING FOR USE OF COMPOUNDED STERILE PREPARATIONS IN A HOME SETTING:

A. The pharmacist shall maintain documentation that the patient has received training consistent with Subsection F of 16.19.4.16 NMAC.

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

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

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

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

(3) documentation of patient training.

[16.19.36.14 NMAC - N, 6-28-14]

HISTORY OF 16.19.36 NMAC: [RESERVED]

Meeting Minutes

Sterile Compounding Committee
Advisory to the NM Board of Pharmacy

Thursday October 9, 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, Adela Padilla, Teri Rolan, Ray Goellner

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1. Announcements – Amy Buesing
    a. Congratulations to committee member Phil Saucedo: NMSHP 2014 Dorothy Dillon awardee
    b. Kudos to committee member Catherine Cone: presenter at 2014 NMSHP Balloon Fiesta Symposium (Compounding Sterile Preparations – Learning from Past Mistakes to Prevent Future Ones-A review of USP <797> (PowerPoint slides available at NMSHP website under Balloon Fiesta Symposium schedule)
2. Concern – Ray Goellner
    a. Ray described a quality issue that took place at his hospital pharmacy regarding variability among clean room certifiers. Ray initially requested for NMBOP to "license" clean room certifiers. Amy brought this issue to the August NMBOP meeting where it was discussed and established that it would require a statute change and the NMBOP was not in favor of pursuing a change in statute at this time.
    b. Much discussion regarding certification provided by NSF to an individual vs. certification standards set by CETA.
    c. Committee felt that this was an education issue and warranted no further revisions to regulations.
    d. Committee encourages PICs to request/validate individual's NSF certification status.
    e. Kristina Wittstrom will review supplemental guidelines to determine if additional language may be needed to reinforce PIC responsibility to assure that clean room certifying personnel are performing job responsibilities according to USP<797> standards.
3. NMAC 16.19.36 - Committee
    a. Committee reviewed revisions from previous meetings (Attachment A).
    b. Revisions are denoted in red. Rationale for revision recommendation provided in blue box. Thanks to Kristina Wittstrom for tracking changes and providing document.
    c. Committee requests NMBOP to notice for rules hearing at January meeting.
    d. Majority of proposed revisions are in Training and Quality Assurance sections.
4. Next Steps
    a. ABuesing will submit changes to 16.19.36 to Doug Scribner, Frank/Liz Latino, Cheranne McCracken for additional feedback prior to January meeting.
    b. ABuesing to notify Doug Scribner and Dean Welage of rational for changes in training section.
    c. Teri Rolan would like to make recommendation to NMBOP at October meeting regarding requirements for non-resident licenses that are shipping sterile compounded products into New Mexico.
    d. Monitor proposed changes to USP<800>.

Next Meeting: To be determined
Submitted by ABuesing 10 October 2014

Appendix F

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

16.2.18.1 ISSUING AGENCY: New Mexico Board of Acupuncture and Oriental Medicine.
[16.2.18.1 NMAC - N, 02-08-13]

16.2.18.2 SCOPE: All doctors of oriental medicine who are certified for expanded practice or who are applicants for certification for expanded practice, as well as all educational courses and applicants for approval of educational courses.
[16.2.18.2 NMAC - N, 02-08-13]

16.2.18.3 STATUTORY AUTHORITY: This part is promulgated pursuant to the Acupuncture and Oriental Medicine Practice Act, Section 61-14A-8.1.
[16.2.18.3 NMAC - N, 02-08-13]

16.2.18.4 DURATION: Permanent.
[16.2.18.4 NMAC - N, 02-08-13]

16.2.18.5 EFFECTIVE DATE: February 8, 2013, unless a later date is cited at the end of a section.
[16.2.18.5 NMAC - N, 02-08-13]

16.2.18.6 OBJECTIVE: Part 18 lists the prerequisites, educational course approval requirements, class hours, curriculum knowledge and skills for each of the following expanded practice categories: basic injection therapy, injection therapy, intravenous therapy and bioidentical hormone therapy.
[16.2.18.6 NMAC - N, 02-08-13]

16.2.18.7 EDUCATIONAL COURSE APPROVAL GENERAL REQUIREMENTS: The board shall approve an educational course for a specific category of expanded practice upon completion of the following general requirements and the specific requirements listed for the specific category of expanded practice educational course approval.

A. The educational course shall provide at least the minimum number of hours of education in the areas listed for the specific category of educational course hours. One hour of education shall be equal to that defined by the accreditation commission for acupuncture and oriental medicine (ACAOM). The education shall be in addition to the education required to meet the minimum educational program requirements for licensure as a doctor of oriental medicine.

B. The educational course application shall include a description of the education being provided as required by the educational course general curriculum defined in 16.2.18.10 NMAC and the educational course curriculum defined for the specific category of expanded practice for which the educational course is applying for approval.

C. The educational course application shall include the curriculum vitae for all teachers, and proposed substitute teachers, and all classes shall be taught by qualified teachers approved by the board with the following qualifications:

(1) the education in the pharmacology of the authorized substances shall be taught by a licensed pharmacist, Pharm D or a Ph.D. in pharmacology; and

(2) the education in the clinical therapeutic use of the authorized substances shall be taught by a licensed health care practitioner with appropriate training and a minimum of five years experience using the authorized substances.

D. The educational course application shall include documentation that all required clinical practice hours shall have a teacher to student ratio of at least one teacher to no more than eight students.

E. The educational course application shall include examples of the test questions that students enrolled in the course are required to successfully pass in order to ensure competence in all required areas. Testing methodology shall be approved by the board and testing shall be administered as approved by the board. The educational course shall send all student test scores and evaluation instruments directly to the board.

F. The educational course application shall include an example of the certificate that shall be given for successful completion of the educational course.

G. Each educational course shall be completed within two years of commencement of that course.

H. A student who is allergic or hypersensitive to an authorized substance may be excused from participating in clinical practice when such an authorized substance is being used.

I. The board has the authority to observe, audit and evaluate educational courses. Each educational course applicant shall agree that the educational course may be observed, audited and evaluated by an authorized member of the board or by an agent of the board, prior to approval, after approval or during any educational course classes. A course audit or evaluation may result in denial, suspension or revocation of the course's approval by the board in accordance with law.

J. The educational course shall specify whether the organization offering the educational course is a sole proprietorship, partnership, LLC, corporation or non-profit corporation and shall provide proof of such legal business status.

K. An educational course shall submit a new application on the form approved by the board, pay the appropriate fee defined in 16.2.10 NMAC and comply with all other new application requirements if any of the following changes:

(1) ownership;
(2) faculty; and
(3) curriculum.

L. An educational course shall inform the board in writing, provided that the educational course certifies that all factors defined in Subsection J of 16.2.18.8 NMAC remain unchanged, if any of the following changes:

(1) name;
(2) address; and
(3) phone number.

[16.2.18.7 NMAC - N, 02-08-13; A, 03-02-14]

16.2.18.8 EDUCATIONAL COURSE APPROVAL BOARD REQUIREMENTS:

A. The board shall have final authority for approval of all educational courses including classes and teachers.

B. The board shall notify the applicant in writing by mail postmarked no more than 75 days after the receipt of the initial application as to whether the application is complete or incomplete and missing specified application documentation.

C. The board shall notify the applicant in writing by mail postmarked no more than 75 days after the notice of receipt of the complete application sent out by the board, whether the application is approved or denied.

