

**AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING**

November 20, 2012

**Renaissance at SeaWorld
6677 Sea Harbor Drive
Orlando, FL 32821
(407) 351-5555**

**PLEASE TURN OFF ALL CELL PHONES, PAGERS, AND BEEPERS DURING
THE MEETING. THANK YOU.**

Board Members:

Cynthia Griffin, PharmD, Chair, Jacksonville
Albert Garcia, BPharm, MHL, Vice-Chair, Miami
Michele Weizer, PharmD, Boca Raton
Gavin Meshad, Consumer Member, Sarasota
Jeffrey J. Mesaros, PharmD, Tampa
Lorena Risch, Consumer Member, Bradenton
DeAnn Mullins, BPharm, Lynn Haven
Debra B. Glass, BPharm, Tallahassee
Leo J. "Lee" Fallon, BPharm, PhD, The Villages

Board Staff:

Mark Whitten, Executive Director
Tammy Collins, Program Operations Administrator

Board Counsel:

David Flynn, Assistant Attorney General

Department of Health Staff:

John J. Truitt, Assistant General Counsel
William Miller, Assistant General Counsel

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the Board's website.

Tuesday, November 20, 2012 - 9:00 a.m.

9:00 a.m. - Call to Order by Cynthia Griffin, PharmD, Chair

All Board members were present, except for Michele Weizer and Gavin Meshad.

Dr. Griffin welcomed individuals in the audience, including Robert Jernigan, Christina Wiggins, Ashley Carr, Cassandra Pasley, Suzie Love and Rebecca Poston with the Department of Health, as well as, David Flynn, the Board of Pharmacy's new Board Counsel.

Dr. Griffin requested that all cell phones, pagers, and beepers be turned off. She informed everyone that the meeting is being recorded and an audio file will be posted on the Board's website after the meeting.

Dr. Griffin stated goals to be accomplished within the time frame of the meeting, which were:

- Review and discuss current regulations, rules and guidelines related to compounding and non-resident pharmacies
- Review results of the voluntary survey of Florida compounding pharmacies that was conducted prior to this meeting
- Review current pharmacy inspection processes and discuss proposed changes
- Determine if appropriate rules and regulations are already in place to manage the oversight of the compounding process and to protect the public, while maintaining the value and integrity of the compounding process
- Determine if appropriate guidelines, rules and penalties are in place for disciplinary action against pharmacies and practitioners engaged in the practice of compounding in the event of negative occurrences
- Propose recommendations that can be acted upon immediately to assess current practices as well as helping with the continued review, development, and refining of rules related to compounding

Dr. Armstrong, State Surgeon General, addressed the Board members and audience through a video presentation with recommendations for permitting practice standards which include:

- Non-resident pharmacies should achieve accreditation and periodic re-accreditation in line with in-state pharmacies
- Any pharmacy compounding sterile products should be required to obtain a special permit
- Compounding pharmacies should be required to meet or exceed the most recent USP 797 Guidelines, including a mandatory audit trail of all compounded drug products
- Compounding of non-commercially available drugs should be based upon a patient specific prescription, with some exception limited to drugs not available due to manufacturing shortages
- More precise definitions for non-patient specific compounding should be established
- Recordkeeping requirements should be strengthened to facilitate the rapid response of health care professionals if an adverse event related to compounded medications occurs
- Minimum disciplinary guidelines should be established for compounding violations that hold the owner and the pharmacy manager accountable

TAB 1 **COMPOUNDING IN PHARMACIES LICENSED AND REGULATED BY THE FLORIDA BOARD OF PHARMACY AND THE FLORIDA DEPARTMENT OF HEALTH, (Cynthia Griffin, PharmD, Chair & Mark Whitten, Executive Director)**

Dr. Griffin opened the floor for discussion on modifications to the current requirements for non-resident pharmacies.

Dr. Fallon stated that non-resident pharmacy applicants should be required to have the same fingerprinting and background checks as required by Florida resident pharmacy applicants.

Dr. Griffin stated that one area for potential concern with non-resident pharmacies is that the pharmacist in charge is not currently required to be a Florida licensed pharmacist; therefore, something to consider is requiring the pharmacist in charge to be specifically licensed in the State of Florida.

Mr. Garcia requested from Board office staff, in regards to Chapter 465, information on legislation or rulemaking processes that have been successful in other states regarding compounding.

Mr. Whitten responded that states who have taken action include Massachusetts who has implemented a survey on compounding, New Jersey has begun rulemaking and Tennessee has formed a focus group to concentrate on compounding.

