

GUAM BOARD OF EXAMINERS FOR PHARMACY

Department of Public Health & Social Services 123 Chalan Kareta, Mangilao, GU 96913 Tel: (671) 735-7407 • Fax: (671) 735-7413

REGULAR SESSION MINUTES

Thursday, January 18, 2018, 7:30 a.m. Terlaje Professional Building, Suite 209 194 Hernan Cortez Ave., Hagatna, GU 96910

MEMBERS PRESENT: Thomas Caruso, Chairperson; Lourdes Phillips, Vice Chairperson; Angelina Eustaquio, Secretary; Racquel Sperrazzo, Member

MEMBERS ABSENT:

OTHERS: Heather Narcis, HPLO; Mary Chargualaf, ExpressMed Representative; Adela Carlos, Harmon Drugs Pharmacist; Glenn Carlos, Harmon Drugs Manager

	TOPIC	DISCUSSION	ACTION
	Call to Order	Chair called the meeting to order at 7:49 a.m. as a Regular Session Meeting.	Quorum Established
)	Proof of Publication Notice	Advertisement printed in the Pacific Daily News on January 11, 2018 and January 16, 2018	Meeting Published in a timely matter
	Review and Approval of Agenda	 Ms. Eustaquio asked to add Newsletter to VII. Other as Letter E. Ms. Sperrazzo moved to approve the agenda as amended. Ms. Eustaquio seconded. All in favor. 	Agenda approved as amended.
	Review and Approval of Minutes	A. December 21, 2017 - Minutes tables as they were unavailable.	Tabled until next meeting.
	Old Business	A. Rules and Regulations 1. Immunizing Pharmacists - Ms. Sperrazzo had a working session with AAG Weinberg and Ms. Mildred Gabriel, GPhA President to discuss the proposed law for Immunizing Pharmacists. Ms. Sperrazzo provided three documents for board members to view. - Document #1 is an article on the latest vaccine policies that AAG Weinberg had emailed members in the early part of October. The workgroup had agreed that pharmacists will be moving away from protocol driven, collaborative practice agreements and immunizing protocols to independent authority to administer immunizations. This was a primary change made to the draft law. - Document #2 is the updated draft law and rules for	A. Ms. Sperrazzo will head the Rules Committee with help from board members. Working session will be scheduled after next meeting or upon review of all information/documents.
		- Document #2 is the updated draft law and rules for Immunizing Pharmacists. Item #1 says that licensed	

- vaccines to adult and pediatric patients. Ms. Sperrazzo included an age disclaimer for the board to review and discuss as it was never decided on. Item #2 states a training requirement for basic life support as well as pharmacists having to comply with Guam and federal requirements for reporting.
- AAG Weinberg asked if the laws and rules were modeled after any states. Ms. Sperrazzo stated that California was used as a model for the law. While California, Connecticut, and other states were used as a model for the rules.
- The intention of the changes is so that the law can be broad and simple, yet follow federal guidelines already in place. As the guidelines change the board won't have to make amendments in the future.
- Mrs. Phillips asked if there was a number 2 under the law section. Ms. Sperrazzo stated that she removed the section regarding collaborative practice agreements as we are trying to move away from that. Mrs. Phillips asked if an option for collaborative practices can be addressed and included in the rules as it may apply to other practices.
- Mrs. Phillips asked if draft addresses immunizing offsite, i.e. community outreaches, health fairs, etc. Ms. Sperrazzo stated it is not addressed but can be brought up for discussion to be included in draft. Ms. Eustaquio asked if there were other things, other than storage, to consider when doing off-site immunizations. Ms. Sperrazzo has not seen any other laws/rules addressing off-site immunizations, but some laws/rules state that it didn't prevent pharmacists from participating in public health events.
- Mr. Caruso asked if there was any consensus if there should or shouldn't be an age limit. His opinion is there should be an age limit of 12 years old or over. Ms. Sperrazzo mentioned that she got the impression that Ms. Gabriel, GPhA and other members would like the age limit to be open. When considering the age limit, there is more to discuss; i.e. informed consent of minors. Mrs. Phillips mentioned that Kmart pharmacists do not want to immunize children, anyone under 18 years of age.
- The draft is still a work in progress. Ms. Sperrazzo stated that the goal is to come up with an updated, final draft before presenting to stakeholders and public. Ms. Sperrazzo has requested for members to review the current draft and email her if there are any comments, ideas, changes, etc.

