**JOINT MEETING**
**BOARD OF PHARMACY and BOARD OF MEDICINE**
**FLORIDA DEPARTMENT OF HEALTH**
**3 p.m., April 6, 2016**

**Hilton Altamonte Springs**
**350 Northlake Boulevard, Altamonte Springs, Florida 32701**
**(407) 830-1985**

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**Meeting Chair Gavin Meshad, Board of Pharmacy, called meeting to order at 3 p.m.**

**Board Members present– Pharmacy**
Debra B. Glass, BPharm, Chair, Tallahassee
Mark Mikhael, PharmD, Vice-Chair, Orlando
Goar Alvarez, PharmD, Cooper City
David Bisaillon, Consumer Member, Bradenton
Leo "Lee" Fallon, BPharm, PhD, The Villages
Jeffrey J. Mesaros, PharmD, JD, Orlando
Gavin Meshad, Consumer Member, Sarasota
Jeenu Philip, BPharm, Jacksonville
Michele Weizer, PharmD, Boca Raton

**Board Members present – Medicine**
Steven Rosenberg, MD, Chair, West Palm Beach
Magdalena Averhoff, MD, Vice-Chair, Coral Gables
Gary Dolin, MD, Bradenton
Bernardo Fernandez, MD, Weston
Brigitte R. Goersch , Consumer Member, Orlando
Jorge J. Lopez, MD, Maitland
Seela Ramesh, MD, Orlando
Nicholas W. Romanello, JD, Orlando
Sarvam TerKonda, MD, Jacksonville
Joy Tootle, Consumer Member, Gainesville
Zachariah P. Zachariah, MD, Fort Lauderdale

**Board Members absent -- Medicine**
Enrique Ginzburg, MD, Miami
James Orr, MD, Bonita Springs
**Merle Stringer, MD, Panama City**

**Board Staff -- present**
Allison Dudley, Executive Director
Emily Roach, Program Operations Admin
Amber Greene, Regulatory Specialist III

**Board Staff -- present**
Adrienne Rodgers, Acting Executive Director
Claudia Kemp, Executive Director

**Board Counsel -- present**
David Flynn, Assistant Attorney General
Larry Harris, Assistant Attorney General

**Board Counsel -- present**
Ed Tellechea, Chief Assistant Attorney General
Donna McNulty, Senior Assistant Attorney General

3 p.m. -- Gavin Meshad called the meeting to order.
Board of Medicine members Enrique Ginzburg and James Orr were excused.

1. Introductions

For the first joint meeting of the Boards of Pharmacy and Medicine, Mr. Gavin Meshad welcomed everyone and asked Board members and staff at the meeting table to introduce themselves.

2. Opening remarks – Lucy Gee, MS, Division Director, Medical Quality Assurance

Lucy Gee, Division Director of the Division of Medical Quality Assurance, Department of Health, said it was an exciting day for the two boards to be meeting together. She said the meeting came out of strategic planning discussions at a recent Board of Medicine meeting.

Ms. Gee said former State Surgeon General John Armstrong was a proponent in having dialogue on emerging issues and the Board of Pharmacy had stepped up to provide the forum when the filling of controlled substances prescriptions became a publicly debated issue. The Board created a special committee and invited people from all aspects of the drug supply chain to talk about solutions for patients having difficulty with pain medications. She said the rule of collaborative meetings is to come with solutions.

Gavin Meshad said he may seem like an unlikely person to lead the joint meeting, as a consumer member. He shared that he had a passion regarding the prescription drug epidemic when he first joined the Board of Pharmacy due to a personal loss. He felt health care providers needed to be more proactive, and he led a Board committee several years ago that looked at the issue. It went inactive after the formation of the Prescription Drug Management Database and pain clinic limitations enacted by the Florida Legislature, but it appears that the pendulum has swung too far the other way. The issue that brought the Controlled Substances Standards Committee together was complaints that pharmacists were not filling legitimate prescriptions. The committee spent its first meeting in June 2015 listening for three hours to patients, physicians and pharmacists speak on their struggles and concerns. The committee identified education, communication and collaboration as the key solutions on which to focus.

“Since I’ve been on the Board, I’ve really wanted to see this joint committee come together,” Mr. Meshad said.

3. Controlled substances prescribing and dispensing

Mr. Meshad said the Controlled Substances Standards Committee tackled a Board rule about validating controlled substances prescriptions that had gotten stale. It revised the rule with

guidelines to follow so that pharmacists could attempt to address questions they had before refusing to fill a prescription. While that rule still ultimately depends on the pharmacist to make a professional judgement, it also involves physicians because it requires pharmacists to reach out to the patient's prescriber.

