MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
August 6-7, 2014

Idaho State Capitol Building, Boise, Idaho

This meeting of the Board was held to conduct regular Board business.

Chairman Holly Henggeler, PharmD, called the meeting to order at 9:30 a.m. In attendance were Board members Nicki Chopski, PharmD; Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member, as well as Mark Johnston, RPh, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Nicole McKay and Colleen Zahn, DAGs; Fred Collings, Chief Controlled Substance Investigator; Lisa Culley and Jaime Sommer, Compliance Officers; Ellen Mitchell and guests.

Dr. Chopski motioned to approve the minutes of the 7/7/14 minutes with a minor correction; Dr. Jonas seconded, motion carried unanimously.

After the approval of the 7/7/14 minutes, Mr. Johnston updated the Board on several action items contained within the 5/29/14 minutes.

The Board took up the matter of Danielle M Guerra, Certified Pharmacy Technician. Dr. Jonas recused herself due to a professional relationship with Dennis Tofteland. Chairman Henggeler called the hearing order. Colleen Zahn, DAG distributed proof of delivery of the Administrative Complaint and Notice of Hearing. Ms. Zahn explained her conversations with Ms. Guerra, attempting to stipulate. Ms. Zahn motioned for the following exhibits be admitted into evidence, and Dr. Henggeler granted the request. Fred Collings testified that he had received a phone call from Guerra on 12/26/13 indicating she had been arrested for DUI when leaving her job at Wal-Mart Pharmacy. Mr. Collings contacted Dennis Tofteland, PIC, and subsequently received an email from him indicating that Guerra has mood swings throughout the day and is unable to stay focused on her tasks. Katie Stuart, Compliance Monitor for Southworth Associates testified that Guerra was non-compliant with her signed contract and hadn't completed the terms of the contract.

Exhibits:

Exhibit A: Proof of delivery USPS
Exhibit B: Nampa Police Department Officer Report for Incident N13-46583
Exhibit C: Nampa Police Department Drug Influence Evaluation Report
Exhibit D: Patient Profile
Exhibit E: Email dated 1/30/14, from Denise Graveline to Fred Collings re: Danielle Guerra and written statement by Costco Assistant General Manager Troy Allen re: Danielle Guerra
Exhibit F: Prescription Drug Order for Danielle Guerra, dated December 23, 2013
Exhibit G: Prescription Drug Order for Danielle Guerra, dated January 8, 2014
Exhibit H: Email dated 1/9/14, from Dennis Tofteland to Fred Collings re: Danielle Guerra, and Email dated 1/21/14, from Spencer Dalling to Fred Collings re: Technician
Exhibit I: Ascent Behavioral Health Evaluation
Exhibit J: PRN Consent for Release of Confidential Information, signed by Danielle Guerra
Exhibit K: Ashwood Recovery Evaluation
Exhibit L: PRN Advocacy Contract for Danielle Guerra

Ms. Zahn motioned to have Exhibits I and K sealed from public record due to the personal health information contained in them. Dr. Henggeler granted the motion. Ms. Zahn concluded her case by asking the Board to revoke Guerra's registration, as she is unfit to practice and was intoxicated at work. After deliberation Dr. Chopski motioned to revoke Guerra's registration, and Mr. Sperry seconded. The motion carried unanimously.

The Board took up the matter of Richard M. Sutton, RPh. Ms. Zahn presented a Stipulation to Continue Hearing until the October 2014 meeting of the Board. Dr. de Blaquiere motioned to accept the stipulation, and Dr. Chopski seconded. The motion carried unanimously.