- 2. Electronic Prescribing
 - Mrs. Phillips sent members an email on January 13,
 2018; contents of email were PDF files of Tennessee's Rules and Guam's Draft on electronic prescribing.
 - Per Mrs. Phillips, the board had contacted Division of Environmental Health (DEH) Controlled Substance Registration (CSR) Program to find out if they allow electronic prescribing of controlled substances. The answer was no, all prescriptions for controlled substances had to be in a written, hard copy per local laws and rules even if federal allows it.
 - At one point, the board had a working group for rules on electronic prescribing. The board used Tennessee Board of Pharmacy's rules as a model and added what was thought to be appropriate into the draft rules. The draft rules were called "Rules for Facsimile and Electronic Medical and Prescription Orders'. It also stated that "no electronic order for controlled substances are accepted per Guam Uniform Controlled Substances Act. Prescriptions must be written."
 - Ms. Sperrazzo asked how old the proposed rules are and if it is possible there are any updates since they were created. Mrs. Phillips stated that the proposed rules were created in 2014 and is not sure if there have been any federal updates. When she spoke with Rosanna Rabago at DEH a year ago, things were slow on their side as far as updates to local rules.
 - Mrs. Phillips suggested forming an active Rules Committee. Mr. Caruso asked Ms. Sperrazzo to chair this committee. Ms. Sperrazzo doesn't mind as long as she doesn't do it alone. Members will assist as well. Ms. Eustaquio and Mrs. Phillips will pull all information/documentation on any other draft rules they have and provide to Ms. Sperrazzo for review.
 - Ms. Sperrazzo will email members to schedule a working session.

B. Harmon Drugs Investigation

- 1. Renewal of Pharmacist License for Adela Carlos
- 2. Renewal of Pharmacy License for Harmon Drugs
 - Ms. Narcis reminded members that in the October meeting it was decided to send a letter to Mrs. Carlos requesting to appear before the board to answer questions regarding the investigation before making a decision on renewal applications. Ms. Narcis had received a letter from Mrs. Carlos dated January 11, 2018. Mr. Caruso read the letter aloud for members.
 - Mrs. Phillips gave a recap of inspections conducted at Harmon Drugs on January 27, 2017 and March 31, 2017. These inspections found that Harmon Drugs

B. The Board will work on disciplinary actions and present documents to Mrs. Carlos at the next board meeting.

- was operating without a licensed pharmacist in the facility. The board consulted with AAG Weinberg and DPHSS Director James Gillan. Mr. Gillan indicated he was going to send an inspector from DEH to conduct an inspection as well.
- Mr. Caruso asked Mrs. Carlos if she understood the seriousness of the violations. Mrs. Carlos stated yes.
 Mr. Caruso informed Mrs. Carlos that the board has discussed possible actions but nothing has been done as of today.
- AAG Weinberg asked if the pharmacy has been open since Mrs. Carlos left. Mr. Glen Carlos confirmed that the pharmacy has been closed since May 1, 2017. AAG Weinberg asked Mrs. Carlos what are her plans; if she will be renewing just her pharmacist license or will she be opening the pharmacy for business. Mrs. Carlos plans to open the pharmacy and continue to serve the community. AAG Weinberg asked Mrs. Carlos if she understood that the pharmacy cannot be open unless there is a licensed pharmacist on duty. Mrs. Carlos stated they will hire a pharmacist if they can find one.
- Mr. Carlos asked what the status is on the renewal of licenses. Mr. Caruso stated that because there has been no contact with Mrs. Carlos, the board has not been able to move forward.
- Mr. Carlos wanted to know if the disciplinary complaint was drawn up after the last inspection because he would like to dispute the inspection score. He stated that the inspectors had Mrs. Carlos sign a report with the score of 84 not 79. In addition, he did not like how the inspectors and auditor showed up at the same time when they were supposed to be separate inspections.
- AAG Weinberg reminded Mr. Carlos that at the moment, the serious matter at hand is that the pharmacy was being operated without a licensed pharmacist present and unlicensed personnel were in the service area where controlled substances and prescription drugs were held. The board, at this point, is not convinced that Mrs. Carlos understands the significance of having left the pharmacy in the hands of unlicensed personnel.
- Now that the board is aware of Mrs. Carlos' plans to reopen, the board does have some minimum requirements such as another inspection, hiring of a full time pharmacist-in-charge, and requiring Mrs. Carlos to pass the MPJE.
- At the moment, the board is not prepared to issue the pharmacy or pharmacist's license renewal today. The disciplinary complaint will be finalized by next meeting for Mrs. Carlos to review. AAG Weinberg