D. If the application is denied, the notice of denial shall state the reason the application was denied.

E. In the interim between regular board meetings the board's chairman or an authorized representative of the board shall issue an interim temporary educational course approval to a qualified applicant who has filed, with the board, a complete application and complied with all requirements for educational course approval. The interim temporary educational course approval shall automatically expire on the date of the next regular board meeting and final educational course approval shall only be granted by the board.

[16.2.18.8 NMAC - N, 02-08-13]

16.2.18.9 EDUCATIONAL COURSE PREREQUISITES:

A. Proof of completion of a course in pharmacology from an accredited institution or the equivalent of at least three college or university credit hours (30-45 contact hours) in pharmacology from an accredited college or university. If the applicant prefers they can sit for a pharmacology final exam at an accredited institution:

(1) proof of completion of a four hour American heart association approved CPR or basic life support (BLS) course; a current card will serve as proof; and

(2) proof of completion of a two hour instruction in the use of inhaled O2 and IM epinephrine for emergency use or inclusion of that education and training in the basic education course curriculum.

B. The basic injection course is a prerequisite to injection therapy certification and intravenous therapy certification.

[16.2.18.9 NMAC - N, 02-08-13; A, 03-02-14]

16.2.18.10 EDUCATIONAL COURSE GENERAL CURRICULUM: The educational program shall provide the doctor of oriental medicine, who successfully completes the program, with the following entry level general knowledge and skills, at the current professional standard of care within the context of an integrative healthcare system, as well as the specific entry level knowledge and skills, at the current professional standard of care within the context of an integrative healthcare system, defined for the specific category of expanded practice educational course approval.

A. Expanded practice and prescriptive authority and oriental medicine: knowledge of how the principles of the developmental system of oriental medicine such as yin, yang, qi and xue apply to the expanded practice certifications.

B. Biomedical knowledge: knowledge of anatomy, physiology, pathology, endocrinology, biochemistry, pharmacology and diagnostic options sufficient to provide a foundation for the knowledge and skills required for the specific category of expanded practice.

C. Pharmacology:

(1) knowledge of the biochemistry, pharmacology, clinical application, safety and handling, side effects, interactions, contraindications, safeguards and emergency procedures for all authorized substances in the formulary defined for the relevant specific category of expanded practice;

(2) knowledge of how to make a differential diagnosis relative to the prescription or administration of authorized substances in the formulary defined for the relevant specific category of expanded practice;

(3) knowledge of the potency and appropriate dosage of single and combined authorized substances in the formulary defined for the relevant specific category of expanded practice;

(4) knowledge of and skill in utilizing appropriate clinic based aseptic technique; and

(5) knowledge of the compounding requirements of the United States pharmacopeia and national formulary (USP-NF) with regard to the authorized substances in the formulary defined for the relevant specific category of expanded practice.

D. Referral:

(1) understanding the limits of their training, knowledge and skill and when it is appropriate to refer; and

(2) knowledge of the options available regarding referral including an understanding of the potential benefit or contraindications of all categories of expanded practice.

E. Emergency care (previous CPR/BLS certification):

(1) knowledge of how to recognize a medical emergency situation arising in the clinic and what emergency outcomes may arise relative to performing the authorized diagnostic and therapeutic procedures and the prescription or administration of the specifically authorized substances, what procedures and substances are best for managing each emergency situation and whom to contact for emergency support and care;

(2) skill in providing first aid until the medical emergency team arrives;

(3) appropriate initial screening for potential allergic or adverse reactions;

(4) skill in identifying and responding to adverse or allergic reactions or mild to severe; vasovagal reactions with knowledge of appropriate support measures depending on the type of reaction:

(a) patient reassurance;

(b) patient positioning;

(c) oral OTC diphenhydramine (benadryl) if appropriate;

(d) inhaled oxygen;

(e) inhaled OTC epinephrine (primatine mist) or IM injected epinephrine if appropriate; and

(f) emergency ambulance transport;

(5) knowledge of the immediate and longer term indications of inadvertent pneumothorax and the appropriate procedure for patient care and guidance in such situations.

F. Record keeping, storage and dispensing of dangerous drugs and controlled substances:

(1) knowledge of the proper storage requirements in the clinic for the drugs, dangerous drugs and controlled substances in the specifically authorized formulary;

(2) knowledge of how to keep accurate records of all authorized drugs, dangerous drugs and controlled substances obtained, stored, compounded, administered or dispensed; and

(3) skill in appropriately handling and using appropriate clean or aseptic technique for all drugs, dangerous drugs and controlled substances in the specifically authorized formulary.

G. Pharmaceutical law:

(1) knowledge of the appropriate areas of New Mexico pharmaceutical law;

(2) knowledge of the appropriate areas of the United States pharmacopeia and national formulary (USP-NF) that relate to compounding of the authorized substances in the formulary defined for the relevant specific category of expanded practice; and

(3) knowledge of drugs, dangerous drugs, and controlled substances and what dangerous drugs or controlled substances that are or are not authorized under the provisions of the specific category or categories of expanded practice for which he is certified.

H. Scope of practice:

(1) knowledge of the areas of the New Mexico Acupuncture and Oriental Medicine Practice Act and the rules of the New Mexico board of acupuncture and oriental medicine that are appropriate to the scope of practice of a doctor or oriental medicine certified for the specific category of expanded practice;

(2) understanding and knowledge of what diagnostic or therapeutic procedures are authorized by the specific category of expanded practice; and

(3) understanding and knowledge of what substances in a specific formulary are authorized for use by doctors of oriental medicine certified for the specific category of expanded practice.

[16.2.18.10 NMAC - N, 02-08-13]

16.2.18.11 BASIC INJECTION THERAPY EDUCATIONAL COURSE APPROVAL: The board shall approve a basic injection therapy educational program upon completion of the following requirements. The educational course shall submit to the board:

A. the completed application form provided by the board;

B. payment of the application fee for expanded practice educational course approval specified in 16.2.10 NMAC;

C. documentation that it will comply with all educational course approval general requirements defined in 16.2.18.8 NMAC;

D. documentation demonstrating that it will provide the educational course general curriculum defined in 16.2.18.10 NMAC;

E. documentation demonstrating that it will provide the basic injection therapy educational course hours defined in 16.2.18.12 NMAC; and

F. documentation demonstrating that it will provide the basic injection therapy educational course curriculum defined in 16.2.18.13 NMAC;

G. documentation of examination and testing to be administered to each applicant with a passing grade of 70 percent to be required for certification to demonstrate learned knowledge.

[16.2.18.11 NMAC - N, 02-08-13]

16.2.18.12 BASIC INJECTION THERAPY EDUCATIONAL COURSE HOURS: The education shall consist of a minimum total of 56 contact hours with at least the minimum number of hours of education in the areas listed below:

A. a minimum of eight hours in pharmacology and biomedical differential diagnosis relative to the prescription, administration, compounding and dispensing of the authorized substances in the basic injection therapy formulary including homeopathic medicines;

B. a minimum of two hours in the drawing and compounding of the authorized substances intended for injection utilizing approved aseptic technique and proper record keeping, storage and dispensing of substances; at least half of the required hours shall be clinical practice;

C. a minimum of 14 hours in orthopedic and neurological evaluation; at least half of these required hours shall be clinical practice;

D. a minimum of two hours in the theory and practice of vapocoolant spray and stretch techniques using the authorized vapocoolants; at least half of these required hours shall be clinical practice;

E. a minimum of 28 hours in the theory and practice of injection therapy including: 11 hours of trigger point therapy and injection of acupuncture points; 11 hours of basic mesotherapy; six hours of basic neural therapy, and therapeutic injections (vitamins), using the authorized substances in the basic injection therapy formulary; at least half of these required hours shall be clinical practice;

