



**Arizona State Board of Pharmacy**  
1616 W. Adams, Suite 120  
Phoenix, AZ 85007  
Telephone (602) 771-2727 Fax (602) 771-2749

**THE ARIZONA STATE BOARD OF PHARMACY  
HELD A REGULAR MEETING AUGUST 27 AND 28, 2014  
MINUTES FOR REGULAR MEETING**

**AGENDA ITEM 1 – Call to Order – August 27, 2014**

President Foy convened the meeting at 9:00 A.M. and welcomed the audience to the meeting.

The following Board Members were present: President Jim Foy, William Francis, Darren Kennedy, Kyra Locnikar, Reuben Minkus, Nona Rosas, and Tom Van Hassel.

The following Board Members were not present: John Musil and Dennis McAllister. The following staff members were present: Compliance Officers Steve Haiber, Tom Petersen, Sandra Sutcliffe, Dennis Waggoner, and Karol Hess, Drug Inspectors Melanie Thayer, Executive Director Hal Wand, Deputy Director Cheryl Frush, and Assistant Attorney General Monty Lee.

**AGENDA ITEM 2– Declaration of Conflicts of Interest**

Due to having a “substantial interest” in the matter, Mr. Kennedy recused himself from participating under Arizona’s conflict of interest laws in the review, discussion, and proposed actions concerning Agenda Item 13, Schedule R, Complaint #4320, Complaint #4331, and Complaint #4333.

Due to having a “substantial interest” in the matter, Ms. Rosas recused himself from participating under Arizona’s conflict of interest laws in the review, discussion, and proposed actions concerning Agenda Item 14, PharMerica – Case 14-0011-PHR.

Due to having a “substantial interest” in the matter, Dr. Foy recused himself from participating under Arizona’s conflict of interest laws in the review, discussion, and proposed actions concerning Agenda Item 8, License Application for Natasha Castro.

Due to having a “substantial interest” in the matter, Dr. Foy recused himself from participating under Arizona’s conflict of interest laws in the review, discussion, and proposed actions concerning Agenda Item 12, Schedule Q, Conference #2 for Complaint #4318 and Conference #4 for Complaint #4321.

Due to having a “substantial interest” in the matter, Dr. Foy recused himself from participating under Arizona’s conflict of interest laws in the review, discussion, and proposed actions concerning Agenda Item 13, Schedule R, Complaint #4334 and Complaint #4335.

**ITEM 3– Approval of Minutes AGENDA**

Following a review of the minutes and an opportunity for questions and **on motion by Mr. Francis and seconded by Mr. Van Hassel**, the Board Members unanimously approved the minutes listed below:

1. June 25, 2014 – Regular Meeting
2. June 26, 2014 – Regular Meeting
3. July 31, 2014 – Telephonic Meeting

**AGENDA ITEM 4– Consent Agenda**

Items listed on the Consent Agenda were considered as a single action item by the Board Members. **On motion by Ms. Rosas and seconded by Ms. Locnikar**, the Board unanimously approved the following items listed on the Consent Agenda.

**4. (1) Resident Pharmacy Permits – Schedule A**

**RESIDENT PHARMACY PERMITS**

<b>Pharmacy</b>	<b>Location</b>	<b>Owner</b>
QoL Meds, LLC	1201 S. 1 <sup>st</sup> Ave., Phoenix, AZ 85003	Specialized Pharmaceuticals
Sun Life Family Health Center, Inc.	2080 W. Southern Ave., Apache Junction, AZ 85120	Sun Life Family Health Center, Inc.
Quail Run Behavioral Health	2545 West Quail Ave., Phoenix, AZ 85027	UHS Phoenix, LLC
University of Arizona Medication Management Center #2	550 E. Van Buren, Building 1, Rooms 1164 & 1167, Phoenix, AZ 85004	State of Arizona Board of Regents

**4. (2) Non-Resident Pharmacy Permits – Schedule B**

**NON-RESIDENT PHARMACY PERMITS (Out of State)**

<b>Pharmacy</b>	<b>Location</b>	<b>Owner</b>
Ability Pharmacy, Inc	558 Hemphill St. , Fort Worth, TX 76104	Ability Pharmacy, Inc
Renner Pharmacy	3005 E. Renner Rd., Ste. 120, Richardson, TX 75082	Renner Pharmacy, Inc.
One Stop Rx, LLC	10106 S. Sheridan Rd., Tulsa, OK 74133	One Stop Rx, LLC
Safe Pharmacy	2920 Motley Dr. #300., Mesquite. TX 75150	Kollam, Inc.

#### 4. (2) Non-Resident Pharmacy Permits – Schedule B - Continued

##### NON-RESIDENT PHARMACY PERMITS (Out of State)

Pharmacy	Location	Owner
SCA Pharmaceuticals, LLC	8821 Knoedl Ct., Little Rock, AR 72205	SCA Pharmaceuticals, LLC
Athena Pharmacy	2025 N. Mount Joliet Rd., Ste. 100, Mount Joliet, TN 37122	Paradigm Healthcare Solutions, LLC
Aureus Pharmacy	532 Broadhollow Rd., Ste. 137, Melville, NY 11747	Town Total Holdings, Inc.
Primrose Pharmacy, LLC	4733 W. Atlantic Ave., Suite C-5, Palm Beach, FL 33445	Althea Group, LLC
Trilogy Pharmacy	2603 Oak Lawn Ave., Dallas, TX 75219	Trilogy Pharmacy, Inc.
Quality Specialty Pharmacy	2233 W. Lomita Blvd., Lomita, CA 90717	Eugene Babenko and Vadim Pinhasov
Special Design Health Care	61 Doctors Park, Cape Girardeau, MO 63703	Aureus Health Services
Dobbs Ferry Pharmacy	18 Cedar St, Dobbs Ferry, NY 10522	Bruce Glickman
Premier Med Services, Inc.	11207 S. La Cienega Blvd. #102, Los Angeles, CA 90045	Premier Med Services, Inc.
Specialty Compounding Pharmacy	13322 Riverside Dr., Sherman Oaks, CA 91423	Afroz Javanfard
Partell Specialty Pharmacy	5835 S. Eastern Ave., Ste. 101, Las Vegas, NV 89119	One Way Drug, LLC
AgeVital, LLC	16 S. Boulevard of the Presidents, Sarasota, FL 34236	AgeVital, LLC
Medimix Specialty Pharmacy	6820 Southpoint Pkwy, Ste. 4, Jacksonville, FL 32216	The Medimix, LLC
Kabafusion, LLC	11818 Rosecrans Ave., #A, Norwalk, CA 90650 (O)	Kabafusion Holdings, LLC
Custom Care Pharmacy, LLC	7007 W. North Ave., Oak Park, IL 60302	Custom Care Pharmacy, LLC
Cascade Specialty Pharmacy	325 NE Hostmark St., Poulsbo, WA 98370	Brandon Knott
Polypill Compound Medications, LLC	4401 Sheridan St. #B, Hollywood, FL 33021	Polypill Compound Medications, LLC
American Homecare Federation, Inc.	31 Moody Rd., Enfield, CT 06083	Diplomat Pharmacy, Inc.
Memorial Compounding Pharmacy	2918 San Jacinto St., Houston, TX 77288	Minu Rx, Ltd.
Paramount Pharmacy	7200 S. 180 <sup>th</sup> St., Ste. 104, Tukwila, WA 98188	Paramount Pharmacy, LLC
Southeastern Medical Compounding, LLC	709 Mall Blvd., Rm 356B, Savannah, GA 31406	Southeastern Medical Compounding, LLC
Apria Pharmacy Network	780 Primos Ave., Ste. D, Folcroft, PA 19032	Apria Healthcare, LLC

(O) = Ownership Change

#### 4. (2) Non-Resident Pharmacy Permits – Schedule B - Continued

##### NON-RESIDENT PHARMACY PERMITS (Out of State)

Pharmacy	Location	Owner
Sentrix Pharmacy and Discount Inc.	6910 Stirling Rd., Hollywood, FL 33024	Sentrix Pharmacy and Discount Inc.
HM Compounding	2478 McDonald Ave., Brooklyn, NY 11223	HMX Services, Inc.
DFW Wellness Pharmacy	711 E. Lamar Blvd., Suite 101, Arlington, TX 76011	Green Oaks Pharma, Inc.
American Specialty Pharmacy	2436 S I-35E, Ste. 360, Denton, TX 76205	American Specialty Pharmacy, Inc.
American Star Pharmacy	6407 S. Cooper St. Ste. 113B, Arlington, TX 76001	AB Pharmacy, Inc.
Conception Pharmacy	1911 Church St., Suite 200, Nashville, TN 37203	Conception Pharmacy, LLC
Biocure, LLC	8700 Commerce Park Dr., Ste. 241, Houston, TX 77036	Biocure, LLC
Complete Care Pharmacy	101 E. Plummer, Chatham, IL 62629	Independence Holding Company, LLC
Complete Care Pharmacy	201 N. 5 <sup>th</sup> St., Springfield, IL 62701	Independence Holding Company, LLC
Xpress Compounding	1000 W. Weatherford St., Ste. 120, Fort Worth, TX 76107	Hall's IV and Institutional Pharmacy, Inc.
RXpress Pharmacy	1000 W. Weatherford St., #100,110, 200, Fort Worth, TX 76102	The Medicine Store Pharmacy, Inc.
Loyola Pharmacy	8400 Lincoln Blvd., Los Angeles, CA 90045	Nima Rodefshalom
Coast to Coast Compounding	780 Simms St. #103, Golden, CO 80401	Wendi Medved
Premier Pharmacy Services	410 Cloverleaf Dr., Baldwin Park, CA 91706	Stephen Samuel
Southern Compounding Pharmacy	3220 Highway 31 South, Decatur, AL 35603	Apothecary Sales, Inc
Gentry Health Services, Inc.	1090 Enterprise Dr., Medina, OH 44256	Gentry Health Services, Inc.
AnazoHealth	5710 Hoover Blvd., Tampa, FL 33634 (O)	Coast Quality Pharmacy, LLC
Midtown Pharmacy	2152 Airport Blvd., Mobile, AL 36606	Prescription Pros, Inc
Irvine Wellness Pharmacy	113 Waterworks Way, #160A, Irvine, CA 92618	Infinite Health Solutions
Inново Specialty Compounding Solutions	162 Summerhill Rd., Ste. D, East Brunswick, NJ 08816	Drug Stores II, LLC
AMI Rx	5296 Old Hwy 11, Ste. 4, Hattiesburg, MS 39402	Advantage Medical Infusion, LLC

(O) = Ownership Change

**.4. (2) Non-Resident Pharmacy Permits – Schedule B - Continued**

**NON-RESIDENT PHARMACY PERMITS (Out of State)**

<b>Pharmacy</b>	<b>Location</b>	<b>Owner</b>
Atlas Drug	8416 Kennedy Blvd., North Bergen, NJ 07675	Ton-Lor Corp.
Advanced Pharmacy	350-D Feaster Rd., Greenville, SC 29615	Advanced Pharmacy, LLC
Gatti Compounding Pharmacy	20 North 7 <sup>th</sup> St., Indiana, PA 15701	Your Compounding Pharmacy, LLC
Vitality Compounding Pharmacy	3501 Health Center Blvd. #1200, Bonita Springs, FL 34135	Estona Management, LLC
Raindrop Pharmacy	2705 N. Sepulveda Blvd., Manhattan Beach, CA 90266	Lisa Johnson
Ultimate Pharmacy	16438 Vanowen St., Unit 201, Van Nuys, CA 91406	Ultimate Pharmacy, Inc.
Webster's Community Pharmacy	2450 N. Lake Ave., Altadena, CA 91001	Michael Miller
Mack Bayou Pharmacy, LLC	82 Mack Bayou Loop, Santa Rosa Beach, FL 32459	Mack Bayou Pharmacy, LLC
National Animal Hospital	300 Ohukai Rd., Ste. C315, Kihei, HI 06753	Vet Meds n More, Inc.
Prescription Management Associates	8301 State Line Rd., Suite 104, Kansas City, MO 64114	Prescription Management Associates, LLC
SunQuest Pharmaceuticals Inc.	150 Eileen Way, Ste. 1, Syosset, NY 11791	SunQuest Pharmaceuticals Inc.
Tri-Coast Pharmacy, Inc.	14141 US Highway 1, Juno Beach, FL 33408	Tri-Coast Pharmacy, Inc.
Pharmazy	9990 Park Meadows Dr., Lone Tree, CO 80124	Zynex Medical, Inc.
Rancho Park Pharmacy	10587 (A) W. Pico Blvd., Los Angeles, CA 90064	Rancho Park Pharmacy
Akina Pharmacy	4080 Lafayette Center Dr, Ste. 270 , Chantilly, VA 20151	Bassem Girgis, Wadid Girgis, Tamer Girgis, Greg Chase