Ms. Mullins stated that it may be worth the Board's time to look deeper into what she feels poses the most danger to Florida citizens which is pharmacies working under the guise of (office use) as a cover for manufacturing.

Dr. Mesaros suggested the Board consider some collaboration with other state boards, and potentially the National Association of Boards of Pharmacy, in regards to pharmacy inspections; specifically when it comes to pharmacies not physically located within the state, if resources in all 50 states would allow a successful collaboration.

ACCREDITATION

Dr. Griffin opened the floor for discussion on requiring accreditation for pharmacists or pharmacies that practice compounding to help ensure patient safety and prudent compounding practices.

Ms. Mullins stated that accreditation for sterile compounding makes sense, but that available accrediting bodies might be a concern. She stated that Pharmacy Compounding Accreditation Board's (PCAB) accreditation standards and compliance indicators crosswalk very nicely with 797, but questions if PCAB can physically produce accreditation or accredited practices in terms of sheer volume. Ms. Mullins stated that when accreditation is being discussed, it is important to also bring up hospital pharmacies non-compliance with 797 and the process of looking

at sterile compounding within community pharmacies, physicians offices, clinics, hospice, home IV, and long term care.

Mr. Whitten spoke about his communication with PCAB and stated that they are willing to take on this challenge, and are looking into ramping up their services and increasing their staff. Mr. Whitten mentioned that he has had contact with other entities that may be interested in the possibility of offering accreditation.

Dr. Mesaros expressed concern with the economic impact of requiring accreditation. His concerns included: will accreditation have a positive or negative impact on the pharmacy; what is the usual expense; what would that type of accreditation entail for them; and in turn, is that going to stop some of the pharmacies from being able to provide a product.

Dr. Griffin opened the floor for public comments.

Michael Jackson with the Florida Pharmacy Association, extended his gratitude to the Board for hosting this meeting, and pledged on behalf of the FPA that they will work closely with the Board of Pharmacy as they search to find solutions to this nationwide problem. Mr. Jackson stated the FPA has taken the position that pharmacies who are interested in looking into the accreditation process be allowed to do so on a voluntary bases through PCAB.

Brian Kahan, Esq. approached the Board to remind them that accreditation is voluntary; licensing and permitting of pharmacies is mandatory; and compliance with regulations to maintain those licenses is also mandatory. Mr. Kahan stated that accreditation may or may not prove to assure the public of any higher level of safety, not that accreditation is right or wrong, but the discussion about accreditation should be tempered with the following concept; will accreditation do something more than already existent regulations do to ensure that an organization that is compounding is in compliance with those existing regulations for the purposes of protecting the public. Mr. Kahan requested that the Board consider any improvements that can be made by minimizing resources and work within the infrastructure that already exists and enhance administrative rules.

Attorney David Flynn, Board Counsel, stated that from his review, it appears that there needs to be more rulemaking authority granted when dealing with non-resident pharmacies and the only way to obtain additional rulemaking authority would be through legislation. Attorney Flynn stated that if there are any critical areas that the Board wants to identify, the Legislative session will begin very soon.

Edwin Bayo, Esq. approached the Board and stated that he does not think there is a deficit in Florida compounding regulations, but maybe enhancing inspections would be suitable. Mr. Bayo suggested accreditation would be appropriate for

compounding pharmacies that reach a certain production level of out-of-state shipped compounded medications.

Mr. Garcia reiterated that in lieu of the meningitis outbreak, it would be good practice for the Board to review Rule 64B16-27.797, F.A.C. Mr. Garcia suggested to the Board that they review this rule during the coming year to ensure the Board is on track to better protect the public.

Greg Carter approached the Board and reminded them that any decision made on accreditation should allow enough time for accrediting bodies to ramp up their resources.

Norman Clemon approached the Board and stated that there should be more focus on aseptic technique and proper hygiene to help prevent future breakouts.

Dr. Griffin reminded the audience that the path to getting to the final solution will require a multi-layered approach and that accreditation may not be the only answer to the solution, but one of the many components that might be necessary to help improve the process.

Ms. Mullins stated reasons the outbreak may have happened include trust of the pharmacist to do the right thing, failure of regulatory enforcement, and culpability of the purchasers. Ms. Mullins reiterated that accreditation would not be a simple fix to the problem.

SPECIAL PERMITS

Ms. Mullins questioned that if California is a great model for special permitting and the New England Compounding Company was still allowed to distribute to California; is special permitting going to fix the problem?

Dr. Griffin stated that special permits won't necessarily fix the problem but will provide an opportunity to know who is engaging in certain practices along with the ability to monitor those practices more closely.