F. a minimum of one hour in pharmaceutical law as provided by the New Mexico board of pharmacy; and

G. a minimum of one in oriental medicine scope of practice relative to the authorized substances and techniques.

[16.2.18.12 NMAC - N, 02-08-13]

16.2.18.13 BASIC INJECTION THERAPY EDUCATIONAL COURSE CURRICULUM: The basic injection therapy educational course curriculum shall provide the doctor of oriental medicine, who successfully completes the course, with the educational course general curriculum knowledge and skills defined in 16.2.18.10 NMAC and the following specific knowledge and skills:

A. orthopedic and neurological physical exam and differential diagnosis:

(1) knowledge of anatomy of the regions to be examined and treated;

(2) knowledge of the most common orthopedic pain differential diagnoses for these areas as well as other medical differential diagnoses that should be ruled out;

(3) skill in interpreting physical exam signs in context as evidence for or against the differential diagnoses;

(4) knowledge of the most important treatment options for these differential diagnoses including but not limited to injection therapy, spray and stretch therapy, exercise, physical medicine, manipulation, manual medicine, acupuncture, moxibustion, medical therapy with herbal medicine, supplements, homeopathic medicines and diet therapy;

(5) knowledge of which basic imaging methods, if any, are useful in the examination of the above differential diagnoses; and

(6) skill in selecting and performing the most appropriate basic orthopedic and neurologic physical examination methods including but not limited to the most basic forms of reflex testing, motor power testing, sensory exam, common orthopedic provocations, ligament stretch testing, accurate palpation and marking of anatomic landmarks, ligament and tendon compression testing and myofascial trigger point compression;

B. general injection therapy:

(1) knowledge of the needles, syringes and other equipment used to perform the various types of injection therapy;

(2) knowledge of appropriate aseptic techniques and clean needle procedures and techniques;

(3) knowledge of the various solutions used in the various styles of injection therapy and skill in properly drawing and compounding into syringes the authorized substances intended for injection, using approved aseptic technique;

(4) knowledge of how to generate and carry out a comprehensive treatment plan that addresses the causative factors leading to pain and dysfunction from the perspective of the understanding of each style of injection therapy, offers post treatment palliation and provides post therapy recommendations to support rehabilitation and prevent recurrence;

(5) knowledge of how to explain to the patient the purpose of the therapy, the expected outcome and possible complications of the therapy that could occur;

(6) understanding that injection therapy techniques authorized for the basic injection therapy certification are limited to intradermal, subcutaneous and intramuscular, injections; and

(7) knowledge of the anatomical locations that are relatively safe for injection therapy, as well as those locations that should be avoided for injection therapy;

C. acupuncture point injection therapy:

(1) knowledge of how acupuncture point injections can complement traditional acupuncture;

(2) knowledge of the conditions that can be treated with acupuncture point injections; and

(3) skill in injecting acupuncture points;

D. trigger point therapy:

(1) knowledge of what a trigger point is, what the causative factors leading to trigger points are, what the most common perpetuating factors are and how to recognize and identify the most common pain referral patterns in the head, back, hip and extremities;

(2) knowledge of how to locate and palpate trigger points; and

(3) skill in locating, injecting and spraying and stretching the most commonly treated trigger points and muscles;

E. neural therapy:

(1) knowledge of the relationship between interference fields, the autonomic nervous system, pain and disease;

(2) skill in identifying common interference fields in the body; and

(3) skill in injecting common neural therapy injection sites such as peripheral nerves, scars, tonsils, intercutaneous and subcutaneous sites;

F. mesotherapy:

(1) knowledge of the mechanism of action of mesotherapy injections for pain and sports medicine and cosmetic treatment; and

(2) skill in injecting using mesotherapy methodology;

G. therapeutic injections:

(1) knowledge of how to evaluate the patient and determine a treatment plan with appropriate dosage, using appropriate authorized substances; and

(2) skill in performing therapeutic injections at appropriate anatomical locations and depths.

[16.2.18.13 NMAC - N, 02-08-13]

16.2.18.14 INJECTION THERAPY EDUCATIONAL COURSE APPROVAL: The board shall approve an injection therapy educational program upon completion of the following requirements. The educational course shall submit to the board:

A. the completed application form provided by the board;

B. payment of the application fee for expanded practice educational course approval specified in 16.2.10 NMAC;

C. documentation that it will comply with all educational course approval general requirements defined in 16.2.18.7 NMAC;

D. documentation demonstrating that it will provide the educational course general curriculum defined in 16.2.18.10 NMAC;

E. documentation demonstrating that it will provide the injection therapy educational course hours defined in 16.2.18.16 NMAC;

F. documentation demonstrating that it will provide the injection therapy educational course curriculum defined in 16.2.18.17 NMAC; and

G. documentation of examination and testing to be administered to each applicant with a passing grade of at least 70 percent to demonstrate learned knowledge (final certification is dependent on instructor's approval).

[16.2.18.14 NMAC - N, 03-02-14]

16.2.18.15 INJECTION THERAPY COURSE PREREQUISITES:

A. licensed doctor of oriental medicine in New Mexico; and

B. board certification in basic injection therapy.

[16.2.18.15 NMAC - N, 03-02-14]

16.2.18.16 INJECTION THERAPY EDUCATIONAL COURSE HOURS: The education shall be completed within two years of commencement of the course as specified in Subsection G of 16.2.18.7 NMAC and consist of a minimum total of 115 hours and with at least the minimum number of hours of education in the areas listed below:

A. eight hours in pharmacology, relevant pharmaceutical law, differential diagnosis relative to the selection, prescription, compounding and administration, of the authorized substances in the injection therapy formulary listed in Paragraph (2) of Subsection F of 16.2.20.8 NMAC, and the use of some of these substances as pain medicine: upon completion and certification in injection therapy some of these substances can be used with previously learned basic injection techniques including trigger point, mesotherapy, and neural therapy techniques;

B. four hours in the art and practice of phlebotomy in order to safely perform injection of ozone or platelet rich plasma when considered as appropriate therapeutic intervention and at least half of the required hours shall be in clinical practice; a certificate of completion of a board approved course in phlebotomy is acceptable;

C. 15 hours in a board approved course in oxidative medicine;

D. 52 hours to include:

(1) the scientific principles of prolotherapy;

(2) aseptic technique as it relates to injecting a joint;

(3) detailed anatomy of joints, supporting soft tissue structures, and specific injection sites;

(4) orthopedic and neurological functional evaluation;

(5) the use of platelet rich plasma and prolozone;

(6) theory and practice of advanced neural therapy techniques;

(7) differentiation and selection of authorized substances in the injection therapy formulary as defined in Paragraph (2) of Subsection F of 16.2.20.8 NMAC; and

(8) at least half of these required hours shall be clinical practice;

E. 30 hours of diagnostic musculoskeletal ultrasound and ultrasound guided musculoskeletal procedures from a board approved course; and

F. six hours in the theory and practice of advanced injection therapy techniques including: mesotherapy including cellulite reduction and apitherapy refer to Subsection H of 16.2.18.7 NMAC; at least half of these hours shall be in clinical practice; a certificate of completion from a board approved course in advanced mesotherapy or apitherapy will be considered to meet these hours. [16.2.18.16 NMAC - N, 03-02-14]