Dr. Henggeler asked Mr. Johnston to present the travel calendar and the financial report. Mr. Johnston reviewed recent and upcoming Board staff travel, including Mr. Fraser attending NABP training in IL, Teresa Anderson traveling to IL, DC, GA and UT for meetings pertaining to the Prescription Monitoring Program (PMP), inspectors attending STARS training in CO, Mr. Johnston attending several fall meetings around the country, Dr. Chopski presenting at ISU's White Coat Ceremony, and 6 members of the Board and staff attending the NABP district meeting in MT. The Board then scheduled three 2015 Board meetings: 1/20 in Boise, 4/9 in Pocatello, and 5/28 in Coeur d'Alene. Mr. Johnston reported that the Board finished fiscal year 2014 by expending 99% of the Board's budget. The federal grant was expended by contracting for several upgrades to the PMP. Personnel appropriation from open positions was expended through the provision of handsome bonus to the Board's staff. Operational appropriation was expended by purchasing a sound system for Board meetings, for which appropriation was not approved by the 2014 legislature for the 2015 fiscal year budget but was subsequently approved for purchase in FY14 by LSO and DFM. As for fiscal year 2015, 7.6% of the year has elapsed, and the Board has expended 6.3% of the budget. Mr. Johnston also noted that the northern Idaho inspector position is again posted.

Dr. Henggeler asked the inspectors to initiate the agenda item: inspector question and answer. Mr. Fraser approached the Board with pictures from a pharmacy applicant that showed that the majority of the pharmacy was constructed with large windows instead of walls. Mr. Fraser referred to rule 605: Pharmacy Security, which bans glass doors, but not even larger glass windows. Mr. Fraser believes that the windows pose a security risk. The Board had no appetite to regulate pharmacy windows. The inspectors had no additional topics to discuss.

Dr. Henggeler asked Mr. Johnston to lead the agenda item entitled legislation and rule review. Mr. Johnston referred the Board to the 7/7/14 minutes for changes to the drafts in the current versions he presented, and he noted that all 5 of the Board's PARFs has been approved, including approval of the outsourcing docket of rules as temporary. Four Legislative Idea Forms had been submitted, but none have been approved yet. Mr. Johnston then began reviewing additional changes to the drafts since the 7/7/14 meeting, most of which were contained in a new draft bill addressing wholesale distribution. This bill is necessary due to mandates within the federal Drug Quality and Security Act that bar the Board from regulating the track and trace of drugs, such as pedigrees. Changes not only affected the Wholesale Drug Distribution Act, but the Idaho Pharmacy Act too. While drafting these necessary changes, Mr. Johnston cleaned up several outstanding, but non-controversial issues. Additionally, the draft seeks to incorporate recommendations by NABP's task force on virtual wholesale distributors, address grey wholesaling, and ban pharmacy distribution of controlled substances. This agenda item was paused, as the Board broke for lunch.

Upon returning from lunch, Dr. Henggeler initiated the negotiated rulemaking session.

Kimberly Greco from Amgen was the first to provide public comment, including a Power Point presentation discussing the complicated manufacturing process for biological products, the difficulty that another manufacturer would have in developing a biosimilar product, and their fear of potential FDA approved interchangeable products. Amgen supports the following 5 points and concentrated their comment on point #5:

1. Substitution should only occur when the FDA has designated a biologic product as interchangeable.
2. The pharmacist should keep records of the substitution.
3. The prescriber should be able to prevent substitution.
4. The patient should be notified of the substitution.
5. The prescriber should be notified of the substitution.

Raulo Frear, PharmD, and President Elect of the Academy of Managed Care Pharmacy (AMCP): supports the Board's intent to recognize federal action regarding biosimilar medication, but is concerned about any variation in the biosimilar definitions that may create an unintended limitation, he requested the Board incorporate the federal definition by reference.

Woody Richards, Americas Health Insurance Plan (AHIP): supports the Board's intent to recognize federal action on biosimilar medications, though is concerned the action may be premature. He requested that the Board delay rulemaking, and consider using federal definitions if moving forward now.

Patrick Plues, Biotechnology Industry Organization: supports the 5 points presented by Amgen and noted that the FDA has released six guidance documents on the subject and plans to release three more.

Bruce Lott, VP Mylan: strongly supports the Board's draft and commented on language that other states had passed. He disagrees with notification to the prescriber.

Alan Brewington, Patient Advocate, Global Health Living Foundation (GHLF), supports patient notification.

Elizabeth Criner, American Cancer Society: strongly supports patient and prescriber notification from a patient safety standpoint.

Paul Cady, RPh and Dean, ISU College of Pharmacy, wants the Board to focus on hard data and keep science at the forefront of the discussions verses making an emotional decision.

After all public comment concerning the Board's draft rule on biosimilar substitution was heard, the Board deliberated, starting with the 5 points that were contained within much of the written and verbal comment.