Mr. Garcia suggested the Board look at what other states have in place and consider advantages and disadvantages; the possibility from an inspection and departmental perspective; and the costs involved. Mr. Garcia reminded the Board that now is the time to make legislative recommendations that the Board feels are warranted.

Mr. Kahan, Esq. approached the Board and stated that there is a permit that already exists and the Board has the ability to work within the administrative rules to address those specific rules that speak to the enteral and parenteral special permit and apply additional requirements that can be regulated.

Mr. Garcia stated that bringing in independent inspectors, who are experts in the field, to support our current inspectors may be a good idea.

Dr. Mesaros requested information on how the Board could expand the rule that is already in place on permits.

Attorney Flynn responded that the Board has much capability to make changes regarding in state pharmacies, but that legislative action would be required to give the Board more authority over non-resident pharmacies, due to the statute being very too specific.

RECORDKEEPING REQUIREMENTS

Dr. Griffin stated that the Board's rule on recordkeeping currently has specific requirements outlining what the permittee should be doing. However, one item up for discussion is if current regulations have language that allows for tracking the integrity of a product from the beginning of compounding to dispensing of that drug to a patient.

Ms. Mullins stated that she feels the current recordkeeping requirements are sufficient; then questioned if there are any unknown holes or insufficiencies that need to be brought to the Board's attention.

Foncia Hutt, a non-sterile/sterile compounding pharmacist, approached the board and stated that the only thing that would be insufficient in recordkeeping is tracking the lot numbers for products that you are using when you are compounding. Ms. Hutt also suggested that a software system that could track and readily pull lot numbers would help with recalls.

Richard Montgomery approached the Board and asked how far of a scope the Board wanted to reach in regards to tracking lot numbers, and brought up the difficulty of that for hospitals.

Dr. Griffin stated that one of the most difficult challenges in the most recent outbreak was identifying where, and to whom, the drug was distributed and administered; and the goal of the Board is to find a way to immediately identify who has a drug in stock and how to get our isolate it if necessary.

Shilish Mane approached the Board and stated that the documentation of lot numbers is not enough; other information that should be documented include what procedure was used to compound the medication, who performed the compound, and who checked the compounded medication.

Attorney Flynn stated that the Board of Pharmacy may need to involve the Boards of Medicine, Osteopathic Medicine, the Board of Dentistry and potentially the Board of

Nursing in order to come up with procedures to track a batch or lot number down to the end consumer when the prescription is non-patient specific.

Mr. Bayo, Esq. approached the Board and requested that they keep in mind that a draft rule, provided on behalf of the Florida Independent Pharmacy Network, further defining compounding for office use is currently undergoing the rule making process, and that this rule specifically requires recordkeeping and tracking of compounded medications.

Holly Neary, a compounding pharmacist, approached the Board and stated that there are states, such as Texas, that require an agreement when you do an office use product; so a pharmacy must be in an agreement with the physician to provide office use products. Ms. Neary also stated that there are states, such as New York, that do not allow non-specific compounds for office use.

RECORDKEEPING REGARDING DISCIPLINARY GUIDELINES

Dr. Griffin opened the floor for discussion on the recently revised disciplinary guidelines; specifically to look at what is already in place regarding discipline for compounding of products, as well as guidelines for penalties associated, and if there are any deficiencies.

Mr. Garcia asked, from a legislative perspective, if there is something the Board could pursue in an effort to hold owners accountable for non-pharmacist owned pharmacies?

Attorney Flynn acknowledged the Prosecution Services Unit as the best department to understand what the Board's strengths and weaknesses are in dealing with those types of cases. He also stated that he is aware of some weaknesses in the disciplinary guidelines and that this would be a good topic to discuss at the December 11 – 12, 2012 Board meeting.

John Truitt, Assistant General Counsel, stated that with the way the statutes are currently set up, the Board can discipline anyone with a permit or a license. For the non-licensed owner of a pharmacy, the pharmacy permit can be disciplined with the PDM being held accountable for certain things. Mr. Truitt suggested the Board may be interested in recommending legislative action to hold the PDM more accountable.

Ms. Mullins reflected back on a disciplinary case from the October Full Board meeting and suggested that when the Department recommends discipline with education requirements, the Board would need more information on the options and more specificity on what those options are going to look like.

Dr. Mesaros inquired as to what kind of action the Board would need to take at the December Board meeting to move any legislative recommendations they would be interested in making.

Dr. Griffin stated that one of the goals of this meeting was to come up with recommendations that the Board can act on fairly quickly going forward at the December Board meeting.