16.2.18.17 INJECTION THERAPY EDUCATIONAL COURSE CURRICULUM: The injection therapy educational course curriculum shall provide the doctor of oriental medicine, who successfully completes the course, with the educational course general curriculum knowledge and skills defined in 16.2.18.10 and 16.2.18.13 NMAC and the following specific knowledge and skills in:

A. regenerative injection therapy (RIT or prolotherapy):

(1) understanding of the scientific principles of prolotherapy, its application, alternatives, risks and consequences;

(2) recognizing the most common pain patterns generated from injured and lax ligaments of the joints of the extremities, lumbar and sacral regions;

(3) the concept of tissue regeneration and proliferation and how it can be promoted in the body;

(4) injecting some of the most commonly treated ligamentous, tendonous, and cartilaginous and intra-articular structures of the joints of the extremities, lumbar and sacral regions;

(5) how to perform regional anesthesia or a nerve block for pain relief; and

(6) the use of diagnostic musculoskeletal ultrasound and ultrasound guided procedures;

B. orthopedic and neurological physical exam and differential diagnosis:

(1) anatomy of the regions to be examined and treated;

(2) selecting and performing orthopedic and neurologic physical examination methods including but not limited to reflex testing, motor power testing, sensory exam, common orthopedic provocations, ligament stretch testing, accurate palpation and marking of anatomic landmarks, ligament and tendon compression testing;

(3) interpreting physical exam signs in context as evidence for or against the differential diagnoses;

(4) most common orthopedic pain differential diagnoses for these areas as well as other medical differential diagnoses that should be ruled out; and

(5) the most important treatment options for these differential diagnoses;

C. how to generate and carry out a comprehensive treatment plan that addresses the causative factors leading to pain and dysfunction from the perspective of the understanding of each style of injection therapy, offers post treatment palliation and provides post therapy recommendations to support rehabilitation and prevent recurrence:

(1) how to explain to the patient the purpose of the therapy, the expected outcome and possible complications of the therapy that could occur; and

(2) anatomical locations that are relatively safe for injection therapy, as well as those locations that should be avoided for injection therapy;

D. perform phlebotomy and collect and centrifuge blood to be used for platelet rich plasma injection; knowledge of diagnostic and physical exam findings which indicate the need for platelet rich plasma as a treatment modality;

E. advanced neural therapy techniques; knowledge and skills as described in 16.2.18.13 NMAC of basic injection;

F. advanced mesotherapy;

(1) how to evaluate and treat the patient with cellulite including determination of a treatment plan, utilizing appropriate substance(s) and dosing to accomplish treatment goals;

(2) how to evaluate and treat fat;

(3) technique of injections to reduce fat or cellulite; and

(4) mechanisms of action of substances used for cellulite and fat reduction;

G. apitherapy;

(1) knowledge of and skill in performing apitherapy; and

(2) understanding theory and application of apitherapy, expected outcomes, benefits and potential risks and complications.

[16.2.18.17 NMAC - N, 03-02-14]

16.2.18.18 [RESERVED]

16.2.18.19 BIOIDENTICAL HORMONE THERAPY EDUCATIONAL COURSE APPROVAL: The board shall have final authority for approval of a bioidentical hormone educational program upon completion of the following requirements. The educational course shall submit to the board:

A. the completed application form provided by the board;

B. payment of the application fee for expanded practice educational course approval specified in 16.2.10 NMAC;

C. documentation that it will comply with all educational course approval general requirements defined in 16.2.18.8 NMAC;

D. documentation demonstrating that it will provide the educational course general curriculum defined in 16.2.18.10 NMAC;

E. documentation demonstrating that it will provide the bioidentical hormone therapy educational course hours defined in 16.2.18.21 NMAC;

F. documentation demonstrating that it will provide the bioidentical hormone therapy educational course curriculum defined in 16.2.18.22 NMAC; and

G. documentation of examination and testing to be administered to each applicant with a passing grade of 70 percent to be required for certification to demonstrate learned knowledge.

[16.2.18.19 NMAC - N, 02-08-13]

16.2.18.20 BIOIDENTICAL HORMONE THERAPY EDUCATIONAL COURSE HOURS: The bioidentical hormone educational course shall consist of a minimum total of 80 hours of education, with at least 24 hours of practical experience defined in Subsections B, E and F of 16.2.18.21 NMAC in the areas listed below:

A. a minimum of eight hours in the pharmacology of bioidentical hormones;

B. a minimum of 18 hours in an overview of the endocrine system, including the anatomy and interactive physiology of the hypothalamic-pituitary-adrenal-thyroid (HPAT) and gonadal axis, the stress response and normal adrenal and thyroid function; also to include normal male and female sex hormone physiology; at least half of these hours shall be in practice or review of case studies;

C. a minimum of 20 hours in theory and practice of endocrinology including evaluation and treatment of the patient with hormonal dysfunction and imbalances including but not limited to; adrenal fatigue, auto-immune endocrine disorders, hypothyroid, hyperthyroid, men's hormone imbalances and women's hormonal imbalances pre, peri and post menopause and consideration and assessment for treatment with bio-identical hormone replacement therapy, BHRT; at least half of these hours will be in practice or review of case studies;

D. a minimum of 14 hours in blood chemistry analysis including but not limited to; CBC, CMP, LFT, lipids, ferritin, homocysteine, vitamin D, iodine, hs CRP, fibrinogen, ANA, ESR, HgBAIC, insulin antibodies;

E. a minimum of two hours in urine analysis;

F. a minimum of 16 hours in the assessment and treatment of hormone and neurotransmitter imbalances through blood, urine and saliva hormone testing and evaluation; appropriate treatment options for the biomedical differential diagnoses including, but not limited to; adrenal fatigue, thyroid imbalances, andropause, menopausal syndrome, and other male and female hormone imbalances; at least half of these hours shall be in practice or case study review;

G. a minimum of one hour in pharmaceutical law as provided by the New Mexico board of pharmacy; and

H. a minimum of one in oriental medicine scope of practice relative to the prescription or administration of the authorized substances.

[16.2.18.20 NMAC - N, 02-08-13]

16.2.18.21 BIOIDENTICAL HORMONE THERAPY EDUCATIONAL COURSE CURRICULUM: The bioidentical hormone therapy educational course curriculum shall provide the doctor of oriental medicine, who successfully completes the course, with the educational course general curriculum knowledge and skills defined in 16.2.18.10 NMAC and the following specific knowledge and skills:

A. bioidentical hormone therapy;

(1) knowledge of anatomy, physiology, endocrinology, pathology, biochemistry, pharmacology, diagnostic and referral options including imaging, and clinical strategies with a focus on hormone pathways, neurotransmitter imbalances, precursors and intermediaries relevant to bioidentical hormone therapy;

(2) knowledge of how to perform a diagnosis of the various aspects of the endocrine and neurotransmitter system using blood, urine, and saliva testing;

(3) knowledge of the application, clinical use, dosage, dosage adjustment or discontinuation consequences and safety concerns relevant to all modes of administration of the authorized substances; and

(4) knowledge of how to explain to the patient the purpose, expected outcome, risks and possible complications of bioidentical hormone therapy as well as the advantages of bioidentical hormone therapy, relative to non bioidentical hormone therapy;

B. non-hormone therapy:

(1) knowledge of how to optimize hormone balance using authorized substances that are not hormones or are hormone precursors, and the benefits and limits of such therapy; and

(2) knowledge of how to explain to the patient the purpose, expected outcome, risks and possible complications of non-hormone therapy as well as the advantages of non-hormone therapy relative to bioidentical hormone therapy.