> **Point #1:** Substitution should only occur when the FDA has designated a biologic product as interchangeable. Obviously, much of the public comment that included this point was derived from a uniform communication that was distributed to prescribers, patients, and various advocacy groups who, in turn, communicated this concern to the Board without studying the Board's draft biosimilar substitution rules. As the Board's draft clearly is in harmony with this point, the Board directed no change.
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> **Point #2:** The pharmacist should keep records of the substitution. Mr. Johnston read Board rule 008, which requires all pharmacy records to be maintained and retained in a readily retrievable form and location for at least three years. Mr. Johnston also read rule 100.01 which requires a pharmacy's electronic record keeping system to be capable of real-time, online retrieval of information stored within for a minimum of 15 months from

the date of entry. Although some of the comment requested a longer retention period, the Board declined to direct changes to the draft that would create a separate record retention period. Mr. Johnston then read rule 130.02, which requires the name of the drug and the name of the manufacturer or the NDC number to be documented in the patient medication record with each generic selection. The Board readily agreed that this parameter should be added to the draft biosimilar substation rules.

Point #3: The prescriber should be able to prevent substitution. Mr. Johnston read rule 130.01: "If a prescriber orders by any means that a brand name drug must be dispensed, then no drug selection is permitted". The Board readily agreed that no substitution should be permitted if the prescriber orders by any means that the prescribed biologic product must be dispensed and directed Mr. Johnston to draft such changes.

Point #4: The patient should be notified of the substitution. Much Board discussion ensued, including the proceedings that surrounded the enactment of Section 54-1770, Idaho Code a few years ago: Notification of Drug Product Selection for Epilepsy and Seizure Drugs. The various drafts of the bill and hearings at the Idaho Legislature were vary contentious. While some of the public comment on the topic included notification and/or patient authorization prior to substitution, such previous debate had already determined that the likely resultant delay in therapy would be too much of a public safety risk. Mr. Johnston read the definition of counseling from the Idaho Pharmacy Act: "Counseling or counsel means the effective communication by the pharmacist of information as set out in this chapter, to the patient or caregiver, in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices. Specific areas of counseling shall include, but are not limited to then name and strength and description of the drug…" The Board determined that patient notification was indeed already required by law as part of counseling and directed no change to the draft.

Point #5: The prescriber should be notified of the substitution. Public comment included mandatory prescriber authorization prior to substitution, but that is prohibited by federal law. Various public comment also included notification prior to substitution, in a reasonable time after substitution, and only upon initial substitution (not for refills). The Board intensely deliberated this point, often referencing public comment, including references to studies that indicate that prescriber notification leads to increased rates of brand drug dispensing and increased health care costs, that a prescriber is unlikely to takes steps such as calling a pharmacy to see what product was dispensed, and that prescriber notification is more likely an attempt to preserve brand name drug market share as opposed to providing better public safety. The Board noted that Florida recently passed a bill that did not require notification and that Massachusetts's bill defined a pharmacy's accurate patient medication record as prescriber notification. The various means of obtaining dispensing information was also discussed, including looking at the dispensed product, calling the pharmacy, and querying Idaho's Health Data Exchange. Ultimately, the Board decided not to make changes to the draft that would mandate prescriber notification.

The Board considered several pieces of public comment concerning the draft definitions within the biosimilar substitution docket of rules. Ms. McKay stated that the Board's focus is simply upon interchangeability, unlike the federal government who has many other duties, such as biosimilar drug approval. The Board's draft definitions do not contain the references to federal law that the federal definitions do; otherwise the definitions are nearly exact. Ms. McKay believes that the lengthy references to federal law in the federal definitions would be confusing

for Idaho citizens and suggested that the Board not change the draft definitions, pursuant to public comment. Mr. Johnston noted that he has routinely heard comment during rules hearings that Idaho legislators do not like to incorporate by reference or make the reader of Idaho law refer to another document to fully understand. The Board agreed with Ms. McKay's assessment of form over substance and did not authorize any changes to the draft definitions contained within the biosimilar docket of rules.

Finally, the Board considered various single points of comment from various pieces of public comment that were not uniformly contained within the majority of the comment received, as well as noting several pieces of public comment that were simply in support of the Board's draft language. The Board directed no additional changes pursuant to such public comment.