Mr. Meshad said committee members were trying to clear up confusion for pharmacists about what to do when they had questions – when should they call the physician? Thus the rule says to contact the prescriber. But physicians on the committee also said sometimes they feel like they are being challenged about the prescriptions they are writing. He suggested opening discussion around the table regarding the steps the pharmacy rule puts in place.

Ms. Gee said the committee's efforts helped reshape the dialogue and helped stop the media message that largely blamed pharmacists. She said the calls to the Department of Health complaining about refusals to fill have decreased, and she said legislators this year were talking about solutions and not blame.

Mr. Meshad said the rule also makes use of EFORSCE, the state's Prescription Drug Monitoring Program database. He said he was a major proponent of the PDMP and is pleased to see it working as a tool in the fight against opioid drug abuse. He encouraged everyone to read the revised rule, 64B16-27.831 -- Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education. He said the committee did have physician members, who helped shape the rule, showing that collaboration between pharmacists and physicians could have an impact on a public health issue. The committee and the Board of Pharmacy wanted to move this discussion about collaboration to a joint meeting between the Boards of Pharmacy and Medicine.

Jeenu Philip, who served on the controlled substances committee, said pharmacists were afraid to fill prescriptions because they were facing pressure from their employers and the DEA to identify and stop opioid prescription abuse. The rule puts a decision-making process in place and gives pharmacists steps to follow to validate prescriptions. It helps pharmacists make the decision to fill or refuse to fill in an appropriate manner.

Mr. Meshad said one very important point of the rule is to initiate conversation with the prescriber. Communication back and forth is paramount. He said he hoped Board of Medicine members felt the same way. The goal of the rule was to ensure that people are treated appropriately while minimizing opioid abuse.

Jeffrey Mesaros, who was on the committee, said that rule making takes time, but the efforts of the committee members and Board staff moved this one through relatively quickly. It was effective December 24, 2015. He stated that the first meeting was mostly a listening session, and

the feedback from patients, prescribers and pharmacists helped direct the committee.

Ms. Meshad said the committee, and eventually the Board of Pharmacy, which ratified the committee's actions, wanted to make a rule that could be applied to the situation. Then the plan was to form education around that. The rule requires a two-hour CE course for pharmacists that they must complete for the next license renewal cycle of February 28, 2017. However, he stated there will continue to be issues around refusals to fill and there will continue to be abuse of controlled substances, so there will continue to be questions around appropriate filling.

The Chair of the Board of Medicine, Steven Rosenberg said he was on a committee of members of the Boards of Medicine and Osteopathic Medicine dealing with overprescribing. During a meeting held in Palm Beach County, he said some of the independent pharmacists indicated they were concerned with physically being held up for oxycodone.

Council to the Board of Pharmacy, David Flynn said the Board of Pharmacy cannot regulate what drug inventory pharmacies keep at any given time. Some patients complained during the committee meetings that they felt they had been lied to about whether a pharmacy had a drug. However, pharmacists also shared that employees in the pharmacy had been threatened at gunpoint for drugs.

Mr. Philip said that the committee wondered after revising the rule what the next step should be. He said he felt if more impact is going to be made, then the two boards need a joint committee that can discuss actions each board can take.

Mr. Meshad said a joint committee would be useful. The Board of Pharmacy does not want to operate in a vacuum. Members want work with physicians.

Mr. Romanello asked whose idea it was to hold the joint board meeting.

Ms. Gee said last year when the Department was looking into the issue of patients having problems filling controlled substance prescriptions written by their physicians, she talked to a lot of people about the problem. She heard from a lot of people what they thought the problem was. The Board of Pharmacy agreed to provide the forum to discuss the problem and its solutions. Now Florida is held out as an example of a state that has done something. The joint effort that could be made by the Boards of Medicine and Pharmacy are similar to the efforts the Board of Medicine and Nursing are doing now on wrong-side surgeries, she said.

Brigitte Goersch asked what she was looking for from the Board of Medicine. What are the problems?

Mr. Flynn said the thread throughout the committee's discussions was education. Also, Board of Pharmacy members feel they are at the point that further collaboration is warranted. How do physicians feel? Also, is the rule impacting physicians, he said. Have calls increased and, if so, is that a problem?

Michele Weizer said her career has been in a hospital, and most physicians who spend a lot of time in a hospital probably have a relationship with their favorite pharmacist. She said she has a relationship with whom she the physicians she works and it would be best if all physicians could get back to the relationship that physicians used to have with their corner drug store pharmacist.

Dr. Rosenberg said he and most physicians have little chance to interact with community pharmacists, both because of the numbers of pharmacies that are within a close vicinity of his practice and because many corporate pharmacies route incoming calls through a central fill pharmacy somewhere else.

Mr. Meshad said the issues the committee heard included patients not understanding why a pharmacist would reject a prescription his or her doctor wrote. He said that if the boards work together, they can bring clarification to what is going on in the pharmacist's world and what is going on in the physician's world.