[16.2.18.21 NMAC - N, 02-08-13]

HISTORY OF 16.2.18 NMAC: [RESERVED]

16.2.20.8 EXPANDED PRACTICE FORMULARIES GENERAL PROVISIONS: The following general provisions shall apply to the expanded practice general formulary and each specific formulary for each specific expanded practice category that follows in this rule:

A. drugs, dangerous drugs and controlled substances are defined in the New Mexico Drug, Device and Cosmetic Act and the New Mexico Controlled Substances Act;

B. all substances from threatened or endangered species, as determined by the convention on the international trade in endangered species of wild fauna and flora and the U.S. fish and wildlife service (http://endangered.fws.gov/), shall be automatically eliminated from expanded practice formularies;

C. definitions from the New Mexico Drug, Device and Cosmetic Act and the New Mexico Controlled Substances Act apply to the appropriate terms in the expanded practice formularies;

D. a doctor of oriental medicine shall comply with all federal and state laws that pertain to obtaining, possessing, prescribing, compounding, administering and dispensing any drug;

E. a substance shall only be approved for use if procured in compliance with all federal and state laws; the various expanded practice formularies do not supersede such laws; and

F. the following drugs, dangerous drugs and controlled substances are authorized in the modes of administration that are specified except as limited or restricted by federal or state law:

(1) **basic injection certification and prescriptive authority:** shall include topical vapocoolants the intradermal intramuscular, and subcutaneous injection of: homeopathic medicines; dextrose; enzymes except urokinase; hyaluronic acid; minerals; sarapin; sodium chloride; sterile water; and vitamins;

(2) **injection certification and prescriptive authority:**

(a) all substances from basic injection module; and

(b) all non-epidural, non intrathecal injection of: alcohol, amino acids, autologous blood and blood products and appropriate anticoagulant, live cell products, ozone, bee venom, beta glucans, caffeine collagenase, dextrose, dimethyl sulfoxide, gammaglobulin, glucose, glucosamine, glycerin, hyaluronidase, methylsulfonylmethane, phenol, phosphatidylcholine, procaine, sodium hyaluronate, sodium morrhuate, therapeutic serum;

(3) **intravenous certification and prescriptive authority:** amino acids, calcium ethylenediaminetetraacetic acid, dextrose, glutathione, homeopathic medicines, lactated ringers, minerals, phosphatidylcholine, sodium bicarbonate sodium chloride, sodium morrhuate, sterile water, water soluble vitamins, autologous blood and blood products with appropriate anticoagulant, live cell products, ozone, and ultraviolet radiation of blood with appropriate anticoagulant except that authority is not provided for total parenteral nutrition;

(4) **non-injectable bioidentical hormone certification and prescriptive authority:** 7-keto dehydroepiandrosterone (7 keto DHEA), cortisone, dehydroepiandrosterone (DHEA), dihydrotestosterone, estradiol (E2), estriol (E3), estrone (E1), hydrocortisone, pregnenolone, progesterone, testosterone, tetraiodothyronine (T4), levothyroxine, thyroxine (T4), & triiodothyronine (T3) combination, triiodothyronine, liothyronine (T3), desiccated thyroid;

G. applicable to any of the four certifications above: subcutaneous or intramuscular injection of epinephrine, inhaled oxygen, and additives necessary to stabilize, preserve or balance pH of approved substances.

[16.2.20.8 NMAC - Rp/E, 16.2.20.8 NMAC, 06/15/2010; Re-pr & A, 11/28/10; A, 02/08/13]

Appendix G

REPORT TO THE NEW MEXICO BOARD OF PHARMACY
CARL FLANSBAUM, PMP DIRECTOR
OCTOBER 2014

Items:

1. Task Force Report
   - I. Recommendations for amending the Model Prescription Monitoring Program Act.
   - II. Recommend that NABP Should Encourage State Boards of Pharmacy to Mandate That Practice Sites Provide Access to PMP Data and Encourage Use of This Data.
   - III. Recommend that NABP Should Collaborate with State Boards of Pharmacy and Other Stakeholders to Educate Health Care Practitioners and Provide Guidelines on How to Utilize PMP Data
   - IV. Recommend that NABP Should Work with State PMPs and Reporters of PMP Data to Ensure the Accuracy and Timeliness of Reported Data, and that Incorrectly Reported Data Is Corrected and that Information for Un-dispensed Prescriptions Is Reversed.
   - V. Recommend that NABP Should Assist the States in Developing Partnerships and If Necessary, Laws and Regulations, for the State Boards of Pharmacy to Increase the Use and Scope of PMP Data
   - VI. Recommend that NABP Should Continue to Develop PMP InterConnect and PMP Gateway in Order to Facilitate Secure Interoperability between State PMPs and Electronic Health Information Systems.

2. Does the board want to entertain the possibility of charging for PMP data?

3. NM PMP Awarded Harold Rogers grant which will fund:

   - I. Expansion of Unsolicited Reporting
   - II. Enhancements to support ASAP 4.2 reporting, support for the DEA suffix and daily reporting compliance monitoring
   - III. Use of NARxCHECK as optional report format within the PMP
   - IV. Prescriber report cards
   - V. Integration projects with Smiths and NMHIC

4. Future PMP Personnel Needs

5. 16.19.29 NMAC Rule changes, total rewrite including

   - I. Reporting/account specifics referenced to PMP website
   - II. Authority given to PMP Director
   - III. Daily reporting starting in 2015
   - IV. Reporting in ASAP 4.2 (Grant requirement)
   - V. Reporting of DEA suffix
   - VI. Reporting of found outlier PMP information to be reported
   - VII. Authority to cancel account (67% of accounts are “inactive”)

Delinquent PMP Reporting Dispensers

Appendix H

ID	6 month count	count since letter	10/14/2014	9/30/2014	9/16/2014	9/2/2014	8/19/2014	7/29/2014	7/15/2014	7/1/2014	6/17/2014	6/3/2014	5/20/2014	5/6/2014	4/15/2014	4/1/2014	3/18/2014	3/4/2014
A	7	1				X			X		X			X	X		X	X
B	6	2				X		X		X			X		X			X
C	6	1				X					X		X		X	X	X	
D	6	1				X				X	X		X		X		X	
E	7	3				X	X	X				X			X	X	X	
F	5	1				X			X			X				X	X	
G	3	1			X						X			X				
H	4	2			X	X						X					X	
I	3	2		X			X			X								
J	3	3		X	X	X												
K	5	1		X									X	X	X	X		
L	4	1		X					X	X				X				
M	3	3	X	X		X												
N	3	3	X		X		X											
O	4	1	X						X		X			X				
P	3	3	X		X		X											

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

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

Appendix I

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

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

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

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

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

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

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

16.19.29.7 DEFINITIONS:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

K. "State" means the state of New Mexico

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

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

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

B. Each dispenser shall submit to the board by electronic means information regarding each prescription dispensed for a drug included under Subsection A of this section. Information to be reported shall conform to the standards developed by the American society for automation in pharmacy (ASAP) and published in the ~~"ASAP telecommunications format for controlled substances", 2009 4.1 edition~~ " Implementation Guide: ASAP Standard for Prescription Monitoring Programs Version 4, Release 2". Information to be submitted for each prescription is defined in the PMP Data Collection manual available on the state PMP Website at http://nmpmp.org. ~~shall include:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(11)~~(2)~~ an individual who request~~'s~~ ~~their~~ his or her own ~~prescription monitoring information~~ PMP report in accordance with procedures established under NMSA 1978, Section 61-11-2(D) ~~NMSA, 1978~~ and Subsection ~~G~~ H of 16.19.6.23 NMAC or;

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

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

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

G. Within the normal functions of PMP information management, analysis and review, any prescribing and/or dispensing patterns of Schedule II – V controlled substances that may be indicative of abuse, misuse or diversion of these substances shall be reported to the appropriate law enforcement or professional licensing, certification or regulatory agency or entity and prescription information required for an investigation shall be provided to these persons.