The Board considered written public comment from Jim Stevenson, RPh, from the Medicine Shoppe in Rexburg, Idaho. Mr. Stevenson would like the draft compounding rules to only require hoods and aseptic environmental control devices to be certified for operational efficiency at least every 12 months, as opposed to the drafted change to 6 months. Elaine Ladd, PharmD, participated in the discussion, in favor of the 6 month change. Dr. Jonas motioned to strike the change to 6 months, therefore preserving the current 12 month requirement. Dr. Chopski seconded. Dr. Henggeler called for the vote: two for and two against. Dr. Henggeler broke the tie with a nay vote and the motion failed. The draft change to 6 months remains. The Board also considered two other requests for clarification by Mr. Stevenson, but directed no change, as the Board believed the rule was clear.

The Board considered Matthew Murray's, PharmD, written public comment. Dr. Murray would like to draft rule 144.03 to pertain only to sterile compounded drug product, as identifying and listing all bases and diluents for topical compounded drug product would be difficult and cumbersome. The Board agreed with Dr. Murray and directed Mr. Johnston to make such change.

The Board considered Dr. Ladd's written public comment. Dr. Ladd appeared in support of her comment and was actively involved in the deliberation. Ultimately, the Board directed Mr. Johnston to make the following changes to the draft compounding docket of rules:

> 240.01: add "in or into Idaho".
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> 240.05.a: add "sterile or the ability to sterilize" in front of non-vinyl gloves.
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> 240.06.b: require training on a routine basis.
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> 240.06.c.ii: Strike "initial" and replace with "periodic".
>
> 241.03.c: change "volatize" to "volatilize".
>
> 242.01: exempt compound positron emission tomography drugs and radio pharmaceutics.

The Board considered the written public comment from Dan Bellingham of HDMA. The Board agreed with Mr. Bellingham's comments concerning the Idaho Wholesale Drug Distribution Act only pertaining to prescription drugs and not devices and that the draft provision to require a wholesale distributor to identify suspicious ordering should only pertain to controlled substances. The Board directed Mr. Johnston to strike "and devices" from the definition of manufacturer and replace "prescription drugs" with "controlled substances" in draft 54-1753(7). Mr. Johnston would also like to add "drugs that are outside of the prescriber's scope of practice" to 54-1753(7). Mr. Bellingham would also like the Board to consider using definitions, word for word, from the federal Drug Quality and Security Act. The Board reviewed some of the federal

definitions, which contained many references to federal code. The federal definition of wholesale distribution was specifically reviewed and deemed to be contrary to Board's desire to remove current actions within Idaho's definition of wholesale distribution that are truly forms of distribution and list such actions as exemptions to licensure. Ms. McKay pointed out that the focus of the federal act is upon licensure, practice standards, and track and trace of prescription drug product, while the Board's focus is now just upon registration and practice standards; therefore many of the federal definitions are not appropriate for Idaho's needs. Mr. Johnston noted that the draft bill did contain some changes pursuant to Mr. Bellingham's comments, such as within the definition of manufacturer, and Mr. Johnston thought that the definition of reverse distributor could be enhanced with federal language. The Board directed Mr. Johnston to review all definitions again, but not to use the federal definitions, word for word.

Dr. Henggeler asked for additional public comment and there was none.

Mr. Johnston resumed the legislation and rule review agenda item, and after much deliberation, the Board directed Mr. Johnston to make the following changes:

54-1705(5): update the definition of "compounding".

54-1732(3)(d)(ii): strike the draft language "that are controlled substances" and create rule changes that would mandate that pharmacy distribution of legend drugs are regulated the same as a wholesale distributor's distribution. Mr. Johnston thought rule #270 was a suitable location for the change.

54-1735: due to the striking of 54-1735(1), change the title to Patient Medication Records

Current 54-1752(16) & 54-1752(17)(l): strike, if additional legal study warrants.

Current 54-1752(17)(k) and draft 54-1754(2): ensure that pharmacy returns are not considered wholesale distribution.

37-2701: make the same changes to the definition of manufacture that HB239 did in 2013.