Jorge Lopez said he has spent the last 22 years in emergency medicine. Most of the people he sees come to the hospital because they are in pain, and he has to determine if it is legitimate. He asked if the Board of Pharmacy has specific criteria for when to call a physician. He recounted a situation that had happened recently where a pharmacist called with questions on a pair of prescriptions he had written.

Mr. Meshad said the Board was careful not to put strict parameters, because the ultimate decision is one based on professional judgment. He said there was a lot of sensitivity to not making a checklist.

Ms. Dudley likened the outcome to the Board of Medicine's rule making process with telemedicine. After much debate, Board members decided they could not list all forms of technology and had to leave it to professional judgment to follow the standards of care.

Dr. Mesaros said that while physicians and pharmacists may no longer have that small-town-style relationship, the Boards can form a workgroup or committee to get into the same room and have a conversation about what practitioners are seeing and what consumers are experiencing. He suggested discussion on the new CDC guidelines for prescribing pain medications. While they were just released, maybe by the time a committee is formed, there would be time to digest them. He suggested physicians and pharmacists together discuss how they will impact practice

and what it will mean to a patient at the pharmacy counter. While the guidelines are new, the problem is not, and both professions need to address it, he said.

Mark Mikhael asked Dr. Lopez if the patient had gotten his prescription filled.

Dr. Lopez said the hospital person who was initially reached could not immediately find the information needed because of the volume of patients. Dr. Lopez said he was called at home but that means he has to rely on his memory to answer specific questions. He and other physicians are looking for a more objective criteria because across Florida there are 7-8 million patients. Is there a number that triggers the pharmacist to call, because he'll be happy to write a prescription for only 18 Percocet if 20 is a number that causes concern?

Dr. Rosenberg suggested that physicians list their specialty on the prescription pad. As a dermatologist, a pharmacist is not expecting to see him write a prescription for 100 Oxycontin. The pharmacist would question. But with an ER doctor, the pharmacist would expect a different type of prescription.

The Board members noted that as a good idea.

Ms. Gee mentioned that that common sense approach had been discussed. For instance, drug supplies have to analyze order volumes. If those companies realize the pharmacy is located next to a Moffitt cancer center, or some similar health care facility with specialized patients, especially those needing controlled substances, the companies might better understand the volume of opioid orders.

Mr. Meshad said maybe ways to identify appropriate drugs according to the type of practice, such as patterns of prescriptions for the ER, would help.

Dr. Mesaros said that maybe a joint committee could work something educational to put on the board and department websites, something that would help patients understand red flags for pharmacists.

Gary Dolin questioned if HIPPA violations would occur with some efforts to convey more patient information.

Dr. Mesaros said if a patient comes in with an oxycodone prescription but is not willing to share health records, then pharmacists cannot address their concerns.

Mr. Flynn said there are objective criteria, such as checking the dosage, checking for contrainterdictions, and the patient has to provide health information for a pharmacist.

Pharmacists are part of the practice of health care.

Lee Fallon said when he was a younger pharmacist, he had a man come in with a prescription for 30 Percocet. He asked him if he had seen the physician and had a thorough check up. The patient said he had. Then Dr. Fallon said he ripped up the script and handed it back to the man and said next time not to go to a gynecologist. Everyone laughed.

Ms. Goersch said she was trying to think of some take-aways from the conversation. She shared that she had hurt her leg three years ago and her husband had to go to multiple pharmacies on a Friday night to try and get her prescription filled. She urged communication and education. During the conversation, Ms. Goersch said she noticed agreement in the room that one of the biggest problems was getting the word out to each Boards constituencies. She chairs the education committee for the Board of Medicine and said the staff works actively to have current data on the website.

Mr. Meshad said the three prongs of the Board of Pharmacy's efforts were education, communication and collaboration. He said Board members recognized that they needed to get the word out about the revised guidelines even before pharmacists were required to complete their continuing education for the next renewal cycle.

Dr. Rosenberg said Ms. Goersch's comment about involving consumers was a good idea. Most fraudulent prescriptions are filled Friday night or over the weekend. He said maybe it is better for a patient to try and fill a prescription at a time the pharmacist can reach the physician.

Ms. Goersch said technology is improving communication. Why can't notification between physicians and pharmacies be better and faster?

Mr. Meshad said pharmacies can get instance information from insurance companies about covered medications and costs. The dollars and cents information is instantaneous. Why can't information from the PDMP database be real-time?

Mr. Philip and Dr. Mesaros talked about e-prescribing and asked if EFORSCE can share in e-prescribing systems.

Debra Glass said she had seen a poll among pharmacists regarding their comfort level is dispensing prescriptions. She said if physicians also checked EFORSCE on the front-end and not just pharmacists on the back-end, that comfort level would rise.