**4. (3) Resident Wholesaler Permits – Schedule C**

**NON-RESIDENT WHOLESALER PERMITS**

<b>Wholesaler</b>	<b>Location</b>	<b>Owner</b>
Caliber Anesthesia, LLC (Full Service-Mobile Anesthesia)	15210 N. Scottsdale Rd., Suite 210, Scottsdale, AZ 85254	Caliber Anesthesia, LLC
RecoverCare, LLC . (Non-Prescription)	1870 West Prince Rd., Ste.18 and 19, Tucson, AZ 85705 (O)	RecoverCare, LLC

**(O) = Ownership Change**

#### 4. (3) Resident Wholesaler Permits – Schedule C - Continued

##### NON-RESIDENT WHOLESALER PERMITS

Wholesaler	Location	Owner
RecoverCare, LLC . (Non-Prescription)	2750 S. 18 <sup>th</sup> Pl., Ste. 150, Phoenix, AZ 85034 (O)	RecoverCare, LLC
M.A.C Anesthesia Services, PLLC (Full Service – Mobile Anesthesia)	8600 E. Via Ventura, Ste. #3, Scottsdale, AZ 85268	M.A.C Anesthesia Services, PLLC
Arizona Pharmacy LLC. (Full Service)	13991 W. Grand Ave., Suite 100, Surprise, AZ 85374	Arizona Pharmacy LLC

(O) = Ownership Change

#### 4. (4) Non- Resident Wholesaler Permits – Schedule D

##### NON-RESIDENT WHOLESALER PERMITS

Wholesaler	Location	Owner
Breg, Inc. (Full Service)	2885 Loker, Ave. East, Carlsbad, CA 92010	Breg, Inc..
MCK Distribution (Full Service)	8721 Jensen Dr., Suite G, Houston, TX 77093	MCK Distribution
Vital Healthcare, LLC (Full Service)	11 East Lathrop Ave., Savannah, GA 31415	Vital Healthcare, LLC
OHL (Full Service)	5510 E. Holmes Rd., Memphis, TN 35118	Ozburn-Hessey Logistics, LLC
Covidien Sales, LLC (Full Service)	2824 Airwest Blvd., Plainfield, IN 46168	Covidien LP
Medico-Mart, Inc. (Full Service)	2323 Corporate Dr., Waukesha, WI 53189	Medico-Mart, Inc.
Lil Drug Store Products, Inc. (Non-Prescription)	1201 Continental Place NE, Cedar Rapids, IA 52406	Lil Drug Store Products, Inc.
BMTM Services, Inc. (Non-Prescription)	3 Label Lane, Swanton, VT 05488	BMTM Services, Inc.
Tolmar Pharmaceuticals, Inc. (Full Service)	701 Centre Ave., Fort Collins, CO 80526	Tolmar Pharmaceuticals, Inc.
Tolmar Pharmaceuticals, Inc. (Full Service)	1201 Cornerstone Dr., Windsor, CO 80550	Tolmar Pharmaceuticals, Inc.
BPI Labs, LLC (Full Service)	4400 Route 9 South, Freehold, NJ 07728	BPI Labs, LLC
Lifecell Corporation (Full Service)	220 Evans Way, Branchburg, NJ 08876	Lifecell Corporation
MWI Veterinary Supply Co. (Full Service)	15845 E. 32 <sup>nd</sup> Ave., Aurora, CO 80011	MWI Veterinary Supply Co.
Tri-Pharma, Inc. (Full-Service)	1290 Kennestone Circle, Bldg, A, Suite 112, Marietta, GA 30066	Tri-Pharma, Inc.

#### 4. (4) Non- Resident Wholesaler Permits – Schedule D - Continued

##### NON-RESIDENT WHOLESALER PERMITS

<b>Wholesaler</b>	<b>Location</b>	<b>Owner</b>
OHL (Non-Prescription)	4001 Adler Dr., Dallas, TX 75211	Ozburn-Hessey Logistics, LLC
Bound Tree Medical, LLC (Full Service)	3221 E. Arkansas Ln., Arlington, TX 76010	BEMS Holdings, LLC
Vital Healthcare, LLC (Full Service)	11 East Lathrop Ave., Savannah, GA 31415	Vital Healthcare, LLC
OHL (Full Service)	5510 E. Holmes Rd., Memphis, TN 35118	Ozburn-Hessey Logistics, LLC
Covidien Sales, LLC (Full Service)	2824 Airwest Blvd., Plainfield, IN 46168	Covidien LP
Medico-Mart, Inc. (Full Service)	2323 Corporate Dr., Waukesha, WI 53189	Medico-Mart, Inc.
Lil Drug Store Products, Inc. (Non-Prescription)	1201 Continental Place NE, Cedar Rapids, IA 52406	Lil Drug Store Products, Inc.
BMTM Services, Inc. (Non-Prescription)	3 Label Lane, Swanton, VT 05488	BMTM Services, Inc.
Tolmar Pharmaceuticals, Inc. (Full Service)	701 Centre Ave., Fort Collins, CO 80526	Tolmar Pharmaceuticals, Inc.
Tolmar Pharmaceuticals, Inc. (Full Service)	1201 Cornerstone Dr., Windsor, CO 80550	Tolmar Pharmaceuticals, Inc.
DV Medical Supply, Inc. (Full Service)	2000 W. 135 <sup>th</sup> St., Gardena, CA 90249	DV Medical Supply, Inc.
Astellas Pharma US, Inc. (Full Service)	4320 Executive Dr., Southaven, MS 38672	Astellas Pharma US, Inc.
OHL (Non-Prescription)	5300 Westport Parkway, Fort Worth, TX 76177	Ozburn-Hessey Logistics, LLC
Nova Biologics, Inc. (Full Service)	1714 Ord Way, Oceanside, CA 92056	Nova Biologics, Inc.
Precious Arrows, LLC (Full Service)	2800-136 Sumner Blvd., Raleigh, NC 27616	Precious Arrows, LLC

#### 4. (5) Non-Resident Manufacturer Permits – Schedule E

##### NON-RESIDENT MANUFACTURER PERMITS

<b>Manufacturer</b>	<b>Location</b>	<b>Owner</b>
Smith & Nephew, Inc.	3510 Winchester Rd., Memphis, TN 38118	Smith & Nephew, Inc.
bioCSL, Inc.	1020 First Ave., King of Prussia, PA 19406	CSL Behring, LLC
CSL Behring, LLC	1020 First Ave, King of Prussia, PA 19406	CSL Behring, LLC

#### 4. (5) Non-Resident Manufacturer Permits – Schedule E - Continued

##### NON-RESIDENT MANUFACTURER PERMITS

<b>Manufacturer</b>	<b>Location</b>	<b>Owner</b>
Retrophin, Inc.	777 Third Ave. 22 <sup>nd</sup> Floor, New York, NY 10017	Retrophin, Inc.
Trinity Sterile, Inc	201 Kiley Dr., Salisbury, MD 21801	Trinity Sterile, Inc
EKOS Corporation	11911 N. Creek Pkwy. South Bothell, WA 98011	EKOS Corporation
Ortho Technology, Inc	17401 Commerce Park Blvd., Tampa, FL 33647	Ortho Technology, Inc
Direct Rx LLC	1111 Alderman Dr., Suite 450, Alpharetta, GA 30005	Direct Rx LLC
Pharmakon Pharmaceuticals, Inc.	14450 Getz Rd. , Noblesville, IN 46060	Pharmakon Pharmaceuticals, Inc.

#### 4. (6) – New Pharmacists – Schedule F

The Board approved the 214 New Pharmacist Licenses listed on the attachments.

#### 4. (7)– New Interns – Schedule G

The Board approved the 186 New Intern Licenses listed on the attachments.

#### 4. (8) – New Pharmacy Technicians – Schedule H

The Board approved the 913 New Pharmacy Technicians listed on the attachments.

#### 4. (9) -Pharmacy Technician Trainee Requests for Approval to Reapply for Licensure – Schedule I

The Board approved the following individuals for one additional two year period.

Ishaq Abbas	Britany Anaya	Lacasma Arthur
Savana Ayala	Cynthia Barcena	Tanya Benavente
Tawny Bruening	Laura Calugan	Jasmine Cantu
Diana Castro	Charmaine Dalton	Rolanda Davis
Thomas Day	Sherenie Detros	Alicia Dill
Danielle Estrella	Joseph Faes	Erik Galletano
Arturina Garcia	Morgan Gill	Dominique Gonzalez
Ami Gutierrez-Jensen	Michael Hardy	Tina Harn
Melsena Harris	Manuel Herrera	Leah Inocian
Robin Jaquez	Shayan Jeddi-Golberenji	John Jennings
Sherla Jensen	Mary Jiminez	Ashley Johnson
Bonneth Knowlton	Nicole Lawrie	Victor Ledo
Sam Levatau	Celina Lopez	Daniel Lopez
Paula Lopez	Michael Luu	Marycela Martinez
Annalyse Mason	Hannah McCormick	Shabrie Mercy
Jalene Mossett	Simon Munguia	Melissa Murray
Angie Nunez	Desiree Ochoa	Claudia Ortega
Philip Paquet	Ivan Quezada	Juan Ramirez

**4. (9) -Pharmacy Technician Trainee Requests for Approval to Reapply for Licensure – Schedule I - Continued**

Anntoinette Rangel	Nellie Reddick	Bianca Rivas
Maria Rodriguez	Rick Rodriguez	Theda Rodriguez
Clara Rubio	Daniel Ruiz	Travis Runnels
Thomas Schultz Jr.	Stephanie Sebastian	Ana Sesmas
Nissi Simmons	Lorena Suleymanova	Vicky Suryadi
Karla Talavera Herrera	Christopher Tweten	Omar Valadez
Rosangela Valencia	Ebony Washington	Briana Weatherall
Ashley Weinhold	Christina Wharton	Darleen Whiteman
Donna Williams	Lorenza Zizzo	

**4. (10) – Consent Agreements – Schedule J**

The Board Members approved the following Consent Agreements:

1. Kelly Downing - 14-0013-PHR
2. Gregory Mowers - 14-0014-PHR

**4. (11) – Complaints with No Violations – Schedule K**

The Board unanimously agreed to dismiss the following complaints and take no further action on the complaints:

1. Complaint #4322
2. Complaint #4332
3. Complaint #4346

**AGENDA ITEM 5– Resident Pharmacy Permits – Schedule L**

**1. Rightway Pharmacy, LLC**

President Foy stated that a representative from Rightway Pharmacy was present to answer questions from Board Members.

**Kandarp Patel, Owner and Pharmacist in Charge**, was present to answer questions from Board Members.

President Foy opened the discussion by asking Mr. Patel to describe his business. Mr. Patel stated that he is the owner of the pharmacy. Mr. Patel stated that the pharmacy would be located in a medical building and would be a retail pharmacy.

Mr. Van Hassel asked Mr. Patel if he plans to do any compounding.

Mr. Patel stated that the pharmacy does have a compounding lab and he plans to do non-sterile compounding. Mr. Patel stated that he plans to complete a compounding course.

Mr. Van Hassel asked Mr. Patel if he plans to do any hazardous compounding.

Mr. Patel replied no. Mr. Patel stated that he would not be compounding any sterile products.

Ms. Rosas asked where the counseling area is located. Mr. Patel stated that the counseling area is located next to the cash register.

### **Arete Pharmacy**

President Foy stated that representatives from Arete Pharmacy were present to answer questions from Board Members.

**Dr. Brendan McCarthy NMD, Owner, Patrick Smith, Pharmacist in Charge, and Robert Buzan, Project Manager,** were present to answer questions from Board Members.

President Foy opened the discussion by stating that the Board had tabled their application at the last meeting so that the applicants could submit an updated floor plan.

President Foy asked the applicants to address the changes that they made in the pharmacy. Mr. Buzan stated that they have increased the size of the sterile room to 100 square feet and have closed off the non-sterile room with a pass thru window.

Mr. Van Hassel asked if the sterile room was a negative pressure room. Mr. Buzan stated that they could change the pressure in the room depending on what they were compounding. Mr. Buzan stated that it could be a positive or negative pressure room.

Mr. Van Hassel stated that the air flow cannot go both ways and it cannot be changed to go back and forth from positive to negative airflow.

Mr. Buzan stated that the room would be used for hazardous compounding.

Dr. McCarthy stated that they plan to compound nutritional IV's down the road.

Mr. Wand asked if the room was 100 square feet. Dr. McCarthy replied yes.

Mr. Van Hassel asked if this would be a full service pharmacy. Dr. McCarthy stated that they would be mainly a compounding pharmacy. Dr. McCarthy stated that they would primarily make compounds for physicians.

Mr. Van Hassel reminded the applicants that they can only prepare a limited quantity for office use.

Ms. Locnikar asked the respondents to describe their business model. Dr. McCarthy stated that they would be a compounding pharmacy for east valley residents.

Ms. Locnikar asked if they would be compounding prescriptions for patients. Dr. McCarthy replied yes.

## Arizona General Hospital

President Foy stated that representatives from Arizona General Hospital were present to answer questions from Board Members.

**Kevin Meek, Chief of Nursing Services, and Bill Ng, Pharmacist in Charge,** were present to answer questions from Board Members.

President Foy asked the applicants to describe their business model for the Board Members.