H~~F~~. The board shall provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients and persons who have received prescriptions from dispensers. [16.19.29.9 NMAC - N, 07-15-04; A, 06-11-11; A, 08-31-12]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(10) number of prescriptions for a specified zip code;~~
~~(11) number of dosage units for a specified drug and specified zip code.~~
~~**E.** The board shall receive a quarterly program outcomes report from staff or contractors. A statistical analysis of the data that does not include protected information should be reported on the web site or in the newsletter.~~
[16.19.29.10 NMAC - N, 07-15-04; A, 06-11-11]

16.19.29.11 AUTHORITY TO CONTRACT: The board ~~is authorized to~~ may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the PMP ~~prescription monitoring program~~. ~~Any~~ A contractor shall ~~be bound to~~ comply with the provisions regarding confidentiality of prescription information in 16.19.29.9 NMAC ~~of this regulation~~ and shall be subject to the penalties specified in 16.19.29.~~12~~ 14 NMAC ~~of this regulation for unlawful regulations~~.
[16.19.29.11 NMAC - N, 07-15-04]

16.19.29.12 REGISTRATION FOR ACCESS TO ~~PRESCRIPTION~~ PMP INFORMATION:
~~**A.** Practitioners with individual drug enforcement administration (DEA) issued numbers will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued to the practitioner. One subaccount per practitioner account is authorized for an agent of the practitioner. The agent designated by the practitioner will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued to the agent.~~
~~**B.** Pharmacies with DEA issued numbers will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued. Pharmacies will designate one individual who will complete and submit a hard copy written, signed and notarized application. After verification of submitted information, a username and password will be issued to the individual. Pharmacies will not be permitted to obtain a subaccount.~~
~~**C.** All registrations will be renewed every three years by completing and submitting a new application.~~
~~**D.** All registrants to the prescription monitoring program will complete a web based training program approved by the board~~
A. Persons authorized for access to PMP information as listed in 16.19.29.9(D)(1)-(7) NMAC must apply for access as described at the PMP website located at http://nmpmp.org. Persons granted access must maintain individual accounts and shall not share access information with other persons.
B. All persons authorized for access to PMP information and applying for such access to the PMP shall successfully a web based training program as determined by the PMP director.
C. Persons reporting prescription information to the PMP, but not authorized for access to PMP information must also apply for access as described at the PMP website located at http://nmpmp.org.
D. The PMP director shall have the authority to set account access and registration renewal requirements necessary for accounts to be considered active and shall also have the authority to cancel inactive accounts.
[16.19.29.12 NMAC - N, 07-15-04; 16.19.29.12 NMAC - N, 06-11-11; A, 08-31-12]

16.19.29.13 INFORMATION EXCHANGE WITH OTHER PRESCRIPTION MONITORING PROGRAMS:
A. The ~~New Mexico~~ board ~~of pharmacy~~ may provide ~~prescription monitoring~~ PMP information to other states' prescription monitoring programs and such information may be used by those programs consistent with the provisions of ~~the~~ this rule.
B. The ~~New Mexico~~ board ~~of pharmacy~~ may request and receive ~~prescription monitoring~~ PMP information from other states' prescription monitoring programs and may use such information under provisions of this rule.
C. The ~~New Mexico~~ board ~~of pharmacy~~ may develop the capability to transmit information to and receive information from other prescription monitoring programs employing the standards of interoperability.
D. The ~~New Mexico~~ board ~~of pharmacy~~ ~~is authorized to~~ may enter into written agreements with other states' prescription monitoring programs or other ~~entities~~ persons hosting compatible information sharing technologies for the purpose of describing the terms and conditions for sharing of ~~prescription~~ PMP information under this section
[16.19.29.13 NMAC - N, 07-15-04; 16.19.29.13 NMAC - N, 06-11-11]

16.19.29.14 PENALTIES:

A. A dispenser who knowingly fails to submit prescription ~~monitoring~~ information to the board as required by this ~~regulation~~ rule or knowingly submits incorrect prescription information shall be subject to disciplinary proceedings as defined in NMSA 1978, Section 61-11-20 ~~NMSA~~.
B. Prescription information submitted to the ~~New Mexico prescription monitoring program (~~PMP~~)~~ is protected health information. ~~Registrants~~ Persons with access to the PMP ~~are required to~~ shall exercise due diligence in protecting this information and access it only as necessary in the course of legitimate professional regulatory or law enforcement duties.
C. ~~Individual registrants~~ A person found to be in violation of this section may be subject to one or more of the following actions.
(1) Termination of access to ~~the program~~ PMP information.

(2) A complaint may be filed with his o

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

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

HISTORY OF 16.19.29 NMAC: [RESERVED]

Appendix J

16.19.6.13 CONSPICUOUS DISPLAY REQUIREMENTS NOTICE OF PERMANENT CLOSURE OF PHARMACIES:

A. Every person shall have his or her license or registration and the license for the operation of the business conspicuously displayed in the pharmacy or place of business to which it applies or in which he or she is employed. All articles, including the following shall be in the vicinity of all prescription departments in full view of patrons:

(1) the pharmacy license
(2) the prohibition of the return of drugs sign
(3) the current board of pharmacy inspection report
(4) the current controlled substance registration
(5) the "patient's bill of right's" as approved by the board.

B. Name tags, including job title and the designation R.Ph., shall be required of all pharmacists while on duty.

C. Pharmacies permanently closing shall notify the public and the board of pharmacy of the closure at least 30 days prior to the final day of service. The notice shall include the last date of service and the name, address, and phone number of the location where patient records will be transferred and /or stored. Notice must also occur by one of the following; newspaper notice, radio broadcast, or other method as approved by the executive director of the board.

PHARMACY CLOSURES 7/1/2012 TO 8/27/2014

PHARMACY	TYPE	DATE RECEIVED	NOTICE DATE	CLOSURE DATE	TYPE OF NOTICE
A	community	7/28/2014	7/27/2014	8/25/2014	verbal; signs in pharmacy
B	community	3/17/2014	2/25/2014	3/13/2014	signs; newspaper
C	community	3/17/2014	2/25/2014	3/13/2014	signs; newspaper
D	community	8/16/2013	7/31/2013	8/30/2013	signs; newspaper
E	community	2/12/2014	2/5/2014	3/7/2014	signs; newspaper
F	community	1/8/2014	1/6/2014	1/26/2014	signs; newspaper; mailer
G	community	12/9/2013	10/2/2013	11/15/2013	signs; mailer; word of mouth
H	community	11/22/2013	11/29/2013	12/15/2013	signs; newspaper
I	community	1/23/2013	1/1/2013	12/24/2013	signs
J	community	10/12/2012	9/24/2012	10/26/2012	signs; in-store handouts
K	community	10/2/2012	9/17/2012	10/30/2012	signs;mailer;newspaper;radio;handouts
L	community	8/23/2012	8/22/2012	9/18/2012	signs; verbal
M	community	8/23/2012	8/22/2012	9/18/2012	signs; mailer; verbal
N	community	8/14/2012	8/14/2012	9/14/2012	signs
O	community	8/9/2012	8/2/2012	8/30/2012	mailer; calls
P	community	8/1/2012	8/1/2012	8/31/2012	signs
Q	community	7/2/2012	7/2/2012	8/2/2012	signs; mailer; word of mouth
R	community	7/12/2012	7/2/2012	7/31/2012	signs; mailer; bag insert
S	chain	1/13/2014	1/13/2014	2/11/2014	signs
T	chain	5/8/2014	5/6/2014	6/4/2014	signs; direct patient notification
U	chain	3/14/2014	3/3/2014	4/1/2014	signs
V	chain	2/24/2014	2/8/2014	3/20/2014	signs
W	chain	1/16/2013	1/16/2013	2/16/2013	signs
X	chain	6/6/2013	6/6/2013	7/6/2013	signs

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

Appendix K

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

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

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

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

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

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

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

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

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

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

Appendix L

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

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

61-11-12. License fees. (Repealed effective July 1, 2016.)