Dr. Jonas motioned to adjourn the meeting until August 14 at 8:00 a.m., Mr. Sperry seconded, motion carried unanimously. Meeting adjourned at 4:50 p.m.

August 14, 2014

Chairman Holly Henggeler, PharmD, called the meeting to order at 8:02 am. In attendance were Board members Nicki Chopski, PharmD; Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member as well as Mark Johnston, RPh, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Nicole McKay and Scott Zanzig, DAGs; Fred Collings, Chief Controlled Substance Investigator; Lisa Culley and Jaime Sommer, Compliance Officers; Ellen Mitchell and guests.

The Board took up the matter of Andrew Welch, PharmD. Mr. Zanzig presented the Request for Entry of Final Order. An administrative hearing was held on May 23, 2014 in which Welch stipulated that he did not oppose revocation of his license. The request presented contains the factual and procedural background; it is the recommendation of the hearing officer that Welch's license be revoked. Mr. Zanzig confirmed Welch received a Notice of Hearing for this date, neither he nor his counsel is in attendance. Mr. Zanzig stated that Welch had stipulated and did not attend the hearing as he did not want to testify. Mr. Zanzig requested the Board revoke

Welch's pharmacist license and controlled substance registration as per the recommendation. Dr. Chopski motioned to accept the order and revoke. Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board took up the matter of Laura Reed, OD. Mr. Zanzig presented the Stipulation and Consent Order. During review of Moore Medical's sales report Mr. Collings found that Reed had purchased controlled substances in December 2013, September 2013 and May 2011. After a search of the Board's licensing data base Mr. Collings discovered Reed's facility was not registered as a Prescriber Drug Outlet (PDO). Mr. Collings visited Reed at her office on January 16, 2014. Reed disagreed that she needed a PDO as she doesn't dispense medications for patient use outside her office. Mr. Collings met with Reed at her office again on January 31, 2014 and took possession of several controlled substances that were expired. During this meeting Reed also admitted she administered outdated controlled substances to her patients; she was not maintaining inventories, invoices or dispensing logs for the controlled substances she had purchased. Pursuant to the Stipulation and Order Reed will not order for wholesale purchase, handle (except as prescribed by another prescriber), administer or dispense any controlled substances, including samples, for office use, will not store controlled substances in her office, home or car and will abstain from personal use or possession of controlled substances, except those prescribed, administered or dispensed to her by another authorized prescriber. Dr. Chopski motioned to accept the stipulation as written, Mr. Sperry seconded, motion carried unanimously.

The Board took up the matter of Thomas F. Call, DDS. Mr. Zanzig presented the Stipulation and Consent Order. During a review of Henry Schein's sales report Mr. Collings found that Call had purchased controlled substances on June 26, 2013. After a search of the Board's licensing data base Mr. Collings discovered Call's facility was not registered as a Prescriber Drug Outlet (PDO). Mr. Collings visited Call at his office on September 17, 2013 and spoke with the office manager who informed Mr. Collings they did not dispense medications. Call telephoned the Board office on September 25, 2013 and admitted to Mr. Collings that he had had purchased controlled substances for his own personal use and acknowledged he knew it was a violation. Pursuant to the Stipulation and Order, Call will not handle (except as prescribed by another prescriber), administer or dispense any controlled substances, including samples, for office use, will not store controlled substances in his office, home or car and will abstain from personal use or possession of controlled substances, except those prescribed, administered or dispensed to her by another authorized prescriber. Dr. Jonas motioned to accept the stipulation as written, Dr. de Blaquiere seconded, and the motion carried unanimously.

Dr. Henggeler asked for public comment and there was none.

Mark Vance, ISU student pharmacist, appeared in support of his written comment concerning rule 330's use of auto-inject epinephrine. Mr. Vance believes that pharmacists should be allowed to inject epinephrine from an ampule or a vial, and he detailed costs, a study pertaining to injection times of the various products, and surrounding state law. The Board and Mr. Vance deliberated, and the Board ultimately decided that epinephrine vials were acceptable, if stocked with dosing instructions, syringes and needles for injection. The Board also approved of epinephrine ampules, if stocked with dosing instructions, filter needles, syringes, and needles for injection. The Board directed Mr. Johnston to draft such changes.