Attorney Flynn stated that he would prefer to have one assigned committee person from the Board that he can ask questions and discuss changes in order to have language ready to be voted on by Board during their meetings, and hit the goal of having rules done within 90 days.

Dr. Griffin opened the floor for further discussion.

Ms. Mullins stated that one of the goals is to have specific instructions for office use. In terms of definition, the Board has clarity on verbiage; the problem lies in people who are masquerading behind office use and providing injectables that are only appropriate for office use.

Robert Montgomery approached the Board and requested clarity in the rule regarding office use.

Ms. Mullins stated that Mr. Montgomery's question, and some questions of her own, may not be able to be answered today; but maybe through committee work, we need to have those questions answered for both the pharmacists and their patients. Ms. Mullins also reminded the Board that we need to be very careful when compounding for cost-savings versus compounding for patient need due to a product not being commercially available.

Dr. Griffin stated that the challenge is how to put requirements in place to address compounding for cost savings versus compounding for need.

Mr. Bayo, Esq. approached the Board and stated that it is important that pharmacists exercise due diligence and create a record.

Dr. Griffin stated that an item for discussion that will continue through future Board meetings is addressing the definition of compounding versus manufacturing, which will not only be a challenge for Florida, but the entire nation.

TAB 2 PHARMACY COMPOUNDING SURVEYS. (David Flynn, Assistant Attorney General)

Dr. Griffin asked Attorney Flynn to review the voluntary survey results and to lead us into a discussion on recommendations as a result of the survey.

Attorney Flynn responded that even though these topics are under his tab, the work done on the survey was performed by the State Surgeon General, the Department of

Health, the Board, and various associations. He also stated that he does not speak for the Department of Health and will only advise as the Board Counsel.

Attorney Flynn reported on the number of people affected by the meningitis outbreak, the number of emergency suspension orders issued by the State Surgeon General post-outbreak, and how this will all play into rule making.

Attorney Flynn reported that the Department of Health sent out a voluntary compounding survey to approximately 8,000 people and had a return rate of approximately 700 (10%). He asked the Board if they wanted to engage in rulemaking to make the survey mandatory in order to increase the return rate.

Dr. Griffin stated that she was disappointed in the number of surveys returned and that it is critical for the Board to know what type of practices are happening, as well as other essential information to help make informed decisions on future rules and processes. Dr. Griffin opened the floor to Board members for questions about the survey.

Mr. Garcia spoke to the Board considering an emergency rule.

Ms. Mullins responded that some of the questions in the survey may have brought confusion. She also stated that the Board should be very careful on how the data is used, and maybe with that in mind, will help the Board and the Department design questions that obtain data that will reveal where the dangers lie.

A recess was taken for Board members to review the Emergency Rule.

Dr. Griffin requested that Cassandra Pasley, Chief of the Bureau of Health Care Practitioner Regulation, address the survey process, explain how the survey was developed, and answer Board member questions.

Ms. Pasley explained that the survey came about from questions in news articles after the meningitis outbreak asking “how many compounding pharmacies are in your state”, with the department not being able to give an answer. The only answer that could be given is that there is x-amount of permits that have the legal authority to compound, which may be a number very different from the actual amount of pharmacies compounding. Ms. Pasley stated that the survey would serve the purpose of giving the Board and the Department a better understanding of what going on in our state.

Ms. Pasley answered Dr. Griffin in great detail and stated that the goal for the survey is not to impose discipline, but to assist the Board and the Department with getting the data needed to make informed policy decisions.

Ms. Pasley answered Board member questions for clarity and revised the survey based on suggestions from the Board members.

Motion by: Dr. Fallon, seconded by Mr. Garcia, to accept the compounding survey. Motion carried.

Attorney Flynn led a discussion on the emergency rule and advised the Board to look at the text section of the rule first, which he advised could be approved or denied, then Board could decide if they want to proceed in an emergency rule fashion.

Dr. Griffin led a discussion between Board members and Board Council on the text of the rule and entertained comments from the public.

Motion by: Mr. Garcia, seconded by Dr. Fallon, to adopt the rule with changes. Motion carried.

Attorney Flynn advised the Board to discuss and review the paragraphs that will be published which state the specific reasons for finding an imminent danger to the public health, safety, or welfare.

Dr. Griffin led a discussion between Board members and Board Council on the text in the paragraphs on finding imminent danger and entertained comments from the public.

Motion by: Ms. Glass, seconded by Dr. Fallon, to approve language to the paragraphs stating the specific reasons for finding an imminent danger to the public health, safety, or welfare. Motion carried.

Attorney Flynn advised the Board to vote on whether the procedure used was fair under the circumstances and welcomed any comments from associations before a vote was made.