A. An applicant for licensure as a pharmacist or pharmacist intern or registration as a pharmacy technician shall pay the following fees, which fees shall not be returnable:

(1) for initial licensure as a pharmacist, a fee set by the board not to exceed four hundred dollars ($400); provided that if the applicant fails a portion of an examination, reexamination is subject to the same fee as the first examination;

(2) for initial licensure as a pharmacist intern, a fee not to exceed twenty-five dollars ($25.00); and

Appendix M

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

16.19.5.7 DEFINITIONS: As used in the internship program.

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

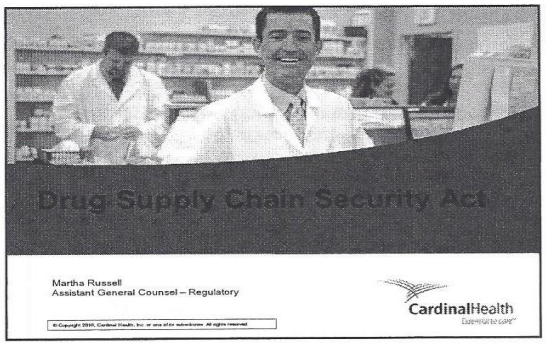
61-11-11. Pharmacist intern; qualifications for licensure. (Repealed effective July 1, 2016.)

The classification of pharmacist intern is established. An applicant for licensure as a pharmacist intern shall:
A. be not less than eighteen years of age and not be addicted to the use of drugs or alcohol;
B. have satisfactorily completed not less than thirty semester hours or the equivalent thereof in a school or college of pharmacy approved by the board; and
C. meet other requirements established by regulation of the board.

Appendix N

District 6 Resolutions
#1
Whereas there is a national and state movement to obtain provider status for pharmacists;
Whereas provider status is important to the advancement of the pharmacy profession;
Therefore be it resolved that NABP follow/adopt APhA provider status model
Therefore be it resolved that NABP work collaboratively with APhA and other pharmacy organizations to have a cohesive message to driver provider status recognition nationally;
Therefore be it further resolved that NABP develop a task force to create model act language to assist boards in oversight and regulation of independent providers in pharmacy practice.
#2
Whereas there is diversity among states regarding pre-licensure experience requirements;
Whereas this diversity in pre-licensure experience requirements may negatively impact new graduates seeking licensure in states other than where they graduated from;
Therefore be it resolved that NABP encourage states to accept ACPE accredited pre-licensure experience as satisfying preliminary licensure requirements;
Therefore be it also resolved that NABP encourage states to adopt the use of a centralized NABP database to confirm graduation of new graduates.
#3
Thank district 7 for hosting 2014 NABP District 6, 7,and 8 meeting
#4
Recognition resolution of former board members who passed away
Larry Griffin New Mexico Board of Pharmacy

DSCSA



Drug Supply Chain Security Act

Martha Russell
Assistant General Counsel – Regulatory

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Learning Objectives:

- Describe the essential characteristics of the DSCSA—drugs and supply chain participants impacted.
- Discuss the changes brought about by the DSCSA and intelligently assess the obligations required of supply chain participants in transferring DSCSA required data.
- Describe the changes that will occur regarding a state's licensing of wholesale distributors.

2

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Drug Quality and Security Act

- The Drug Quality and Security Act was signed by the President on November 27, 2013.
- Contains two main "titles":
  - Title I Drug Compounding: establishes national standards for compounding pharmaceuticals (not discussed here).
  - **Title II Drug Supply Chain Security Act (DSCSA):** establishes a national system for tracing pharmaceutical products through the supply chain, sets national licensing standards for wholesale distributors and third-party logistics providers, and preempts existing state licensing and pedigree requirements.

3

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Drug Supply Chain Security Overview: 3 parts

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.

4

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DSCSA Part 1 of 3 – Traceability

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and **third-party logistics providers.**

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.

5

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Pedigree phased out now traceability

DSCSA Part 1 of 3 – SCOPE
Definition of "Products"

- **The traceability requirements in Phase 1 and 2 apply to PRODUCTS.**
  - Products = prescription drugs in finished dosage form that are for human use.
  - no OTC, medical devices, API, or drugs indicated for animal use
- A number of prescription drugs are exempted from the definition of product, including:
  - Blood and blood components intended for transfusion
  - Radioactive drugs and radioactive biologics
  - Imaging drugs
  - Intravenous products
  - Medical gases
  - Homeopathic drugs
  - Compounded drugs

6

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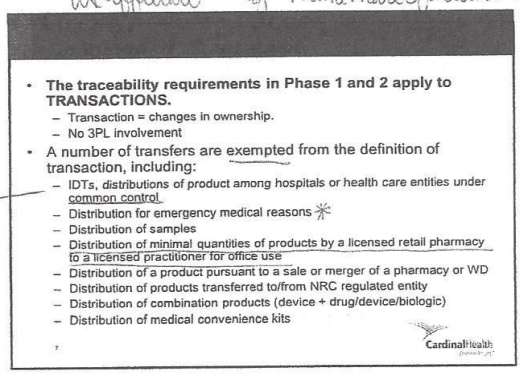