mentioned that it can either be used as a charging document where licenses will be permanently revoked or suspended under conditions. Or it can be used as a settlement agreement with requirements of what needs to be done in order to open business and retain licenses. Mr. Caruso strongly suggested to work out a settlement. The board is trying to be fair to everyone who practices pharmacy on Guam and to ensure public safety.

C. Review and Renumbering of GBEP Forms

- Working session has been scheduled for Sunday, January 21, 2018.
- Hoping to finalize forms 1-11 and 22. Then move on to 12-21. Checklists can be worked into the working session as well.
- Ms. Eustaquio gave Mr. Caruso and Ms. Sperrazzo copies of forms for their review and editing at working session.
- Ms. Eustaquio asked Ms. Narcis to send all checklists and requirements via email.

D. Potential requirements for licensure (disciplinary questionnaire and court/police clearance)

Members will try to add into working session.

E. Referral on Mega Drug - from EnvisionRx

- Ms. Narcis reminded Mr. Caruso that at the last meeting he mentioned he will do a follow up with Mr. Frank Campillo at SelectCare Insurance.
- During their last discussion, Mr. Campillo informed Mr. Caruso that SelectCare had found five other pharmacies, including one in Saipan, that were billing for Relion insulin. SelectCare conducted their own investigation/audit and has settled the issue regarding the claims. Mr. Campillo did not give Mr. Caruso specifics.

F. Complaint GBEP CO-16-01

- Ms. Eva Aguon has reviewed the data files provided by the Medicaid office and it has opened more questions than it answered.
- There are at least 2-3 other products that raised questions about supply chain. Those products were the OneTouch Ultra glucometer, Rectacort HC, and Lipodox.
- Ms. Aguon found that one patient had 401 prescriptions filled within a two year period, approximately 18-19 prescriptions a month. A lot of controlled substances.
- Per Ms. Aguon, there are 108,000 claims from May 2015 to June 2017. Calculations show an estimate of 180 claims per day, assuming the pharmacy is open 7 days a week.
- December 2015 sparked interest. The pharmacy was trending at 4,000 prescriptions in a month, but in

C. Next working session is scheduled for January 21, 2018 at 2:00p.m. at the GMH Skilled Nursing Unit.

- D. Forms Committee will bring up in working session. Tabled.
- E. Mr. Caruso will follow up once again with Mr. Campillo

F. Ms. Narcis will contact Mrs. Arcangel at Medicaid office to schedule a meeting regarding findings.

- December 2015 it dropped to 112-120 prescriptions. Then in January to April 2016, the claims increased by 10-20%.
- In order to understand what is going on with claims, will need to go to Medicaid office and inspect the actual documents that were submitted and inquire about the reimbursement policies.
- AAG Weinberg asked if this information was shared with the Medicaid office. It has not been shared yet as Ms.
 Aguon discovered information in the last two days. Ms.
 Narcis will contact Teresa Arcangel at Medicaid office to set up a meeting to discuss findings.
- AAG Weinberg mentioned that if the AG's Office needs to be brought in, let him know.

G. Inquiry from Stephanie March, PharmaLicense LLC, regarding Virtual Manufacturer

- Ms. Greenwood was supposed to send a draft response to members for review before sending to Ms. March.
- Mrs. Phillips recalls Ms. Greenwood stating that she had a conversation with a few individuals at the NABP Forum.
 Anyone looking to apply as a Virtual Manufacturer raises a big red flag.
- Board decided to remove Virtual Manufacturing from application if it was included.
- Ms. Eustaquio will follow up with Ms. Greenwood if this was done. If not, Ms. Eustaquio will send response.