Mr. Meek stated that Arizona General Hospital would be a new hospital operated by Adeptus Health. Mr. Meek stated that the hospital would be a full service acute care hospital. Mr. Meek stated that the hospital would have 16 inpatient rooms, two operating rooms, and an emergency room. Mr. Meek stated that why would also have a laboratory and radiology suite. Mr. Meek indicated that the pharmacy would have a USP 797 compliant room.

Mr. Van Hassel asked about the staffing of the pharmacy. Mr. Meek stated that the pharmacy would be opened from 6 am to 10 pm during the week and 8 am to 8 pm on the weekends. Mr. Meek stated that after hours services would be provided by Cardinal Health. Mr. Meek stated that they would be hiring an additional pharmacist to help the pharmacist in charge. Mr. Meek stated that they would also be hiring pharmacy technicians. Mr. Meek stated that an Omnicell would be placed on the floors to obtain after hours medications.

Ms. Rosas asked who would be doing the compounding after hours. Mr. Meek stated that if a compound is needed after hours the pharmacist would be contacted to come in and prepare the medication.

**Med-Pharm LLC – Requested to table their application until the October meeting**

### RESIDENT PHARMACY PERMITS

**On motion by Mr. Van Hassel and seconded by Ms. Rosas,** the Board unanimously approved the resident pharmacy applications listed below pending final inspection.

### RESIDENT PHARMACY PERMITS – Schedule L

Pharmacy	Location	Owner
Rightway Pharmacy LLC	10503 W. Thunderbird Blvd. 101B, Sun City, AZ 85351	Rightway Pharmacy LLC
Arete' Pharmacy	4657 S. Lakeshore Dr., Suite 2, Tempe, AZ 85282	Ryne Reed, Wendi Reed, Dr. Brendan McCarthy
Arizona General Hospital	AGH Laveen. Inc.	

**AGENDA ITEM 6– Non- Resident Pharmacy Permits – Schedule M**

**NON-RESIDENT PHARMACY PERMITS**

**On motion by Mr. Van Hassel and seconded by Mr. Kennedy**, the Board unanimously agreed to approve the following Non- Resident Pharmacy Permit.

**NON-RESIDENT PHARMACY PERMIT**

<b>Pharmacy</b>	<b>Location</b>	<b>Owner</b>
Express Scripts	2040 Route 130 North, Burlington, NJ 08016	Express Scripts Pharmacy, Inc.

**AGENDA ITEM 7 - Special Requests- Schedule N**

**#1 Abdulmid Althaghfi**

**Abdulmid Althaghfi** appeared on his own behalf to request to take the MPJE exam for the fourth time.

President Foy opened the discussion by asking Mr. Althaghfi why he was appearing in front of the Board.

Mr. Althaghfi stated that he is requesting that the Board allow him to take the MPJE exam for the fourth time.

Dr. Foy asked Mr. Althaghfi about his scores and how he has studied for the exams. Mr. Althaghfi stated that he has updated materials that he is now studying. Mr. Althaghfi stated that he had not previously taken any law review courses and just studied the materials. Mr. Althaghfi stated that he is now taking a law review course with a university professor and has updated study materials.

Mr. Van Hassel asked Mr. Althaghfi if there was any part of the law exam that was difficult for him. Mr. Althaghfi stated that he has difficulty reading scenarios and his professor is reviewing different scenarios with him. Mr. Althaghfi stated that he is doing an internship at the University of Arizona outpatient pharmacy and he is able to review the law in this setting.

eed to allow Mr. Althaghfi to take the MPJE exam for a fourth time.

**#2 Fahad Alnoah**

**Fahad Alnoah** appeared on his own behalf to request that the probation imposed on his Pharmacist license per Board Order 12-0025-PHR be terminated.

President Foy opened the discussion by asking Mr. Alnoah why he was appearing in front of the Board.

Mr. Alnoah stated that he is requesting that the Board terminate his probation.

Dr. Foy noted that Mr. Alnoah is asking for his probation to be terminated early. Dr. Foy noted that his Consent Agreement was signed in September.

Mr. Minkus asked Mr. Alnoah why he is requesting that his probation be terminated early. Mr. Alnoah stated that his probation is scheduled for removal in September and the next meeting is in October. Mr. Alnoah stated that he cannot be a pharmacist in charge until his probation is removed and he has the opportunity to become a pharmacist in charge.

Dr. Foy asked Mr. Alnoah what he has learned from this probation. Mr. Alnoah stated that he has learned that you must follow the rules. Mr. Alnoah stated that he must be responsible and not bend the rules.

Ms. Locnikar stated that she is concerned about individuals asking for their probation to be removed early.

Mr. Lee stated that the Board could make a motion to remove the probation on a specific date or have the respondent appear at the next meeting.

**On motion by Ms. Locnikar and seconded by Mr. Kennedy**, the Board unanimously agreed to terminate the probation of Mr. Alnoah's pharmacist license per Board Order 12-0025-PHR effective September 22, 2014.

### **#3 Andrea Stump**

**Andrea Stump** appeared on her own behalf to request that the probation imposed on her Pharmacist license per Board Order 12-0006-PHR be terminated.

President Foy opened the discussion by asking Ms. Stump why she was appearing in front of the Board.

Ms. Stump stated that she is requesting that the Board terminate her probation. Ms. Stump stated that she made a mistake and you can either choose to learn from your mistake or you can keep going in the direction that you are going. Ms. Stump stated that she chose to learn from her mistake.

Dr. Foy asked Ms. Stump if she is employed. Ms. Stump stated that she is employed at a mail order facility and is surrounded by accountability.

Mr. Minkus stated that her request to remove probation is also a month early. Ms. Stump stated that she can wait or come back to the next meeting.

**On motion by Mr. Francis and seconded by Ms. Rosas**, the Board unanimously agreed to terminate the probation of Ms. Stump's pharmacist license per Board Order 12-0006-PHR effective September 28, 2014.

Ms. Locnikar asked that the request to terminate probation early be placed on a future agenda for discussion.

## **AGENDA ITEM 8– License Applications Requiring Board Review – Schedule O**

### **#1 Natasha Castro**

**Dr. Foy was recused due to a conflict of interest.**

**Natasha Castro** appeared on her own behalf to request to proceed with Pharmacy Technician Trainee licensure.

Mr. Van Hassel opened the discussion by stating that Ms. Castro appeared at the last meeting and the Board tabled her application until she could provide letters of reference from her employer (CVS) indicating that there are no employment issues. Mr. Van Hassel stated that Ms. Castro has provided the requested letters.

Mr. Van Hassel asked Ms. Castro if she needed the license to complete her education. Ms. Castro stated that obtaining the license will enable her to complete her pharmacy technician program at Tucson College.

Mr. Van Hassel asked Ms. Castro about her job at CVS. Ms. Castro replied that she works as a clerk at CVS. Ms. Castro stated that she has made mistakes in the past. Ms. Castro stated that she plans to be a smart and careful person in her new career as a pharmacy technician.

**On motion by Mr. Francis and seconded by Mr. Kennedy,** the Board approved Ms. Castro's pharmacy technician trainee license application.

### **#2 Marc Gasca**

**Marc Gasca** appeared on his own behalf to request to proceed with reciprocity.

President Foy opened the discussion by asking Mr. Gasca why he was appearing in front of the Board.

Mr. Gasca stated that he would like permission to sit for the MPJE exam. Mr. Gasca stated that he was cited last July by the California Board for a calculation error. Mr. Gasca stated that the error involved the conversion of elemental zinc to the salt form.

Mr. Kennedy asked Mr. Gasca what he has done to prevent this error from occurring again. Mr. Gasca stated that he has references for salt conversions and the calculations are now approved by multiple pharmacists.

Mr. Van Hassel asked Mr. Gasca why he wants an Arizona license. Mr. Gasca stated that he started the process prior to Arizona eliminating the requirement for an Arizona licensed

pharmacist for a non-resident pharmacy permit and he is trying to complete the process he started.

**On motion by Mr. Kennedy and seconded by Mr. Van Hassel,** the Board unanimously agreed to approve Mr. Gasca's pharmacist license application.

### **#3 Mark Neufeld**

**Mark Neufeld** appeared telephonically on his own behalf to request to proceed with reciprocity.

President Foy opened the discussion by asking Mr. Neufeld why he was appearing in front of the Board.

Mr. Neufeld stated that he would like to proceed with reciprocity.

Dr. Foy asked if he was disciplined by the Nevada Board. Mr. Neufeld stated that he received a letter of reprimand from the Nevada Board. Mr. Neufeld stated that he was involved in the mis-filling of a prescription as an Intern.

Dr. Foy asked Mr. Neufeld why he did not attend the Board hearing. Mr. Neufeld stated that he received a letter from the Board demanding that he appear at the Board Meeting in Reno. Mr. Neufeld stated that at the time he was in pharmacy school in Las Vegas. Mr. Neufeld stated that due to monetary issues and the fact that he would miss school he called the Board Office and asked if he could appear by tele-conference or attend the Board Meeting in Las Vegas. Mr. Neufeld stated that the person he talked to failed to document the fact that he called.

Dr. Foy asked Mr. Neufeld about the letter of reprimand. Mr. Neufeld stated that he accepted the fine and letter of reprimand. Mr. Neufeld stated that he told them that he had called the Board but did not pursue the issue. Mr. Neufeld stated that he regrets his decision in not asking for a continuance.

Dr. Foy asked Mr. Neufeld about the prescription error. Mr. Neufeld stated that he did not make the error but was held accountable because he was involved in the filling of the prescription. Mr. Neufeld stated that he had accepted the prescription from the patient and typed the prescription into the computer. Mr. Neufeld stated that the prescription was typed correctly.

**On motion by Mr. Van Hassel and seconded by Mr. Francis** the Board unanimously agreed to approve Mr. Neufeld's pharmacist license application.

### **AGENDA ITEM 9– Ascribe Pharmacy Deviation Request- {R4-23-701.04 (B) (3)}**

President Foy stated that individuals from Ascribe are present to answer questions from Board Members concerning their deviation request.

The following individuals were present from Ascribe: Ray Brinkley, Dr. Reif Gillum, Judy Scrillo, and Steve Kaufer. Roger Morris, Legal Counsel for Ascribe, was also present.

President Foy asked the individuals to address their deviation request. Mr. Morris stated that Ascribe is asking for a deviation for R4-23-701.04 (B) (3) to allow CII medications in an automated dispensing system in a Long Term Care Facility. Mr. Morris stated that Ascribe has 7 facilities using an automated dispensing system. Mr. Morris stated that other states allow CII medications to be placed in automated dispensing machines and the company has had no issues in other states. Mr. Morris stated that they are asking to add CII medications to the automated dispensing machines. Mr. Morris stated that the machines are located in a locked area and there is a camera visualizing the person taking the medication from the machine. Mr. Morris stated that an e-mail is sent to the pharmacy when the medication is removed.

Mr. Wand asked if a blanket waiver could be given since there would be other companies asking for the same consideration. Mr. Lee stated that the Board can grant deviations for experimentation. Mr. Lee stated that the regulations do not specify that a deviation is for an individual. Mr. Lee stated that the Board could grant a general deviation provided that the machines were checked to see if they met the deviation.

Mr. Wand stated that he could develop a blanket waiver that the Board could approve at the next meeting. The waiver would need to include how the waiver is applied, the designee, and the standards that must be met for the waiver.

**On motion by Mr. Van Hassel and seconded by Mr. Kennedy,** the Board unanimously agreed to grant the deviation request by Ascribe to allow them to place CII medications in an automated dispensing system in a Long Term Care Facility. {(R4-23-701.04 (B) (3))}

#### **AGENDA ITEM 10– Rule Change R4-23-701.04 (B) (3)**

President Foy asked Mr. Wand to address this issue. Mr. Wand stated that the Board office has had requests to allow CII medications in automated dispensing machines in Long Term Care Facilities. Mr. Wand stated that the requests are prompted by the change of Hydrocodone medications to CII status.

Mr. Kennedy asked about the background. Mr. Wand stated that the rule was originally written not allowing CII medications in the machine. Mr. Wand stated that other states allow the medications in the machines without any issues.

Mr. Van Hassel noted that due to technology changes he is in favor of allowing CII medications to be placed in automated dispensing machines in Long Term Care Facilities.

**On motion by Mr. Van Hassel and seconded by Mr. Kennedy,** the Board unanimously authorized the staff to begin the rulemaking process to allow CII medications in automated dispensing machines in Long Term Care Facilities.

## **AGENDA ITEM 11– Reports**

### **Executive Director**

#### **Budget Issues**

Mr. Wand stated that he is currently preparing the budget for review.

#### **Personnel Issues**

Mr. Wand stated that he is requesting a full-time rules writer in the new budget. Mr. Wand stated that he would need to have the position approved.

#### **Statutory Changes**

Mr. Wand reviewed the proposed statutory changes that Ms. Sutcliffe has written. Mr. Wand stated that the Board would need to have a sponsor for a bill for the proposed changes.

### **Deputy Director Report**

Ms. Frush reviewed the Compliance Officers Activity Report and the Drug Inspector Report with the Board Members.