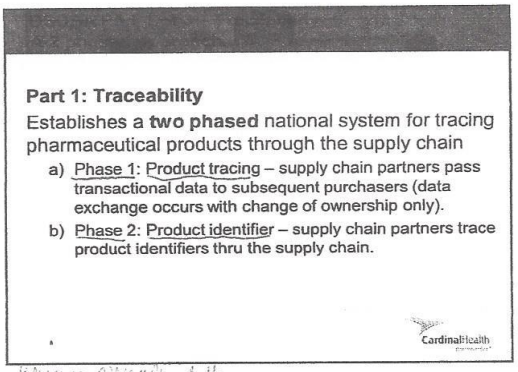

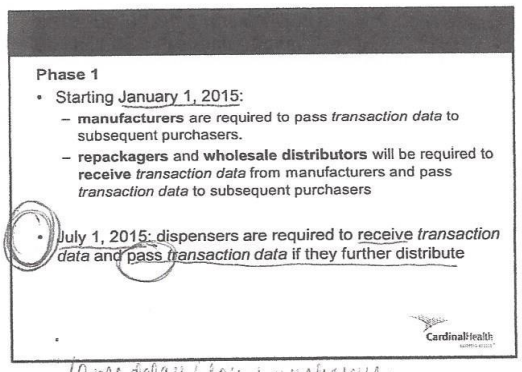

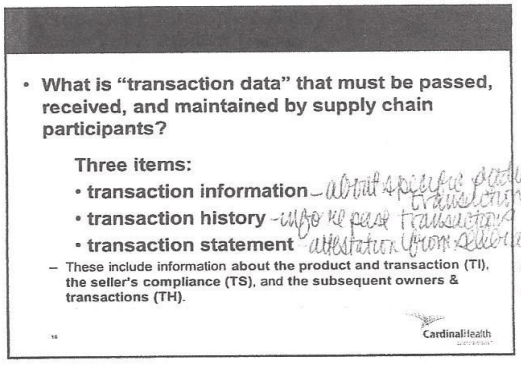

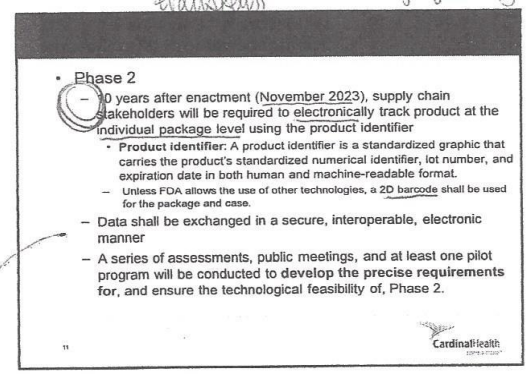

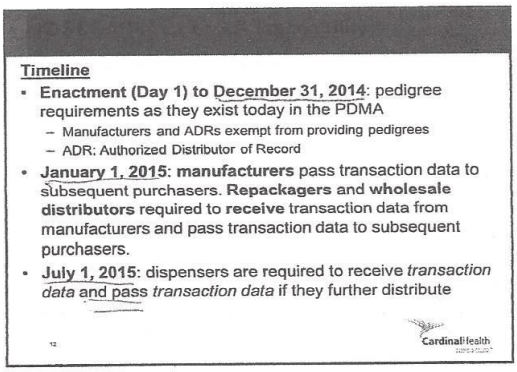

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H(1) are licensing matters, H(2) is limited to personnel matters, H(7) is pending or threatened litigation.

2023 - electronic data sharing

Timeline continued...

(frameworks for Phase 2)

- 2017: **Four** years after enactment, we are still in Phase 1, but the framework for Phase 2 begins. Manufacturers must affix a product identifier to each individual package and homogenous case.
- 2018: Beginning **five** years after enactment, repackagers must affix a product identifier to each individual package and homogenous case.
- 2019: Beginning **six** years after enactment, wholesale distributors must only **accept** products that contain the required product identifier; and verify product identifier before redistributing returned products
- 2020: Beginning **seven** years after enactment, dispensers must only **accept** products that contain the required product identifier.

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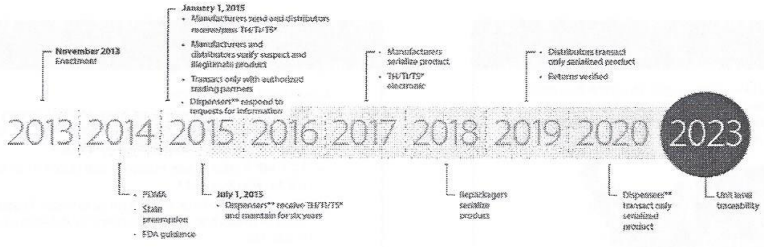
ASN - advanced shipping notice

November 2014 - FDA chas to issue standards for data transmission (guidance document) (wholesalers working w FDA) or November or may be delayed

Drug Supply Chain Security Act timeline

Prescription drug traceability



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goal - all state license 3PL & wholesalers renewal concurrently

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and **third-party logistics providers.**

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.

3PL & wholesale distributors only

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- The Act sets out seven broad categories of licensing standards for **wholesale distributors and for 3PLs.**
  - Storage and handling, maintenance of records, bond, background checks, physical inspections.
  - November 2015: FDA will issue regulations to further define those standards.
    - Regulations will be FINAL by November 2015 and EFFECTIVE November 2017.
      - This gives states two years (November 2015 to November 2017) to revise their wholesale distribution and licensing requirements to match FDA's.

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& manufacturers & dispensers

right now: only FL has separate 3PL licensing category

- States will continue to license wholesale distributors and 3PLs, but they will be required to do so utilizing the federal standards that FDA establishes.
- In the absence of a home state licensing program that satisfies the federal requirements, a federal licensing program will be established to license wholesale distributors and 3PLs. only resident license
- DSCSA does not discuss a state's licensing of manufacturers or repackagers (just says that they are not to be considered wholesale distributors).

~35 states license manuf (WI & OR if sell into state)

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CA - created 3PL licensing category

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements); preempts state laws and regulations regarding wholesale distributor and 3PL licensure in 2017.

November 27, 2013

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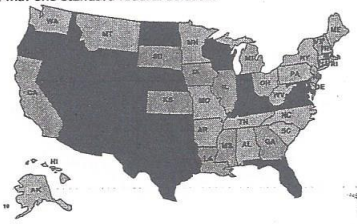
state-level preemption

Pedigree preemption: As of November 2013, eighteen states had state prescription drug pedigree requirements in effect. Immediately upon enactment, the DSCSA preempted all state pedigree laws and we were be left with one standard federal solution.



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- Licensing Preemption:
  - The Act also preempts state laws and regulations regarding wholesale distributor and 3PL licensure that are inconsistent with the standards established by the Act.
  - FDA will finalize these licensing standards in 2015 and they will be effective 2017.
  - States may continue to regulate wholesale distributors and 3PLs in areas that are not covered by the licensing standards in the Act.

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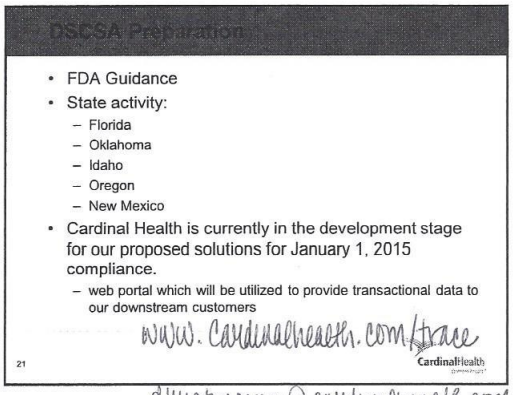
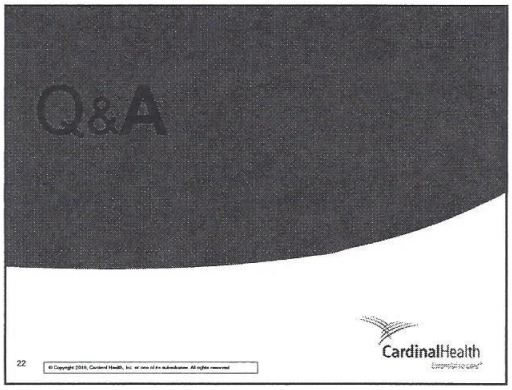
November 2015 - licensing standards issued

November 2017 - licensing standards effective to give states time to Δ license regulations



www.Cardinalhealth.com/trace

drugtracing@cardinalhealth.com



www.fda.gov / Drugs / DrugSafety / DrugIntegrityand SupplyChainSecurity / DrugSupplyChainSecurityAct / default.htm

Dispensers required to hold records x6 years
Can use 3rd party (eg wholesaler portals) to store data for you as long as have contract to do so

Licensing Buckets past Dispenser

Wholesaler etal

DSA
Separate licensure for wholesaler & 3PL seperate from manufacturer

* We need to determine if we will have to Δ statute to accomodate being able to license wholesalers & 3PL consistent w federal requirements.

Secondary wholesalers still an issue for at least 10 years

FDA website - Know Your Supplier