H. Schedule of Inspection of Retail and Wholesale Outlets

- Ms. Eustaquio and Mrs. Phillips will conduct inspection of Public Health Inarajan on 01/24/2018 at 2pm.
- Ms. Eustaquio and Ms. Sperrazzo will try to do inspection of SuperDrug Agana before next board meeting.
- Ms. Mary Chargualaf informed the board that MedPharm wants to expand their existing pharmacy room and would like to know if there is any changes in requirements needed to be completed. Mr. Caruso stated that requirements are all the same. They will need to submit floor plan, security contract, etc.
- Inspections tabled until next meeting.

I. PTCB Representatives

- PTCB representatives conducted presentation in November 2017.
- Informative
- Per Ms. Narcis, it was kept on the because it was decided in November that the board will recap what happened at presentation.

J. Questions from Meeta Chadha

 Ms. Eustaquio read notes from October meeting that stated Mr. Caruso will send a letter to all boards about prescription requirements. G. Ms. Eustaquio will follow up with Ms. Greenwood on draft response and then send a formal response, via email, to Ms. Stephanie March.

H. Tabled.

I. Presentation was done in November.

J. Ms. Narcis will send an email to all members regarding meeting schedules

	 Mrs. Phillips mentioned that currently pharmacists are just asking patients for information if it is missing. If DEA number is missing, pharmacists either call physicians, look it up on the Department of Justice website, or on the CSR listing from DEH. Ms. Eustaquio suggested to do what Guam Board of Examiners for Optometry does; send a letter that lists people who are allowed to prescribe. Per Mrs. Phillips, Mr. Joseph Quinata wrote one in 2013-2014 but was never aware if it made it to other board's agendas. Ms. Narcis was requested to email members with meeting schedules for Allied Health, Nursing, Medical and Dental Board. 	for Allied Health, Nursing, Medical and Dental boards.
New Business	 Controlled Substances Registration Requirement Ms. Narcis checked with DEH as to why some Non-Resident applicants had their CSR Application and payments returned. Per Michelle Lastimoza at DEH, they do not register off-island distributors. AAG Weinberg asked Ms. Lastimoza for more clarification on their rules regarding registration for controlled substances. Ms. Lastimoza informed him that the individual/facility must be located on Guam in order to obtain a Guam CSR as they cannot inspect off-island facilities, as required in the law. Upon further email discussions, Mr. Tom Nadeau (DEH) informed AAG Weinberg that if the AG office is interpreting the law differently then he is ok with that. They just want to be consistent in the interpretation and application of the law. Mr. Nadeau is requesting for an office memo from the AG's office to register off-island applicants so that they can include in their SOP (Standard Operating Procedures). AAG Weinberg asked the board for their opinion and should it be enforced that applicants obtain a Guam CSR. Board agrees and recommends registering applicants with DEH CSR Program. AAG Weinberg will discuss more with AG's Office. 	AAG Weinberg will further discuss the interpretation of law and memo with the Attorney General's Office.
Old Business	New Pharmacy Location Inspection - Mr. Caruso stopped by last month and everything is in place. Pacific Healthcare Pharmacy is currently open for business	Pharmacy has passed inspections and requirements and is open for business.
New Business	A. Recommendation Letter for Gary Roy	A. Ms. Narcis will prepare recommendation letter for Mr. Caruso's signature and routing to Governor's Office.

B. New - Non-Resident Facility

- Express Scripts OH
- 2. J. Knipper and Company, Inc IN
- 3. J. Knipper and Company, Inc NJ
- 4. J. Knipper and Company, Inc NJ
- Priority Healthcare Distribution, Inc dba CuraScript SD Specialty Distribution – AZ
- Priority Healthcare Distribution, Inc dba CuraScript SD Specialty Distribution –OH
- 7. Priority Healthcare Distribution, Inc dba CuraScript SD Specialty Distribution –TN

C. New - Pharmacist by Endorsement

- 1. Cano, Joseph V
- 2. DeHaemers, John P
- 3. Redman-Sullivan, Melody
 - Cano, Joseph is pending License Verification from Home State and one Letter of Recommendation.
 Tabled pending receipt.
 - Ms. Sperrazzo moved to approve DeHaemers, John and Redman-Sullivan, Melody for licensure pending passing of MPJE. Ms. Eustaquio seconded. All in favor.