Mr. Jackson approached the board and stated that he does not represent any national associations but encouraged Board staff to make information on the emergency rule available to National Associations and he pledged to share what the Board has done with the National Associations.

Mr. Bayo, Esq. approached the Board and stated that on behalf of the Florida Independent Pharmacy Network, they were aware of these proceedings and believe that they have received appropriate notice of what has been going on.

Motion by: Dr. Fallon, seconded by Dr. Mesaros, to approve the basis for finding that the procedure used is fair under the circumstances. Motion carried.

Motion by Dr. Mesaros, seconded by Dr. Fallon, for the amended changes to the paragraphs stating the specific reasons for finding an imminent danger to the public health, safety, or welfare. Motion carried.

Richard Palombo, R.Ph, a member of the New Jersey Board of Pharmacy and former President of NABP, was invited by Mr. Garcia to say a few words. Mr. Palombo stated that he was not here to represent the New Jersey Board of Pharmacy, nor NABP, but just as the Florida Board of Pharmacy is facing a large amount of issues and has been affected by the outbreak in a significant way, so has the New Jersey Board. Mr. Palombo stated that New Jersey has proposed Legislation that would require PCAB as an accreditation for both 795 and 797 compounding and had continued discussion with the Board members on that topic.

TAB 3 DOH PHARMACY INSPECTION PROCESS. (Jeane Clyne, Chief of Investigative Services Unit)

Jeane Clyne spoke briefly on the inspection history, process, and forms used for sterile compounding. Ms. Clyne stated that the more she has learned about sterile compounding, the more deficiencies she sees in the current inspection form used. Ms. Clyne assured the Board if any permitting requirements are changed, enforcement would look into hiring expert contracted employees.

Mr. Garcia asked Ms. Clyne what her thoughts were towards 797 inspector training and if the Board could help the Department in having inspectors go through in depth training through a contracted agency. Mr. Garcia expressed concern on what level of expertise her inspectors have in 797 compounding.

Further discussion occurred between Board members and Jeane Clyne between the wording and specificity of the rule and the process of inspections.

The Board reviewed the draft inspection form and Dr. Griffin stated that discussion of the draft inspection form would occur during the December 2012 Board meeting.

Ms. Mullins and Ms. Clyne discussed the need of increased resources in order to perform more detailed inspections.

Dr. Griffin suggested that Ms. Clyne be prepared to present recommendations to the Board on how the Board can assist in any training needs that have been identified.

TAB 4 DEPARTMENT OF HEALTH'S PUBLIC PROTECTION CONCERNS, (Cassandra Pasley, BSN, JD, Chief, Bureau of Health Care Practitioner Regulation)

Dr. Griffin stated that the Board has three categories of priority in terms of how the Board may want to address this issue moving forward, which include short-term, intermediate, and long-term goals. Dr. Griffin stated that a short-term goal

accomplished at this meeting was approving the emergency rule that allows the Board to implement the mandatory survey.

Dr. Griffin opened the floor to Board members for items they would like to see addressed for immediate follow up.

Items the Board members decided are of immediate importance are as follows:

- Re-visit Cases with Sterile Compounding Issues
- Inspector Training
- Non-Resident Pharmacies Compliance with Florida Law
- Possible Requirement of FL Pharmacist in Non-Resident Pharmacy
- USP Standards – Physician Exemption
- Collaboration with other Professional Boards
- Proposed Legislation
- Disciplinary Guidelines

Mr. Garcia and Mr. Whitten suggested having Board meeting conference calls in 2 week intervals during the legislative session to review newly submitted bills and legislative actions.

Ms. Pasley stated that she gives all condolences to the patients and their family members who have suffered from medical errors, particularly compounding errors. She thanks the Board and the Department of Health for their leadership and ensuring action to protect patients. She reiterated that the Department of Health is committed to working with the Board and for the Board to make sure all administrative needs are met.

Kristina Wiggins, Deputy Secretary of the Department of Health, stated that Dr. Armstrong is committed and proactive in addressing these issues and gave her condolences to patients and their family members who have had to deal with this issue. Ms. Wiggins stated that it is a priority of the Department to work hard and resolve this to the best of our abilities.

Dr. Griffin opened the floor to public comments.

Dale Moody approached the Board and explained his wife's experience with medical errors and his interaction with the Department of Health.

Brenda Moody approached the Board and explained her experience with medical errors and her interaction with the Department of Health.

Motion by: Mr. Garcia, seconded by Ms. Glass, to adjourn the meeting at 3:54 p.m.
Motion carried.