During the months of June and July, the Compliance Staff issued letters for the following violations:

#### **Pharmacy Violations**

1. Outdated medications – 2
2. Water not working properly – 1
3. Pharmacy technician trainee compounding – 1
4. Unlicensed pharmacy technician working in a pharmacy – 1

#### **Controlled Substance Violations**

1. Controlled Substance Overage -6
2. Controlled Substance Shortage -7
3. Failed to separate controlled substance invoices - 1

#### **Documentation Violations**

1. Expired Immunization certificates - 1
2. Failure to document counseling – 1
3. Failure to document compounding process and equipment used – 1
4. Failure to document the verifying pharmacist on a compound – 1
5. Failure to sign the daily signature log – 1
6. Failure to document the cleaning of a mechanical counting device – 1
7. Failure to document the validation of a mechanical counting device – 1

#### **The following areas were noted on the inspection reports for improvement:**

1. Maintaining of compounding records

**Areas outside the inspection reports that may be of interest:**

1. Address and employment changes should be reported to the Board within ten days.
2. Fingerprinting required for all new licensees.
3. Tramadol is now controlled.
4. Hydrocodone products that are now Schedule III will become Schedule II on October 6, 2014.

**PAPA Report – Schedule P**

Lisa Yates was present to represent the PAPA program. Ms. Yates stated that there are a total of forty-one (41) participants in the PAPA program. Ms. Yates stated that two participants have completed the program, one participant has voluntarily quit the program due to him retiring and moving to another state, and one new participant has come into the program. Ms. Yates indicated that there are two pending participants.

Ms. Yates indicated that there was one concern. Ms. Yates stated that since the initial issues the individual has now missed another screen and did not go the weekly meeting.

Mr. Van Hassel asked if the individual was working. Ms. Yates replied yes.

**On motion by Mr. Van Hassel and seconded by Dr. Foy**, the Board Members decided to hold a telephonic meeting to consider a summary suspension for the one concern and address the the issues with the individual that left the program.

**AGENDA ITEM 12 – Conferences – Schedule Q**

**Conference 1– Complaint #4317**

The following individuals were present to discuss the complaint:

1. Remon N. Abd-El Malak – Pharmacist – Respondent
2. Heraldo Ruiz – Pharmacy Technician – Respondent
3. Ginny Thompson – Pharmacist in Charge - Witness
2. Kelly Stokes – Pharmacy Supervisor – Witness

President Foy asked Mr. Haiber to give a brief overview of the complaint.

Mr. Haiber stated that the complainant stated that her husband was not counseled on his new prescription for an antibiotic. The complainant stated that a pharmacy technician asked them if they had any questions about the medication. The complainant stated that she asked the technician what the doctor had ordered. The pharmacy technician replied that the doctor had ordered an antibiotic. The complainant stated that they were not acknowledged by the pharmacist. The complainant stated that this is the third prescription that she had picked up at this store without being counseled. The pharmacy technician stated that he did ask the patient if he had any questions for the pharmacist and the patient replied no. The pharmacist stated that he would have gladly counseled the patient if he would have responded differently to the pharmacy technician. Documentation of the counseling was recorded and reflects the patient's refusal.

Dr. Foy asked Mr. Abd-El Malak if it is the normal practice at the pharmacy to not counsel patients receiving new prescriptions since the complainant stated that this is the third new prescription she has picked up and counseling was not provided.

Mr. Abd-El Malak stated that it is not the normal practice. Mr. Abd-El Malak stated that if the prescription is a new prescription the pharmacy technician would bring the prescription to the counseling window and he would counsel the patient.

Dr. Foy asked what happened that day because counseling did not occur. Mr. Abd-El Malak stated that he was on the phone and was not involved in the supervision of the technician.

Dr. Foy asked Mr. Abd-El Malak if he is concerned about the patient not being counseled and the documentation of the refusal of counseling. Mr. Abd-El Malak stated that his normal practice is to acknowledge the refusal of counseling.

Dr. Foy asked Mr. Ruiz to address the complaint.

Mr. Ruiz stated that he usually does not spend much time at the cash register. Mr. Ruiz stated that the patient asked for his prescription and he grabbed the patient's bag. Mr. Ruiz stated that the patient's wife came to the counter and asked what medication was prescribed. Mr. Ruiz stated that he told her the name of the medication and that it was an antibiotic. Mr. Ruiz stated that he did ask the patient if he had any questions for the pharmacist. Mr. Ruiz stated that it was not his intention to avoid counseling. Mr. Ruiz stated that when he worked at the cash register he would ask the patient if they had any questions for the pharmacist.

Dr. Foy asked Mr. Ruiz why the patient did not get to speak to the pharmacist. Mr. Ruiz stated that he got lost in the transaction because he does not usually run the cash register and the fact that the prescription was a new prescription. Mr. Ruiz stated that he did not send the prescription to the counseling window for the pharmacist to speak with the patient.

Dr. Foy told Mr. Ruiz that the issue is that he asked the patient if they had any questions for the pharmacist. Mr. Ruiz stated that prior to this incident he would always ask the patients if they had any questions for the pharmacist when he was at the register. Mr. Ruiz stated that he now longer asks the patients if they have any questions for the pharmacist.

Ms. Rosas asked Mr. Ruiz how he knows if the prescription is a new prescription or a refill. Mr. Ruiz stated that the paperwork indicates if the prescription is a new prescription or a refill. Mr. Ruiz stated that he scanned the scan tag for the price and did not realize the prescription was a new prescription.

Dr. Foy asked Mr. Abd-El Malak about his signing the log for the refusal of counseling when he did not know that the patient refused counseling. Mr. Abd-El Malak stated that he would document counseling after the fact. Mr. Abd-El Malak stated that he would wait till the end of the day and document counseling. Mr. Abd-El Malak stated that he has now changed his practice and documents the acceptance or refusal of counseling when he performs counseling.

Mr. Van Hassel asked Mr. Haiber what is the practice at this store concerning counseling. Mr. Haiber stated that he did not observe any non-compliance with counseling practices at the pharmacy while he was conducting the complaint investigation. Mr. Haiber noted that he did observe different staff members and not the ones involved in the complaint.

Mr. Abd-El Malak stated that he documents the acceptance or refusal into the computer at the time he counsels the patient.

Dr. Foy asked what follow up was conducted with the staff concerning counseling. Ms. Thompson stated that she held a meeting with her associates. Ms. Thompson stated that they have removed pharmacy bags from the register so that the prescriptions cannot be bagged at the Register. Ms. Thompson stated that the staff has reviewed the computer based learning on counseling and have completed continuing education units on counseling.

**On motion by Mr. Van Hassel and seconded by Ms. Rosas**, the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

### **Conference 2– Complaint #4318**

**Dr. Foy was recused due to a conflict of interest.**

The following individuals were present to discuss the complaint:

1. Cheryl Nakamura – Pharmacist – Respondent
2. Amanda Navarrette – Pharmacy Technician - Respondent
3. Bruce Beckwith – Pharmacy Supervisor – Witness
4. Roger Morris – Legal Counsel for the Respondents and CVS

Chairperson Van Hassel opened the discussion by asking Mr. Petersen to give a brief overview of the complaint.

Mr. Petersen stated that the complainant's prescription for Fluconazole 100mg with directions to take 2 tablets the first day then take 1 tablet daily for 9 days was incorrectly filled with flecainide 100mg tablets on 3/25/2013. The prescription was picked up by the complainant's daughter. The daughter stated that the pharmacist asked her if her mother had any heart issues. The daughter stated that she not aware of any heart issues. The pharmacist asked the daughter why her mother was taking the medication. The daughter stated that she told the pharmacist that her mother was taking the medication for bacteria in her stomach and her cough. The daughter stated that the pharmacist appeared confused but completed counseling her. The pharmacist in charge stated that the records indicate that she performed counseling. The pharmacist in charge stated that the daughter stated that she was counseled by a male but there were no male pharmacists or interns on duty that day. The complainant stated that she experienced heart fluttering and confusion after taking the medication. The error was discovered when the patient returned to her doctor because of the side effects. The prescription was correctly filled on 4/8/2014. The prescription was incorrectly entered by the pharmacy technician and the pharmacist did not catch the error during verification. The pharmacist indicated that the

prescription was written badly and should have been verified with the doctor. The pharmacist also did not catch the error at counseling.

Mr. Van Hassel asked Ms. Navarrette to address the error and how she enters prescriptions into the computer system. Ms. Navarrette stated that she enters the first three letters of the drug name and the strength. Ms. Navarrette stated that the prescription was written poorly and she entered FLE100 and selected fleccaanide.

Ms. Nakamura stated that when she verifies the prescription she looks at the hard copy and matches the label to the hard copy. Ms. Nakamura stated that she also misread the prescription. Ms. Nakamura stated that the directions were typed correctly but the drug was wrong.

Mr. Van Hassel asked Ms. Nakamura if she thought the directions were appropriate for this medication. Ms. Nakamura stated that she does not remember counseling the patient and there were no male pharmacists or interns on duty that day. Ms. Nakamura stated that when a family member picks up a prescription she tells the family member to call the pharmacy if they have any questions.

Mr. Van Hassel asked Ms. Nakamura if the patient's daughter told her that her mother did not have heart issues why did she not ask more questions. Ms. Nakamura stated that she does not recall the interaction with the daughter but if the daughter would have said that her mother did not have heart issues she would have held onto the prescription and called the doctor.

Mr. Morris stated that counseling records indicate that Ms. Nakamura performed counseling but she does not recall the incident. Mr. Morris stated that the clerk that day was also a female.

Mr. Kennedy asked Ms. Nakamura when she documents counseling. Ms. Nakamura stated that she used to remove the sticker and document counseling later. Ms. Nakamura stated that during rush hours she would document the counseling on the receipt and log the counseling during the day when she had time. Ms. Nakamura stated that she now documents counseling while she is counseling the patient.

Mr. Kennedy asked if the prescription is typed from the scanned copy or the hard copy. Mr. Kennedy noted that the security feature on the prescription would make the prescription difficult to read. Ms. Nakamura stated that if the scanned prescription is difficult to read the hard copy is pulled and the doctor is called.

Mr. Morris noted that the scanned image does not show the security features (illegal). Mr. Morris stated that the security features show when the prescription was copied for the investigation.

Mr. Van Hassel noted that a gastroenterologist usually does not write for heart medications. Ms. Nakamura stated that she did not even notice the doctor's specialty.

Ms. Nakamura stated that she met with her staff and reviewed the input of prescriptions. Ms. Nakamura stated that during counseling they would be asking open-ended questions. Ms.

Nakamura stated that prior to entering the prescription if a technician cannot read the prescription they were instructed to ask the pharmacist to read the prescription for them.

**On motion by Mr. Kennedy and seconded by Mr. Francis,** the Board unanimously agreed to issue a non-disciplinary letter to the pharmacy technician requesting that she complete 3 hours of CE on the prevention of medication errors or patient safety.

**On motion by Mr. Kennedy and seconded by Mr. Francis,** the Board unanimously agreed to issue a non-disciplinary letter to the pharmacist requesting that she complete 6 hours of CE on the prevention of medication errors or patient safety.

### **Conference 3 – Complaint #4319**

The pharmacist requested a postponement until the October meeting.

### **Conference 4 – Complaint #4321**

**Dr. Foy was recused due to a conflict of interest.**

The following individuals were present to discuss the complaint:

1. Sharon Woodward – Pharmacist – Respondent
2. Natalie Gillis – Pharmacist - Respondent
3. Charles Curtis – Pharmacy Supervisor – Witness
4. Roger Morris – Legal Counsel for the Respondents and CVS

Chairperson Van Hassel opened the discussion by asking Mr. Haiber to give a brief overview of the complaint.

Mr. Haiber stated that the complainant stated that her son's refill prescription was filled with Lexiva instead of his prescribed Lialda. The complainant's son consumed the medication for 5 days and experienced some stomach pains. The pharmacist labeled the manufacturer's bottle and bypassed the scan.

Mr. Van Hassel asked the respondents to address the complaint. Ms. Woodward stated that she was the overnight pharmacist that printed the label and labeled the bottle. Ms. Woodward could not explain why the accuracy scan was bypassed. Ms. Woodward stated that her usual practice is to scan the receipt and the stock bottle. Ms. Woodward stated that if the barcode does not scan it would state "Bypass accuracy scan". Ms. Woodward stated that if she bypassed the accuracy scan it was by mistake. Ms. Woodward stated that she labeled the bottle and left the medication to be finished the next day.

Mr. Van Hassel stated that the paperwork shows that the accuracy scan was not completed and not that the label did not scan correctly.

Mr. Van Hassel asked Ms. Woodward if she attached the label to the bottle that night. Ms.

Woodward replied yes.

Ms. Gillis stated that she performed the DUR check and verification of the product the next morning. Ms. Gillis stated that did not realize that the wrong manufacturer's bottle was labeled. Ms. Gillis stated that the bottles of the two products are similar in size.

Mr. Van Hassel asked Ms. Gillis if she scanned the bottle when it was pulled from the shelf. Ms. Gillis stated that the filling pharmacist would have scanned the bottle for accuracy. Ms. Gillis stated that she scanned the label on the bottle to bring up the verification information. Ms. Gillis stated that she did not open the sealed manufacturer's bottle to identify the contents.