D. New - Pharmacy Technician

- 1. Bergonia, Mark Anthony RPT
 - Ms. Sperrazzo moved to approve Begonia, Mark for licensure. Ms. Eustaquio seconded. All in favor.

E. New - Pending Item(s) - Applicants have been emailed/called

Pharmacist by Endorsement

- 1. Besteman, Gina Application for Endorsement
- 2. Frobel, David Application for Endorsement
- 3. Kassim, Tokunbo Verification of Licensure
- Renfer, Christine Clarification if disciplinary action was resolved
- 5. Smith, Heather Verification of Licensure
- 6. Strike, Bruce Original Verification of Licensure

Renewal - Pharmacy Technician

 Shin, Jongkeon – Completion of Pharmacy Technician Renewal Application

Non-Resident Facility

- 1. Complete Care Pharmacy
 - Clarification on #4, DEA copy, CSR (if needed)
- ESI Mail Pharmacy Service, Inc. dba ESI Distribution Services
 - Clarification on application #4, copy of DEA and CSR
- 3. ESI Mail Pharmacy Service, Inc. dba Express Scripts

B. Tabled until next meeting.

C. DeHaemers, John and Redman-Sullivan, Melody are approved for licensure pending passing of MPJE.

Cano, Joseph tabled pending receipt of home state license verification.

- D. Begonia, Mark is approved for Pharmacy Technician license.
- E. All pending applications have been tabled.

	 Copy of DEA and CSR Independence Holding Company LLC dba Complete Care Pharmacy Clarification/Correction on #6, copy of DEA and CSR Sina Drug, LLC dba Onco360 – KY Clarification of what business intention is/what is being shipped to Guam Sina Drug, LLC dba Onco360 – NY Clarification of what business intention is/what is being shipped to Guam Smith Medical Partners, LLC Clarification on #4, copy of DEA and CSR Walgreens Specialty Pharmacy, LLC DEA and CSR copy 	
Other	A. Reassignment of Margaret Greenwood's Duties - Ms. Eustaquio will send response letter for Virtual Manufacturing to Ms. Stephanie March - Mrs. Phillips will assist Ms. Eustaquio with inspection of Public Health Inarajan - Ms. Sperrazzo will oversee the working session on Immunizing Pharmacists Laws and Rules - Mr. Caruso asked if Ms. Greenwood will be returning and if she is open to assisting with inspections. Per Ms. Narcis, Ms. Greenwood is willing to assist. Ms. Narcis will draft letter for Ms. Greenwood as an authorized agent of the board for Mr. Caruso's signature.	A. Assignments have been reassigned. Ms. Narcis will draft an authorize agent letter for Ms. Greenwood.
	B. Change of PIC 1. FHP Pharmacy - New PIC is Sunny Suhr 2. Perezville Pharmacy - New PIC is Patrick Pang	B. Noted.
	C. NABP Forum November 2017 – Report from Margaret Greenwood Ms. Narcis printed copies for all members to review.	C. Members will review report from Ms. Greenwood.
	 D. NABP Notices/Meetings Update on New NABP Online Systems Ms. Narcis informed members that NABP will be making online system changes between March and April. MPJE Item Development Workshop – March 6-8, 2018; NABP Headquarters Members decided to ask Mrs. Phillips if she would like to attend this year as she has done it before. NABP 114th Annual Meeting – May 5-8, 2018; Denver,CO Ms. Sperrazzo will check with work schedule if she is able to attend. 	D. Ms. Narcis will email notices to members for their review.
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GBEP Regular Session Minutes January 18, 2018 Page **10** of **10**

	 4. APhA Training – May 30 – June 3, 2018; Sal Lake City, UT - Ms. Eustaquio may be able to attend. 	
	E. NABP Newsletter	E. Tabled.
Announcement	The next Pharmacy Board Meeting is scheduled for Thursday, February 15, 2018 at 7:30a.m, HPLO Conference Room	
Adjournment	Ms. Sperrazzo moved to adjourn meeting at 10:55 a.m. Ms. Eustaquio seconded. All in favor.	