Mr. Philip related what he called his greatest success story as a district supervisor in Jacksonville. He said he brought together a group of pharmacists and physicians from a pain management

group who were struggling with getting prescriptions filled. They had dinner together and came up with some solutions. What ultimately helped the process was that patients would be given doctor's notes from their visit and had the option to show them to the pharmacist to resolve any questions.

Mr. Meshad suggested the executive directors of the Boards meet to coordinate on specific topics. The Boards should meet just to meet, but he said he couldn't see how it wouldn't benefit all the stakeholders for communication to continue between the two Boards. He also suggested a Board of Medicine member join the Controlled Substances Standards Committee when it meets in the future. He said members of both Boards probably would prefer to discuss the issues in a smaller forum.

4. Legislation – Allison M. Dudley

Ms. Dudley said a number of bills this Legislative session discussed controlled substance prescribing. She gave specific information on the following:

a. HB 1241 – Ordering of Medication

Ms. Dudley said it makes changes to Chapter 381.887, Florida Statutes, which allows a pharmacist to dispense Naloxone to a patient or caregiver of a patient who is in danger of suffering an overdose to opioids based upon a non-patient specific standing order entered into by the pharmacist and the prescriber.

The bill makes clear that a physician assistant and a nurse practitioner can order controlled substances in a hospital setting and a nursing home.

She noted that the FDA recently approved a naloxone spread that she understands will be a less expensive alternative.

b. HB 423 – Drug Prescription by ARNPs and Pas

Ms. Dudley said it allows nurse practitioners and PA’s to prescribe controlled substances. She clarified that a physician only has to register to prescribe controlled substances if they are routinely prescribing for chronic nonmalignant pain.

She said the bill creates a committee to create a negative formulary. She said the Board of Pharmacy has to appoint a member of the committee and Dr. Mesaros had agreed to serve.

Ed Tellechea clarified that Florida law only allows physicians to prescribe out a pain management clinic.

c. SB 964 – Prescription Drug Monitoring Program

Ms. Dudley indicated that SB 964 had been signed, which allows a physician or pharmacist to appoint a designee to access the PDMP.

d. SB 1604 – Drugs, Devices, and Cosmetics

Ms. Dudley said the bill addressed something discussed during the Controlled Substances Standards Committee. It raises the unit doses of a controlled substance that must be assessed by a wholesale distributor from 5,000 to 7,500 doses.

The bill also requires the Department of Health to create a pamphlet about controlled substances, which will go on department websites.

Mr. Meshad asked questions about who was creating the pamphlet and what content was required. Dr. Mesaros read from the bill. Dr. Sarvam TerKonda pointed out that the bill requires federal grants to achieve the mandated educational mission.

Ms. Dudley assured the assembled group that the Division of Medical Quality Assurance and the entire Department of Health are serious about education and have the tools to educate the public. She said the Boards would certainly put the pamphlets on their websites.

5. Sterile compounding update – Allison M. Dudley

Ms. Dudley recapped how the New England Compounding Center thrust Florida into a health care crisis over sterile compounding. She said the Legislature and the Board put licensing requirements in place for in-state pharmacies and out-of-state pharmacies, which have been established for more than a year. She reminded physicians that if they needed compounded sterile products from outside Florida, they should check the Department of Health's license verification website to make sure they are registered in Florida.

Ms. Dudley said information about the FDA’s MedWatch was included in the meeting materials, which instructs physicians and patients what to do if someone has adverse reactions to sterile compounded drugs.

Ms. Gee said the sterile compounding regulations have been another huge success story. Florida has not experienced a single recall, she said. The National Association of Board of Pharmacy

holds up the state as a role model and North Carolina has written into its rules that a pharmacy that passes inspection in Florida is approvable.

6. Cross-practices issues and opportunities for collaboration

Dr. Rosenberg asked about patients being able to transfer e-prescriptions if they shop around and find a better price. He said patients with higher-deductible insurance plans are becoming more aware of price.

Dr. Fallon told him that the patient should ask the pharmacy whose services they want to use to have it transferred.

Mr. Philip said the only issue is a Schedule II controlled substance, but anything less can be transferred. He explained that by law the pharmacy has to transfer the prescription.

7. Board member comment

8. Public comment

Win Adams, a former Board of Pharmacy consumer member, asked if it was practical under electronic records and prescriptions to include photos.

He also asked about tying Current Procedural Terminology (CPT) codes to National Drug Code (NDC) numbers. Dr. Weizer explained NDC bar codes are required under federal law for manufacturers and other information would not be allowed. Dr. Rosenberg suggested that CPT codes could be tied to IPC codes.

The meeting was adjourned at 4:40 p.m.

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*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 boards' websites.*