Mr. Van Hassel asked Mr. Curtis if there is a report that could be printed to show what bottles were scanned and which bottles were not scanned.

Mr. Curtis stated that there are issues with the documentation of the scanning and the coding will be changed in November. Mr. Curtis stated at this time prescriptions that are filled by automation show that accuracy scan has been bypassed. Mr. Curtis stated that the new coding would document the scanning in a different fashion.

Mr. Kennedy asked Ms. Gillis if she receives notification that the scan was bypassed when she verifies the prescription. Ms. Gillis stated that a red bar would appear on the screen if the accuracy scan was bypassed and the pharmacist would override the alert.

Mr. Kennedy asked about the medications being stored close together in the pharmacy. Ms. Woodward stated that the products have been separated in the pharmacy.

Mr. Morris stated that the pharmacists have changed their verification procedures.

Ms. Woodward stated that during the filling process she fills one prescription at a time in a quarantine area. Ms. Woodward stated that she was filling too many prescriptions at one time.

Ms. Gillis stated that when she verifies a prescription she verifies the product against the stock bottle. If the medication is in the manufacturer's original bottle, then she double checks the NDC number. Ms. Gillis stated if the medication is not in a stock bottle she will look at the product when it shows an accuracy bypass scan occurred. Ms. Gillis stated that these two products have been separated in the pharmacy.

**On motion by Mr. Francis and seconded by Mr. Kennedy,** the Board unanimously agreed to issue a non-disciplinary letter to both pharmacists requesting that they complete 6 hours of CE on the prevention of medication errors or patient safety.

### **Conference 5 – Complaint #4326**

The following individual was present to discuss the complaint:

1. Anthony Sammartino – Pharmacist in Charge – Respondent

President Foy opened the discussion by asking Ms. Sutcliffe to address the complaint. Ms. Sutcliffe stated that there were five complaint issues.

Ms. Sutcliffe stated that the first issue was that a patient received Abelcet 300mg instead of Ambisone 320mg. The complainant also indicated that the pharmacy drew the wrong labs on the patient and froze the Abelcet to save and reuse the medication. Ms. Sutcliffe stated that the wrong drug was dispensed and the compounding records were not complete.

Ms. Sutcliffe stated that the second issue was that a patient received the wrong dose of Cubicin. The complainant alleged that the pharmacist in an attempt to save money would water down the product and would freeze the product. Ms. Sutcliffe stated that the pharmacist explained his compounding techniques and no violations were found. Ms. Sutcliffe stated that the pharmacist provided information on freezing Cubicin.

Ms. Sutcliffe stated that the third issue was that IVIG was dispensed for 2 patients after the prescriptions had expired. The prescription for the one patient was filled once past the allowed number of refills. The prescription for the second patient was written to dispense a 3 month supply to be infused every 2 weeks for 3 months. The patient did not take the IVIG on a regular every 2 week schedule. The pharmacy dispensed the medication for a total of a 3 month supply. Ms. Sutcliffe noted that one order was signed by an agent and not the prescriber.

Ms. Sutcliffe stated that the fourth issue was that the complainant indicated that the pharmacist made the mixing technician send 3 patient's Vancomycin mixed in 120ml of sterile water. Ms. Sutcliffe stated that the pharmacist in charge stated that NS liter bags were on back-order and sterile water was discussed as an alternative. The pharmacist in charge stated that they did not use the sterile water and had used a combination of NS liter bags and 100 ml bags to make the Vancomycin that day. The pharmacist stated that the use of the 100 ml bags was not properly documented on the compound sheet.

Ms. Sutcliffe stated that the complainant indicated that the "plans of care" for two patients show 2 different signatures and the pharmacist admitted to her and other employees that he forges a doctor's signature when the doctor will not sign orders or "plans of care". Ms. Sutcliffe stated that the pharmacist in charge stated that the pharmacy "plans of care" do not require a physician's signature because they are pharmacy records used by pharmacy staff to monitor the progress of a patient's condition.

Dr. Foy asked Mr. Sammartino to address the complaint and provide details related to the various allegations.

Mr. Sammartino stated that the technician that filed the complaint no longer works at the pharmacy and her friend that also worked at the pharmacy no longer works at the pharmacy also. Mr. Sammartino stated that he hired the one technician to help in the compounding area but the technician decided that she wanted to work in the intake area instead of being a technician. Mr. Sammartino stated that the technician was transferred to the intake area where she received referrals and coordinated the intake process.

Mr. Sammartino stated that he hired the second technician who was a friend of the first technician. Mr. Sammartino stated that the technician had some compounding experience and inventory management. Mr. Sammartino stated that he worked with the technician at the VA. Mr. Sammartino stated that he spent 6 to 7 hours a day training the technician. Mr. Sammartino stated that the technician did not always agree with his methods and he told her that if she could demonstrate a better method with sound evidence he was willing to look at another method.

Dr. Foy asked about the watered down product. Mr. Sammartino stated that the patient did not receive a watered down product. Mr. Sammartino explained how he made the product and how it was dispensed in a 20ml syringe.

Ms. Rosas asked about freezing the product. Mr. Sammartino stated that often he would reconstitute extra and froze the product. Mr. Sammartino stated that it was not done frequently and he would not make more than a 7 day supply. Mr. Sammartino stated that he may over compound a few vials and save the medication by freezing instead of destroying the product.

Ms. Rosas asked how long an expiration date he would place on the product. Mr. Sammartino stated that he would give the product a 90 day expiration date but the medication would usually be used in a few days.

Mr. Sammartino stated the technicians met with the general manager to express their concerns. Mr. Sammartino stated the technicians felt that he was diluting medications. Mr. Sammartino stated that he met with the technicians and the general manager to discuss the issues. Mr. Sammartino stated that the intake technician also had issues with two nursing directors.

Mr. Minkus asked Mr. Sammartino if the technicians had presented a better way or easier way to do things. Mr. Sammartino stated that if the technicians had brought different ideas that would result in better patient care he would have made changes.

Mr. Minkus asked if anything had changed after the technicians had expressed their concerns to the general manager. Mr. Sammartino stated that he reviewed the issues with the technicians during their meeting and no changes were made to the procedures.

Mr. Van Hassel asked Mr. Sammartino to address the abelcet area. Mr. Sammartino stated that he made the error. Mr. Sammartino stated that the prescription order came with incomplete information. Mr. Sammartino stated that the dose was missing and the facility that transmitted the order had used Amphotericin B in the past. Mr. Sammartino stated that he used the Amphotericin B because he did not notice the Ambisome written on the second line.

Mr. Van Hassel asked about the IVIG order that was filled past the expiration date. Mr. Sammartino stated that he used to build the prescriptions from scratch on each new prescription. Mr. Sammartino stated that the technician was familiar with the computer system and showed him how to cut and paste from an old prescription to create a new prescription. Mr. Sammartino stated that the doctor had faxed in a new prescription and when he used the cut and paste function he did not change the refills correctly. Mr. Sammartino stated that he did obtain a signed prescription from the doctor for that fill.

Mr. Van Hassel asked Mr. Sammartino if he carries a gun to work .

Mr. Sammartino stated that he does not take his gun into the work place and is left in his car. Mr. Sammartino stated that he has a concealed weapons permit. Mr. Sammartino stated that the technicians worked different hours and the one technician did not have a ride to work so the nursing director would pick up

the technician. Mr. Sammartino stated that the nursing director did not want to pick up the technician any longer and he picked the technician up for three weeks and that is how she knew that he had a concealed weapon in the car.

Dr. Foy asked about the training documentation for the two technicians. Mr. Sammartino stated that they had completed a risk management assessment for both employees. Mr. Sammartino stated that one technician breezed through the assessment but the second technician had difficulty. Mr. Sammartino stated that training was based off that assessment.

Ms. Locnikar asked about the freezing of the drug. Mr. Sammartino stated that he received a call from the lab stating that the patient's potassium was low. Mr. Sammartino stated that he contacted the physician and the patient was sent to the ER for potassium infusions. Mr. Sammartino stated that the driver returned with the additional doses of the Abelcet and placed the drugs in the freezer in back in the receiving area. The driver does not have access to the pharmacy. Mr. Sammartino stated that the error was discovered and the drug was destroyed. Mr. Sammartino stated that he did do research and found that Abelcet could not be frozen.

Ms. Rosas asked who discovered the error with the Abelcet. Mr. Sammartino stated that he discovered the error on 5/3/2014. Mr. Sammartino stated that he goes to the office on Saturdays to complete his paperwork. He stated that he discovered the error and completed a risk management report. Mr. Sammartino stated that he contacted the physician and the patient's caregiver.

Ms. Rosas asked if the low potassium levels were due to the error. Mr. Sammartino stated that it is not clear if the error caused the low potassium levels because all amphotericin forms can cause low potassium.

**On motion by Mr. Van Hassel and seconded by Ms. Rosas,** the Board unanimously agreed to issue an advisory letter to the pharmacist concerning accuracy of records and documentation of training.

### **AGENDA ITEM 13– Complaint Review – Consideration of Complaints on Schedule R**

President Foy opened the discussion by stating the Board Members would review all the complaints on schedule S.

**Complaint #4301**

**On motion by Mr. Van Hassel and seconded by Mr. Kennedy,** the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

**Complaint #4320**

**Mr. Kennedy was recused due to a conflict of interest.**

**On motion by Dr. Foy and seconded by Mr. Van Hassel,** the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

**Complaint #4328**

**On motion by Mr. Van Hassel and seconded by Mr. Kennedy,** the Board unanimously agreed to issue an advisory letter to the pharmacist concerning accuracy and an advisory letter to the technician concerning the selling of prescriptions to the correct patient.

**Complaint #4331**

**Mr. Kennedy was recused due to a conflict of interest.**

**On motion by Dr. Foy and seconded by Mr. Van Hassel,** the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

**Complaint #4333**

**Mr. Kennedy was recused due to a conflict of interest.**

**On motion by Mr. Van Hassel and seconded by Mr. Francis,** the Board unanimously agreed to offer the Pharmacy Technician Trainee a Consent Agreement with the following terms: \$250 fine and 9 hours of CE on medication error prevention to be completed within 6 months.

**Complaint #4334**

**Dr. Foy was recused due to a conflict of interest.**

**On motion by Ms. Rosas and seconded by Mr. Kennedy,** the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

**Complaint #4335**

**Dr. Foy was recused due to a conflict of interest.**

**On motion by Mr. Francis and seconded by Mr. Minkus,** the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

### **Complaint #4340**

**On motion by Mr. Van Hassel and seconded by Mr. Minkus**, the Board unanimously agreed to dismiss the complaint and take no further action on the complaint.

### **Complaint #4345**

**On motion by Mr. Van Hassel and seconded by Mr. Francis**, the Board unanimously agreed to table their decision until the PAPA evaluation is sent to the Board for review.

### **AGENDA ITEM 15 – Wells Pharmacy Network – Case 14-0019-PHR**

President Foy stated that the Board has received a letter from Wells Pharmacy Network concerning the Consent Agreement that was offered to them in response to an FDA warning letter. President Foy stated that Wells Pharmacy Network is declining to sign the Consent Agreement and is requesting a formal hearing.

**On motion by Mr. Kennedy and seconded by Ms. Rosas**, the Board unanimously agreed to rescind their action offering a consent agreement to Wells Pharmacy Network.

The Board members discussed various options and decided to send a Compliance Officer to Florida to conduct an inspection.

**On motion by Ms. Locnikar and seconded by Mr. Minkus**, the Board unanimously agreed to table the complaint until a Compliance Officer conducts an inspection at the pharmacy and the Board can review the outcome.

### **AGENDA ITEM 17– Call to the Public**

President Foy announced that interested parties have the opportunity at this time to address issues of concern to the Board; however the Board may not discuss or resolve any issues because the issues were not posted on the meeting agenda.

Roger Morris came forth to address the Board. Mr. Morris stated that the DEA announcement which changes Hydrocodone products to a CII would allow the pharmacist to fill any prescriptions written prior to October 6, 2014 as a CIII with refills available to be filled until April 2015.

### **AGENDA ITEM 18 – Future Agenda Items**

The following items will be placed on a future agenda for discussion:

1. Early appearance for approval of probation termination
2. Blanket waiver for CII medications in an automated dispensing machine in Long Term Care Facilities

The meeting recessed at 3:35 P.M. until August 28, 2014 at 9:00 A.M.

### **AGENDA ITEM 1 – Call to Order – August 28, 2014**

President Foy convened the meeting at 9:00 A.M. and welcomed the audience to the meeting.

The following Board Members were present: President Jim Foy, William Francis, Darren Kennedy, Kyra Locnikar, John Musil, Reuben Minkus, Nona Rosas, and Tom Van Hassel. The following Board Member was not present: Dennis McAllister. The following staff members were present: Compliance Officers Steve Haiber, Tom Petersen, Sandra Sutcliffe, Dennis Waggoner, and Karol Hess, Drug Inspectors Melanie Thayer, Executive Director Hal Wand, Deputy Director Cheryl Frush, and Assistant Attorney General Monty Lee.