Dr. Henggeler welcomed participants for the agenda item: counseling discussion. In attendance were Al Carter, PharmD, Walgreens; Rory Lambert, PharmD, Rite-Aid; Lonnie Reiber, PharmD, Fred Meyer; Pam Eaton of the Idaho State Pharmacy Association; Lynette Berggren and Curt Ater, PharmD, from Albertsons, and from Wal-Mart were Aaron Bishop, Jeff Dalke, PharmD, and Debbie Mack. Ms. Mack presented a Power Point showing screen shots of Wal-Mart's

soon to be released computer enhancements, including the documentation of counseling. Afterwards, Dr. Henggeler proceeded to ask each panelist previously distributed questions concerning counseling documentation, counseling policy, work flow, and pharmacy electronic record keeping systems. While the discussion revealed several similarities between the pharmacies, differences were also discussed. For example, Albertsons utilizes pharmacist biometric fingerprinting as a hard stop when counseling is required. Fred Meyers issues daily passwords to pharmacists to enter, which creates a hard stop when counseling is required. Wal-Mart's new system will also hard stop for a pharmacist to document counseling when required, while Rite-Aid, Walgreens, and the independent's systems allow for a technician or pharmacist to document that counseling occurred. Walgreen's electronic record keeping system did not capture offers to counsel, so their pharmacies were keeping a hard copy log to satisfy this requirement. Dr. Ater noted that dispensing physicians and mail order pharmacies were noticeably absent from the discussion. Mr. Sperry believed that the offer to counsel on refills was not needed, and he was satisfied with mail service distribution of paperwork and toll free numbers on the shipments that he personally received. The discussion was lively and lengthy and upon its conclusion the Board discussed potential changes to law. Via unanimous consent, the Board did not believe that changes to Idaho Code were needed at this point. Dr. Jonas motioned to not change rule 105: patient Counseling Documentation. Dr. Chopski Seconded, and Dr. Henggeler called for the vote. The motion passed with 3 in favor and Mr. Sperry opposed. The Board instructed Mr. Johnston to pen a newsletter article that reaffirmed counseling law and highlighted recent counseling discipline. The Board directed the inspectors to highlight counseling when inspecting. Historically, the Board has only disciplined for counseling violations that were discovered as part of an investigation into a misfilled prescription, but the Board directed the Board's staff to address egregious counseling documentation violations, up to and including noticing the PIC and pharmacy for hearing. The Board also directed Mr. Johnston to hold a similar session with dispensing prescribers and mail service pharmacies, including out-of-state compounding pharmacies. Dr. Henggeler thanked the participants, especially those who traveled great distances to attend.

Dr. Henggeler asked for public comment and there was none.

Eric Litner, RPh, Consonus Pharmacy addressed the Board with a request to add nurse electronic transcription and subsequent electronic delivery to Section 54-1733, Idaho Code: Validity of Prescription Drug Orders. Mr. Litner presented a Power Point detailing Consonus' software that has been integrated with pharmacy software and is used in long term care facilities. Kris Ellis from the Idaho Health Care Association indicated they are in support of such a change and offered her assistance in running a bill to complete this change. Mr. Johnston noted that a hospice agency had requested changes to 54-1733 years ago that would allow a hospice nurse to transmit prescription drug orders to a pharmacy just like a nurse in an institutional pharmacy is allowed to do. At that time, the Board agreed conceptually but declined to run the change. As the hospice agency never ran their own bill and the issue still exists within 54-1733, Mr. Johnston suggested adding this change to the proposed bill. Additionally, Mr. Johnston believes that 54-1733 could use substantial reorganization, as it reads poorly due to all the various changes over the years that were not run by the Board. The Board directed Mr. Johnston to submit a Legislative Idea Form and develop such language for review at the October 2014 meeting.

Jaime Sommer asked for clarification of what can be changed on a schedule II prescription drug order, as the Board's policy printed in a Newsletter seemed to conflict with rule 110.03: tampering. The Board agreed that the rule did not prohibit pharmacies from utilizing the policy.

Hearing no further discussion Dr. de Blaquiere motioned to adjourn, Dr. Jonas seconded, motion carried unanimously. Meeting adjourned 2:27 p.m.