### **AGENDA ITEM 2– Declaration of Conflicts of Interest**

Due to having a “substantial interest” in the matter, Dr. Musil recused himself from participating under Arizona’s conflict of interest laws in the review, discussion, and proposed actions concerning Agenda Item 16, Integrity Rx Specialty and Vasco Rx Deviation Request.

### **AGENDA ITEM 8– License Applications Requiring Board Review – Schedule O**

#### **#4 Hieu Ngyuen**

**Hieu Ngyuen** appeared on his own behalf to request to proceed with reciprocity.

President Foy opened the discussion by asking Mr. Ngyuen why he was appearing in front of the Board. Mr. Ngyuen stated that he would like to proceed with reciprocity.

Dr. Foy asked Mr. Nguyen to explain his disciplinary action. Mr. Nguyen stated that in 2010 he was arrested on a shoplifting charge because he went through the glass doors of a store to receive an emergency call and received a deferred adjudication. Mr. Nguyen stated that he did not report this charge to the Louisiana Board.

Dr. Foy asked Mr. Nguyen why he wants to move to Arizona. Mr. Nguyen stated that his fiancée lives in Arizona and he would like to move to Arizona.

Ms. Rosas asked about the 2013 allegations. Mr. Nguyen stated that he did not receive notification from the Board because someone with the same name was sent his documents. Mr. Nguyen provided copies of the documents.

**On motion by Mr. Van Hassel and seconded by Ms. Rosas**, the Board unanimously agreed to approve Mr. Ngyuen’s pharmacist application.

## **AGENDA ITEM 12 – Conferences – Schedule Q**

### **Conference 6 – Complaint #4237 – Case 14-0021-PHR**

The following individuals were present to discuss the complaint:

1. Jacqueline Cavanagh – Pharmacist – Respondent
2. Yolanda Douthard – Chief of Pharmacy Services for Phoenix Children’s Hospital – Respondent
3. Angela Serio-Harney – Executive Vice President of Operations for Maxor
4. Tom Kirschling – Corporate Compliance for Maxor
5. Roger Morris and Christine Cassetta – Legal Counsel for Ms. Cavanagh and Phoenix Children’s Hospital

President Foy opened the discussion by asking Mr. Haiber to give a brief overview of the complaint.

Mr. Haiber stated that during a complaint investigation by the Compliance Officers the following allegations were investigated:

1. Compounding of hazardous products was performed without protective equipment
2. Lack of compounding training for technicians
3. Compounding preparation recipes were not provided
4. Lack of pharmacist supervision of compounding technician activities
5. Compounding room sanitation

President Foy asked the respondents to address the complaint and allegations.

Mr. Morris stated that Phoenix Children’s Hospital contracts with Maxor Pharmacy Services to operate the outpatient pharmacy at Phoenix Children’s Hospital (PCH). Mr. Morris stated that Ms. Serio-Harney would address the issues. Ms. Serio-Harney is the Executive Vice President of Operations at Maxor.

Ms. Serio-Harney stated that she hired Lyle Brauner to be the pharmacist in charge in July of 2011. Ms. Serio-Harney stated that Mr. Brauner was given the basic Maxor policies and asked for input on changing the policies. Ms. Serio-Harney stated that Mr. Brauner was tasked with developing the technician training program and compounding program. Ms. Serio-Harney stated that Mr. Brauner was given carte blanche for training programs. Ms. Serio-Harney stated that it was assumed that Mr. Brauner had attended a training program.

Ms. Serio-Harney stated that the last three years the pharmacy operated smoothly. Ms. Serio-Harney stated that the prescription volume increased, wait times were acceptable, and there were only a few medication errors. Ms. Serio-Harney stated that quality reports were sent to Ms. Douthard.

Ms. Serio-Harney stated that nothing suggested that there egregious issues within the pharmacy. Ms. Serio-Harney stated that it was never mentioned that they were compounding hazardous medications in the pharmacy. Ms. Serio-Harney stated that she visited the pharmacy in January

and she had no idea hazardous compounds were being made in the pharmacy.

Ms. Serio-Harney stated that while she was on maternity leave Mr. Brauner met with Ms. Douthard on May 2, 2014 concerning hazardous materials that were being compounded. Mr. Brauner revealed on May 5, 2014 the products that were being made and that enhanced protection was needed. Mr. Brauner indicated that they needed a hood. Ms. Serio-Harney stated that Mr. Birdsong at Maxor told Mr. Brauner to quit compounding the medications immediately.

Ms. Serio-Harney stated that two weeks later a complaint was filed by the technician with OSHA. Ms. Serio-Harney stated that Mr. Brauner's employment was then terminated.

Mr. Morris asked Ms. Cavanagh to address the complaint and allegations. Mr. Morris stated that Ms. Cavanagh is now the current pharmacist in charge.

Ms. Cavanagh stated that she was hired in March of 2012. Ms. Cavanagh stated that she did have compounding experience. Ms. Cavanagh stated that she noticed deficiencies in the pharmacy and brought the issues up to Mr. Brauner and was told that they do not do that here. Ms. Cavanagh stated that some of the issues related to good compounding guidelines. Ms. Cavanagh stated that she backed down because she was afraid of losing her job.

Ms. Cavanagh stated that Mr. Brauner had a tendency to get angry and created an intimidating work environment. Ms. Cavanagh stated that she should have turned Mr. Brauner into the Board or reported the issues to Maxor. Ms. Cavanagh stated that she did not know what to do.

Ms. Cavanagh stated that the technicians were compounding the medications and the ingredients were not verified before they were made. Ms. Cavanagh stated that Mr. Brauner did not think it was necessary to check the compounds. Ms. Cavanagh stated that she told the technician to come to her to check the compounds. Ms. Cavanagh stated that she could not guarantee that she checked every compound that was made. Ms. Cavanagh stated that there were medications that she knew that they should not be making and she talked to Mr. Brauner about those medications. Ms. Cavanagh stated that she did not know that other medications needed to be made in a hood. Ms. Cavanagh stated that it was her job to know which medications should have been made in a hood. Ms. Cavanagh stated that she is making corrections going forward.

Ms. Cavanagh stated that she is now the pharmacist in charge and has changed functions in the pharmacy. Ms. Cavanagh stated that all compounds are checked before and after being compounded. Ms. Cavanagh stated that only a pharmacist is compounding in the pharmacy. Ms. Cavanagh stated that she has developed new compounding sheets. Ms. Cavanagh stated that to ensure that the proper equipment is being used any products that need to be compounded in a biological safety cabinet is on a bright red form indicating that it is a hazardous or chemo medication.

Ms. Cavanagh stated that everyone must sign a sheet indicating they understand that when certain medications are handled they must wear masks and gloves. Ms. Cavanagh stated that they have a chemo spill kit in the lab and every other Friday the hospital cleans the lab.

Ms. Cavanagh indicated that she would attend an off-site compounding course when she finds the right course.

Mr. Morris asked Tom Kirschling from Maxor to address the audits he conducted at the site. Mr. Kirschling stated that he was contacted on June 3, 2014 to conduct an inspection at the site. Mr. Kirschling stated that he has pediatric and compounding experience. Mr. Kirschling stated that he is familiar with USP 797 and compounding regulations.

Mr. Kirschling stated that he investigated the situation and for employee safety and the patient's safety immediate steps were taken to move the compounding to the inpatient system.

Mr. Kirschling stated that he recommended training, documentation, and facilities be updated to be 795 compliant. Mr. Kirschling stated that Ms. Cavanagh has made some changes and he is assisting in the compliance.

Dr. Foy asked Mr. Kirschling if he conducted any prior audits of the facility. Mr. Kirschling stated that he did not conduct any previous audits. Mr. Kirschling stated that this was the first audit he conducted at the site.

Ms. Serio-Harney stated that visual inspections were conducted at the site. Ms. Serio-Harney stated that she reviewed dispensing records, purchase records, and medication errors. Ms. Serio-Harney stated that no red flags were raised and there were no employee complaints.

Ms. Serio-Harney stated that she was not aware that they were compounding chemo drugs in January and had not been aware that they had been compounding the medications since 2011.

Dr. Foy asked Ms. Serio-Harney if she reviewed the purchase records. Ms. Serio-Harney replied that she did review the purchase records but did not realize they were compounding chemo medications.

Mr. Morris asked Ms. Douthard , Chief of Pharmacy Services at PCH, to address the issues in the complaint.

Ms. Douthard stated that she joined the staff at PHC on April 1, 2013. Ms. Douthard stated that she is in charge of all the Phoenix Children Hospital sites. Ms. Douthard stated that she was aware that there was a contracted pharmacy in the building.

stated that she met with Mr. Brauner and walked the space with him. Ms. Douthard stated that they were outgrowing their current space.

Ms. Douthard stated that she asked Mr. Brauner if he had SOPs and he replied that he did. Ms. Douthard stated that she did not look at his SOPs.

Ms. Douthard stated that she met Ms. Serio-Harney via telephone.

Ms. Douthard stated that there was no evidence of hazardous compounding. Ms. Douthard

stated that Mr. Brauner told her that less than 20% of their business is compounding. Ms. Douthard stated that Mr. Brauner did have prn help as his volume had increased.

Mr. Wright, Pharmacy Operations Manager at PCH, met with Mr. Brauner and indicated the business metrics were good.

Ms. Douthard stated that they had looked at the Board inspections and the inspections looked good.

Ms. Douthard stated that Mr. Wright contacted her and stated that they needed to meet with Mr. Brauner concerning the compounding of hazardous compounds.

Ms. Douthard stated that they asked Mr. Brauner and Ms. Schweitzer to bring a list of the compounds that they are currently compounding and the products they anticipate compounding.

Ms. Douthard stated that when she reviewed the list she also saw three products that were teratogenic. Ms. Douthard stated that she told them to stop compounding the medications at this point.

Ms. Douthard stated that she asked Mr. Wright to contact Ms. Frush at the Board of Pharmacy to see if the Board would allow the outpatient pharmacy to prepare the products in the inpatient pharmacy. Ms. Frush told Mr. Wright that she would talk with Mr. Wand because she had some concerns and would call him back. Ms. Frush told Mr. Wright that she discussed the issues with Mr. Wand and they stated that the outpatient pharmacy could use the inpatient pharmacy but there were several issues that needed to be addressed. Ms. Frush told Mr. Wright that the individuals (pharmacists or technicians) need to be properly trained on the compounding of the products. Also, if a technician compounds the medications they must be properly supervised. Ms. Frush told Mr. Wright that the inpatient pharmacy could compound the medications for the outpatient pharmacy. Ms. Douthard stated that the issues raised by the Board were the same concerns that she had concerning the compounding of the medications.

Ms. Douthard stated that they decided that the outpatient pharmacy would schedule a time to use the hood in the inpatient pharmacy and the employees needed to be trained.

Ms. Douthard stated that their current options are to redesign the space for the outpatient pharmacy, continue to use the inpatient pharmacy hood, or outsource the preparation of the hazardous compounds.

Dr. Musil asked Ms. Serio-Harney how many outpatient childrens hospital pharmacies they manage. Ms. Serio-Harney stated just this one. Ms. Serio-Harney stated that they manage a specialty infusion pharmacy for children.

Dr. Musil asked Ms. Serio-Harney if they conducted any audits and reviewed compounding policies. Ms. Serio-Harney stated that they had not conducted any audits prior to this complaint. Ms. Serio-Harney stated that they sent out three compounds for testing and two of the products were fine.

Dr. Musil asked Ms. Serio-Harney if they conducted any compounding audits in their contracted pharmacies. Ms. Serio-Harney replied no.

Mr. Van Hassel asked Ms. Cavanagh when she started at PCH and what position she held. Ms. Cavanagh stated that she started as a staff pharmacist in March of 2012.

Mr. Van Hassel asked if there was any additional staffing. Ms. Cavanagh stated that Mr. Brauner was the only other full-time pharmacist. Ms. Cavanagh stated that there was additional prn help.

Mr. Van Hassel asked about the cleaning of the compounding room. Ms. Cavanagh stated that the room was cleaned daily.

Mr. Van Hassel asked Ms. Cavanagh what was used to clean the room. Ms. Cavanagh stated that the room was never cleaned that they used Lysol wipes to clean the counters.

Mr. Van Hassel asked Ms. Cavanagh about the supervision of the technicians. Ms. Cavanagh stated that she expressed her concerns to Mr. Brauner but she was afraid of going around him to check the compounds. Ms. Cavanagh stated that it was not an excuse but she was placed in a hard position. Ms. Cavanagh stated that she could not guarantee the workflow issues.

Mr. Van Hassel asked Ms. Cavanagh if she believed that the technician was adequately trained. Ms. Cavanagh stated that there were some deficiencies that she noted. Ms. Cavanagh stated that she believes that there was not enough supervision of the technicians. Ms. Cavanagh stated that one of the technicians indicated that the training course was a joke.

Mr. Van Hassel asked Ms. Serio-Harney about the training course Mr. Brauner attended. Ms. Serio-Harney stated that she signed the expense sheet authorizing Mr. Brauner to attend a training class and assumed he attended a class.

Dr. Musil asked about the compounding sheets that were used in the past. Ms. Cavanagh stated that the compounding sheets used in the past indicated the drug and concentration and the number of tablets to be made. Ms. Cavanagh stated that there were no specific instructions. Ms. Cavanagh stated that they listed the lot number and expiration date of the items used. Ms. Cavanagh stated that there were no step by step procedures.

Dr. Musil asked if there was a master formula record. Ms. Cavanagh stated that no formulation sheet was used.

Dr. Musil asked what corrections Ms. Cavanagh has made. Ms. Cavanagh stated that the new sheet identifies the individual that prepared the compound and the verifying pharmacist. Ms. Cavanagh stated that the lot number, expiration date, and NDC number of the product used is recorded. Ms. Cavanagh indicated that if it is a hazardous product it is made in a biological safety cabinet.

Mr. Minkus asked Ms. Serio-Harney if there is any follow up with the forms to see if people are doing what they are supposed to be doing. Ms. Serio-Harney stated that the processes were driven by barcode technology and no red flags were raised.

Mr. Minkus asked Ms. Cavanagh why she did not come forth when these issues occurred. Ms. Cavanagh stated that she could not change her actions that occurred in the past.

Mr. Van Hassel asked Mr. Kirschling about changes at the site. Mr. Kirschling stated that there are still some issues that need to be addressed. Mr. Kirschling stated that they use USP 797 as best practices for employee and patient safety. Mr. Kirschling stated that they would have an independent expert inspect the site when the remodel is finished.

Dr. Foy asked Ms. Serio-Harney what plans they have going forth to monitor the site. Ms. Serio-Harney stated that they plan to use an outside consultant. Ms. Serio-Harney stated that have plans to audit the compounding records.

Dr. Foy asked Ms. Douthard if there are internal departments providing audits. Ms. Douthard stated that risk management and the legal department would be providing audits.

Mr. Francis asked Ms. Serio-Harney how they manage other compounding sites. Ms. Serio-Harney stated that she is not aware of any other sites doing this type of compounding.

Ms. Rosas asked who the pharmacist in charge was when this incident took place. Ms. Cavanagh replied that Mr. Brauner was the pharmacist in charge.

Ms. Rosas asked Ms. Cavanagh who was responsible for checking the technicians work. Ms. Cavanagh stated that she and Mr. Brauner were responsible for checking the technician's work. Ms. Cavanagh stated that prn pharmacists were also responsible for checking the technician's work.

Dr. Foy asked Ms. Serio-Harney if Maxor has an ethics line that is confidential. Ms. Serio-Harney stated that they have a 1-800 compliance line. Ms. Serio-Harney stated that the employee should report the incident to the first line supervisor and move up the chain to the next position. Ms. Serio-Harney stated that the number is posted in the pharmacy and on the ADP site (payroll site).

Dr. Foy asked Ms. Cavanagh if she was aware that she could report issues. Ms. Cavanagh stated that she was not aware that she could report issues in this manner.

Ms. Serio-Harney stated that each employee receives a handbook and the information is in the handbook.

Mr. Kirschling stated that the number is listed on the front page of the ADP site.

Ms. Douthard stated that she told Ms. Cavanagh that she can take issues to the hospital staff because the hospital is the permit holder.

Dr. Foy asked Ms. Cavanagh if she ever went to Ms. Douthard with issues. Ms. Cavanagh replied no. Ms. Cavanagh stated that when she started she did not know anyone and all communication was with Mr. Brauner and no one else within the hospital.

Ms. Douthard stated that Mr. Brauner did not always have direct access to someone within the hospital because there was a lot of transition occurring in the staffing. Ms. Douthard stated that her position was vacant for a long period of time.

Mr. Francis asked about the training programs that Maxor offers online. Ms. Serio-Harney stated that they offer abuse training, HIPAA training, harassment training, and prescription filling. Ms. Serio-Harney stated that the completion of these programs are tracked at the corporate level.

Mr. Minkus asked Ms. Serio-Harney how often the complaint process has been used. Ms. Serio-Harney stated that she is not sure and would have to ask for the statistics.

Mr. Kennedy asked Ms. Cavanagh if they were preparing hazardous products when she started in 2012. Ms. Cavanagh replied that they were preparing hazardous products before she started and in the past year the business doubled.

Mr. Kennedy asked Ms. Cavanagh if she talked to Mr. Brauner about preparing hazardous products without a hood. Ms. Cavanagh stated that she did not know that the products were to be made in a hood. Ms. Cavanagh stated that she does not recall when she brought up other compounding issues with Mr. Brauner.

Mr. Kennedy asked Ms. Cavanagh when she became aware of the issues. Ms. Cavanagh stated that the complaint became evident at the end of April

Mr. Kennedy asked what happened to the concerns that she and the technicians expressed to Mr. Brauner. Ms. Cavanagh stated that that as far as she knew the complaints stopped at Lyle.

Ms. Rosas asked if there were any complaints that involved these compounded medications. Ms. Serio-Harney stated that there were no issues related to the compounds.

Mr. Wand asked if there were any mistakes found when they checked the technicians work. Ms. Cavanagh stated that no wrong medications were used but she did have an issue with the way the technician qs'ed a medication.

Ms. Locnikar asked if Maxor provides CE education for the pharmacists and technicians. Ms. Serio-Harney stated that they completed the employee training provided.

Ms. Locnikar asked if the training was internally through the hospital. Ms. Serio-Harney stated that Maxor has their own internal training program.

Dr. Foy stated that the hazardous drug policies were last updated in August of 2012.

Mr. Kirschling stated that they have updated those policies to include USP 800.

Dr. Foy asked if there were hazardous compounding policies in effect in 2012. Ms. Cassetta stated that they only had policies for oral medications that were not compounded.

Dr. Foy asked if these policies were provided to Mr. Brauner. Ms. Serio-Harney stated that the new policies developed in 2014 were not provided to Mr. Brauner.

Dr. Musil asked about the compounding assessment. Mr. Kirschling stated that the employee reviews the ASHP online program on sterile products and must have a passing assessment score.

Dr. Musil asked what happens if the employee fails the quiz. Mr. Kirschling stated that the pharmacist in charge would not certify the individual to compound if they do not pass the test. Mr. Kirschling stated that it would be up to the pharmacist to determine how many times the employee can take the test.

Dr. Musil asked who supervises the technicians in the lab. Ms. Serio-Harney stated that no technicians are compounding at this time.

Dr. Foy asked Ms. Serio-Harney did she communicate to Mr. Brauner that this was a compounding pharmacy when his background was in retail pharmacy. Ms. Serio-Harney stated that she told Mr. Brauner that there would be a fair amount of compounding.

Dr. Foy asked Ms. Serio-Harney why Mr. Brauner was hired if he had no compounding training. Ms. Serio-Harney stated that Mr. Brauner was working fulltime prior to the pharmacy opening. Ms. Serio-Harney stated that Mr. Brauner could have made up the gap by taking an outside compounding course prior to the opening of the pharmacy.

Dr. Foy noted that Mr. Brauner would not have had any experience in pediatric compounding. Ms. Serio-Harney stated that they purchased a recipe book and paid for training. Ms. Serio-Harney stated that she had assumed Mr. Brauner attended a training course.

**On motion by Dr. Musil and seconded by Mr. Francis**, the Board unanimously agreed to offer a consent agreement to Ms. Cavanagh with the following terms:

1. A fine of \$3,000
2. Attend a compounding training course
3. Probation for one year. May appear in front of the Board in 6 months from the effective date of the Consent to ask for the probation to be removed if the fine and training have been completed.

A roll call vote was taken. ( Ms. Locnikar – aye, Dr. Musil – aye, Mr. Francis – aye, Mr. Minkus-aye, Ms. Rosas – aye, Mr. Kennedy – aye, Mr. Van Hassel – aye, and Dr. Foy – aye)

**On motion by Dr. Musil and seconded by Mr. Kennedy**, the Board unanimously agreed to offer a consent agreement to Phoenix Childrens Hospital Outpatient Pharmacy with the following terms:

1. The permit be placed on suspension for two years with the suspension stayed

2. A fine of \$5,000
3. Two inspections within 12 months at the cost of the permit holder. After the second inspection, the pharmacy shall appear before the Board. If the pharmacy fails either inspection, the pharmacy shall appear before the Board.

A roll call vote was taken. ( Ms. Locnikar – aye, Dr. Musil – aye, Mr. Francis – aye, Mr. Minkus-aye, Ms. Rosas – aye, Mr. Kennedy – aye, Mr. Van Hassel – aye, and Dr. Foy – aye)

### **Conference 7 – Complaint #4237 – Case 14-0017-PHR**

The following individuals were present to discuss the complaint:

1. Lyle Brauner – Pharmacist - Respondent
2. Dr. Steven Perlmutter – Legal Counsel for Mr. Brauner

President Foy stated that Mr. Haiber had given a brief overview of the complaint concerning the compounding of hazard products without protective equipment, lack of pharmacist supervision of compounding technician activities, compounding recipes not maintained, and lack of compounding training for technicians.

President Foy asked Mr. Brauner to address the complaint.

Mr. Brauner stated that he was hired three years ago by Maxor to be the pharmacist in charge at the outpatient pharmacy at Phoenix Children’s hospital. Mr. Brauner stated that at the time he was still employed at Safeway. Mr. Brauner stated that he did complete the online training for Maxor at this time. Mr. Brauner stated that he had 8 days to open the pharmacy.

Mr. Brauner stated that he attended an orientation at Phoenix Children’s Hospital concerning Hospital policies.

Mr. Brauner stated that he was given three pharmacist applications and he was to select from those applications. Mr. Brauner stated that he selected a pharmacist that had compounding experience because his compounding experience was limited. Mr. Brauner stated that when he had worked at Fry’s he had compounded Miracle mouth wash and some Questran compounds.

Mr. Brauner stated that when he arrived at the pharmacy to start work there were no drug bays and no drugs ordered. Mr. Brauner stated that the computers were just being set up and there was a laminar flow hood in the compounding room.

Mr. Brauner stated that Maxor did not know what kind of compounds they would be making but did offer the service.

Mr. Brauner stated that they opened the pharmacy with two full time pharmacists and two fulltime technicians. Mr. Brauner stated that he asked if the pharmacy could open at a later date to get everything in order. Mr. Brauner stated that his request was denied.

Mr. Brauner stated that when they opened the pharmacy they used a spiral ring notebook to document their compounding. They did develop a compounding work sheet.

Mr. Brauner stated that because he did not have experience compounding he hired Ms. Cavanagh when the first pharmacist quit. Mr. Brauner stated that Ms. Cavanagh indicated that they should be documenting the lot number and expiration date , so that was added to the sheet.

Mr. Brauner stated that the pharmacy was making money for Maxor and most of the compounding was being done by pharmacy interns and pharmacy technicians.

Mr. Brauner stated that he was directed by Ms. Angela Serio-Harney to send the technicians to a pharmacy compounding course. Mr. Brauner stated that the technicians were sent to a program certified by Sanford Brown college.

Mr. Brauner stated that the pharmacy was a busy pharmacy and they filled approximately 1,500 prescriptions a week. Mr. Brauner stated that they did not have enough staffing and the technicians usually went to the back room to do the compounding.

Mr. Brauner stated that after a technician came to him expressing her concerns about compounding hazardous substances he had a meeting with Phoenix Children's Hospital (PCH) and Maxor. Mr. Brauner stated that he wanted to be transparent with both companies that they had been compounding hazardous medications.

Mr. Brauner stated that as a result the compounding recipe sheets were revamped and policies were put into place to insure the pharmacy was compliant.

Mr. Brauner stated that he would not have taken the job if he knew what he knows today. Mr. Brauner stated that he was not given the proper time to open the pharmacy or the proper equipment.

Mr. Brauner stated that Ms. Serio-Harney stated that he was sent to training. Mr. Brauner stated that he did not go to any training since he could not leave the pharmacy for more than one day due to the pharmacy volume.

Dr. Foy asked Mr. Brauner if he had a good understanding of the pharmacy expectations when he opened the pharmacy. Mr. Brauner replied no.

Dr. Foy asked Mr. Brauner what occurred when they had a request to make a compound. Mr. Brauner stated that he referred the request to the other pharmacist.

Dr. Foy asked about the compound recipe worksheets. Mr. Brauner stated that they stopped pulling the recipe sheets and would make the products in bulk. Mr. Brauner stated that the ingredients were on the compounding sheet and the recipe books were left on the shelf.

Dr. Foy asked why it took until 2014 for these concerns to be raised. Mr. Brauner stated that no concerns were brought to him by the staff.

Mr. Van Hassel asked if they checked every compound that was made by the technicians. Mr. Brauner stated that they did not check every compound that was made.

Mr. Van Hassel asked Mr. Brauner why he did not put in a request for a biological safety cabinet sooner. Mr. Brauner stated that he was not aware they needed a biological safety cabinet because the recipes were not pulled.

Mr. Van Hassel asked Mr. Brauner if the technicians and staff pharmacists were intimidated by him. Mr. Brauner stated that he has managed multiple pharmacies and thinks of the other employees as colleagues. Mr. Brauner stated that one of the employees had worked with him previously. Mr. Brauner stated that he worked hard and is demanding of his employees.

Dr. Foy stated that there is an e-mail from Mr. Brauner dated July 29, 2011 indicating that he had ordered all supplies and completed training. Mr. Brauner stated that he completed Maxor's online training which included the following: fraud prevention, HIPAA, Rx entry, and use of the cash register. Mr. Brauner stated that this year Maxor added harassment training.

Dr. Foy asked Mr. Brauner if he was privy to PCH policies. Mr. Brauner stated that the only PCH policies that he was familiar with were the employee conduct policies.

Mr. Brauner stated that PCH did little to promote the pharmacy. Mr. Brauner stated that communication improved after Ms. Douthard arrived. Mr. Brauner stated that he did mention to Ms. Serio-Harney that it was difficult to communicate with the hospital. Mr. Brauner stated.

Mr. Brauner stated that he reported the prescription volume and financials to PCH.

Dr. Musil asked who constructed the pharmacy. Mr. Brauner stated that he believed the pharmacy was designed by PCH. Mr. Brauner stated that at his initial interview with Ms. Serio-Harley he addressed the issue of pharmacy storage. Mr. Brauner stated that the pharmacy was built to look pretty.

Dr. Musil asked about the size of the compounding room. Mr. Brauner stated that the pharmacy was built before he arrived and that was the size of the room that Eric Sinner the operations manager had approved.

Mr. Brauner stated that when he was looking in the file that he discovered on the back of the initial inspection report were items that needed to be purchased or completed. Mr. Brauner stated that he did order a compounding book and was developing a training manual after he found the reports.

Ms. Rosas asked Mr. Brauner if he had been given access to PCH's computer system. Mr. Brauner stated that the pharmacy operates off the Maxor network. Mr. Brauner stated that he can log on to PCH system to obtain third party information for insurance billing.

Dr. Foy asked Mr. Brauner about Maxor not knowing that they were making hazardous compounds. Mr. Brauner stated that they started making the products when the pharmacy opened. Mr. Brauner stated that the first pharmacist did not mention that these medications

required special attention and Ms. Cavanagh did not mention that these medications required special attention. Mr. Brauner stated that he did order masks, goggles, and gloves.

Dr. Foy asked Mr. Brauner about making the products in the inpatient pharmacy. Mr. Brauner stated that this was not an ideal solution because they had limited time to use the hospital hood. Mr. Brauner stated that they were making bulk products in the hospital and partial filling prescriptions and mailing the remainder.

**On motion by Dr. Musil and seconded by Mr. Francis**, the Board agreed to offer Mr. Brauner a consent agreement with the following terms:

1. A fine of \$5,000 dollars
2. Completion of an off-site compounding training course
3. Probation for one year. May appear in front of the Board in 6 months from the effective date of the Consent to ask for the probation to be removed if the fine and training course have been completed.
4. Can be a pharmacist in charge during the probation period

A roll call vote was taken. ( Ms. Locnikar – aye, Dr. Musil – aye, Mr. Francis – aye, Mr. Minkus-aye, Ms. Rosas – aye, Mr. Kennedy – nay, Mr. Van Hassel – nay, and Dr. Foy – aye)

### **Conference 8 – Complaint #4336**

The following individuals were present to discuss the complaint:

1. Troy Albright – Pharmacist – Respondent
2. Ken Baker – Legal Counsel for Mr. Albright

President Foy opened the discussion by asking Mr. Waggoner to give a brief overview of the complaint.

Mr. Waggoner stated that the Board Office received a call from Banner Good Samaritan Regional Medical Center on 11/27/2013 concerning the discovery of a contaminated vial of Calcium Gluconate 10% injection. It was determined that the contaminated vials were made by Rx Formulations.

Mr. Waggoner stated that he visited Banner Good Samaritan and Rx Formulations. Mr. Waggoner stated that he noticed the black particles in the vial at Banner Good Samaritan.

Mr. Waggoner stated that he has made multiple visits to the site and accompanied an FDA inspector to Rx Formulations.

Mr. Waggoner stated that the Board Members have a copy of various visits and at the last Board Meeting the Board asked him to conduct a follow- up inspection. Mr. Waggoner stated that the Board has received copies of that inspection.

Mr. Baker stated that he would like to clarify several points. Mr. Baker stated that the FDA referred to good manufacturing practices which are not the same as compounding regulations.

Mr. Baker stated that the products were not patient specific because they were being made for hospital use. Mr. Baker stated that Mr. Albright made the medications for stat orders due to shortages. Mr. Baker stated that the products Mr. Albright made were not commercially available at the time due to shortages. Mr. Albright would only compound commercially available products if they were not available.

Mr. Baker stated that Mr. Albright that did not solicit Banner's business. Mr. Baker stated that Mr. Albright was going to discontinue making any products for Banner in September because they were building their own pharmacy. Mr. Baker stated that Mr. Albright was contacted by Banner to continue compounding medications for them on a month to month basis because their pharmacy was not ready.

Mr. Baker stated that Mr. Albright has canceled the contract and only compounds patient specific medications. Mr. Baker stated that Mr. Albright does no batch compounding.

Dr. Foy asked Mr. Albright if he had any prior issues with the FDA. Mr. Albright stated that he did not have any previous issues with the FDA.

Dr. Musil asked Mr. Albright about USP 71 testing. Mr. Albright stated that if it is greater than 25 units then it must be tested.

Dr. Musil asked Mr. Albright if he prepared 40 units of 100 cc each how many are sent for testing. Mr. Albright replied 10% for testing.

Dr. Musil asked Mr. Albright why he only sent 5 mls for testing. Mr. Albright stated that the technician sent 5 ml but they would normally send 10%.

Dr. Musil asked about the product testing. Mr. Albright stated that the product was identified as calcium gluconate.

Dr. Musil asked about the fine crystals that were present in the product. Mr. Albright stated that the pharmacist saw crystals in the product. Mr. Albright stated that they reviewed their lot and procedures. Mr. Albright stated that the product is temperature sensitive and it could have been handled incorrectly.

Dr. Musil asked Mr. Albright if he had documentation supporting a 30 day beyond use date. Mr. Albright stated that his understanding is that the product could be used for 30 days. Dr. Musil stated that the product is a high risk product and should have an expiration date of 3 days.

Dr. Musil asked about the environmental concerns that were found by the FDA and the Board. Mr. Albright stated that he has purchased a new autoclave.

Dr. Musil asked about the ceiling tiles if they met USP 797 and certification standards. Mr. Albright stated that a technician had gauged the tiles with a mop. Mr. Albright stated that the ceiling tiles and the electrical outlet had been replaced.

Dr. Musil asked about bubble point testing that was noted by the Board Compliance Officer. Mr. Albright stated that for filters up to 25mm no bubble point test is required. Mr. Albright stated that he uses a double filter.

Dr. Musil indicated that USP 797 requires bubble point testing. Mr. Albright stated that the products were sent for testing and there was no bacterial growth found in the product.

Dr. Musil discussed the practice of bringing trash can liners into the room with Mr. Albright.

Dr. Musil asked Mr. Albright if he quarantined the product when he made a batch. Mr. Albright replied yes. Dr. Musil told Mr. Albright that he needs to add the quarantine to his policies.

Dr. Musil asked Mr. Albright if he is monitoring the contaminants in his clean room. Mr. Albright stated that he used a different method than the FDA to monitor the contaminants.

**On motion by Dr. Musil and seconded by Ms. Rosas**, the Board unanimously agreed to offer Rx Formulations a consent agreement with the following terms:

1. 1 year suspension with the suspension stayed for 2 years
2. \$3,000 fine
3. 2 inspections at the cost of the permit holder. After the second inspection the permit holder must appear before the Board and discuss the findings.

If the pharmacy fails either inspection, they must appear before the Board.

A roll call vote was taken. ( Ms. Locnikar – aye, Dr. Musil – aye, Mr. Francis – aye, Mr. Minkus-aye, Ms. Rosas – aye, Mr. Kennedy – aye, Mr. Van Hassel – aye, and Dr. Foy – aye)

#### **AGENDA ITEM 14 – PharMerica – Case 14-0011-PHR**

**Ms. Rosas was recused due to a conflict of interest.**

President Foy stated that representatives from PharMerica are present to request that the Board reconsider their decision concerning Case 14-0011-PHR. Dr. Foy stated that the Board has offered PharMerica a Consent Agreement.

**Marta Broksas, Pharmacist in Charge, and Robert Sarvas, Operations Director**, were present to request that the Board reconsider their decision on Case 14-0011-PHR.

Mr. Sarvas opened the discussion by stating that they would like the Board to resolve the complaint informally.

Dr. Foy stated that the pharmacy still had violations when they were inspected in May. Mr. Sarvas stated that the violations have been corrected. Mr. Sarvas stated that personnel have changed. Mr. Sarvas stated that they have instituted practices to only allow employees in the pharmacy. Mr. Sarvas stated that the lens cover has been replaced. Mr. Sarvas stated that no pharmacy technician trainees are compounding.

Dr. Foy asked about the training program for sterile and non-sterile products. Mr. Sarvas stated that they have a training program and they do test the products. Mr. Sarvas stated that the policies were in his office.

Mr. Van Hassel asked the respondents if they read the consent agreement. Ms. Broksas stated that they are required to have one additional inspection.

Mr. Van Hassel asked if they agree with the findings. Mr. Sarvas stated that they agree with the findings.

Dr. Musil asked what they meant by formal versus informal. Mr. Sarvas stated that they want it not to be public.

Dr. Musil asked what they meant by formal versus informal. Mr. Sarvas stated that they want it not to be public.

Mr. Wand stated that he believes they do not want it to show as disciplinary action taken against the pharmacy. Mr. Wand stated that a Consent Agreement is disciplinary.

**On motion by Mr. Francis and seconded by Mr. Van Hassel**, the Board unanimously agreed to leave their decision as it stands to issue the Consent Agreement and if the Consent Agreement is not signed within 15 days the case would proceed to hearing at the October meeting.

### **AGENDA ITEM 16 – Integrity Rx Specialty and Vasco Rx Deviation Request**

#### **Dr. Musil was recused due to a conflict of interest.**

The following individuals were present to answer questions from Board Members concerning their deviation request.

1. Jeffrey Karp – Integrity Pharmacy
2. Paul Vasililauskas – Vasco Rx
3. Mark Boesen – Legal Counsel for the Pharmacies

President Foy asked the individuals to address their deviation request.

Mr. Boesen stated that Integrity is a new start up pharmacy helping patients with infertility issues. Mr. Boesen stated that many of the products to treat infertility issues are compounded products and Integrity does not have the resources to set up a compounding lab. Mr. Boesen stated that Integrity has asked Vasco to support their services by compounding medications in a shared service arrangement. Mr. Boesen stated that Vasco would like to place a remote dispensing machine in Integrity,

Mr. Karp stated that compounding is essential with infertility treatments. Mr. Karp stated that compounding should be left to the experts and that is why he wants to enter into a shared service agreement with Vasco.

Mr. Vasililauskas stated that they would enter into a shared service agreement and he would place a pyxis machine in an area at Integrity.

Dr. Foy asked the individuals to explain the process. Mr. Karp stated that the prescription would be entered by Integrity and electronically transferred to Vasco. Mr. Karp stated that the patient must agree to the transfer. Mr. Karp stated that Vasco will mix a three to five day batch and place in the Med-Dispense machine in Integrity. Mr. Karp stated that Vasco will track the lot numbers of the products dispensed. Mr. Karp stated that Vasco will be on site each day in Integrity's space. Mr. Karp stated that the compounded product would be labeled and checked by the Vasco pharmacist.

Mr. Karp stated that they are trying to eliminate drug misadventures. The patient will receive one order instead of two different orders from two different pharmacies.

Mr. Wand asked about the shared services. Mr. Boesen stated that they would have a written agreement between the two pharmacies.

Mr. Van Hassel asked about the advantage of having the machine in the pharmacy. Mr. Karp stated that there is an acuity in the patient needing their medication.

Dr. Foy asked if the products are patient specific. Mr. Karp stated that they are labeled for the patient.

Mr. Kennedy asked who the patient would call if there was an issue. Mr. Karp stated that they could call either pharmacy.

Dr. Foy stated that he is not sure that it satisfies the shared service regulations.

Ms. Rosas asked if the prescriptions in the machine are patient specific. Mr. Karp stated that they are compounded without the patient's name. Mr. Karp stated that the technology would coordinate the inventory.

Dr. Foy stated that if Mr. Vasililauskas is compounding medications that are not patient specific he is a manufacturer. Mr. Vasililauskas stated that he is compounding in anticipation of the prescriptions so he is not a manufacturer.

Dr. Foy stated that in order to grant a deviation there must be a rule that they want waived.

Mr. Lee stated that the Board could use R4-23- 614.

The Board agreed to grant Integrity Pharmacy and Vasco Pharmacy a deviation for R4-23-614.

**AGENDA ITEM 17– Call to the Public**

President Foy announced that interested parties have the opportunity at this time to address issues of concern to the Board; however the Board may not discuss or resolve any issues because the issues were not posted on the meeting agenda.

No one came forth.