

AGENDA

Florida Board of Pharmacy
Controlled Substances Standards Committee Meeting

June 9, 2015, 2 p.m.

B Resort & Spa
1905 Hotel Plaza Blvd.
Lake Buena Vista, FL 32830

Committee Members:

Gavin Meshad, Committee Chair
Michele Weizer, PharmD, Board Chair
Jeffery Mesaros, PharmD, J.D.
Jeenu Philip, BPharm
Winfield "Win" Adams, CSA

Board Counsel:

David Flynn, Assistant Attorney General

Special Committee Members:

Michael Jackson, BPharm, Florida Pharmacy Association
Gary Cacciatore, Cardinal Health
Mark Rubenstein, M.D., Florida Medical Association
Harold Dalton, D.O., Fla. Society for Interventional Pain
Physicians
Natasha Polster, Walgreens
Betsy Ferguson, CVS
Andre Ourso, J.D, Executive Director, Fla. Board of Medicine
Christy Robinson, Executive Director, Fla. Board of Osteopathic
Medicine

Participants in this public meeting should be aware that these proceedings are being recorded.

Tuesday, June 9, 2015 – 2 p.m.

The meeting was called to order at 2:02 p.m.

1. Introductions

Ms. Allison Dudley said Betsy Ferguson was unable to attend. She stated that speakers would be limited to three minutes.

Committee Chairman Gavin Meshad explained that the committee was initially formed to make recommendations for the Prescription Drug Monitoring Program and database and had been inactive since 2014. He said it had been reactivated with a new purpose – to address the issues that have arisen since the pill mill problem was curbed. Several non-voting members were added to the committee to represent physicians, wholesalers and pharmacy businesses. Mr. Meshad said the committee was convened to hear from all interested parties.

2. Discussion

- Patient Perspective
 - Emails

- Public Testimony

Jeffrey Kaufman - Clermont, Fla.

Peter Aldean – Ocoee, Fla.

Barbara Fowler – Clermont, Fla.

Lesley Hilton Young – Jacksonville, Fla.

Raymond Parreault – Clermont, Fla.

Karen Bishop – Orlando, Fla.

Geoffrey Johnson – Kissimmee, Fla.

David Johnson – Orange Park, Fla.

Lorraine White – Deltona, Fla.

Tracey Andrzejewski – Port St. Lucie, Fla.

Vicki Teran – Haines City, Fla.

The speakers described their struggles and the struggles of loved ones who are unable or have significant issues getting pain medications filled.

Following is a summary of key points, but please listen to the audio for individual stories:

http://ww10.doh.state.fl.us/pub/bop/Audio/Controlled_Substance_Standards_Committee_06092015/

- Traveling to multiple pharmacies to fill prescriptions or being unable to fill prescriptions affects patients' quality of life.
 - Many are incapacitated by pain if medications are not maintained at the prescribed level.
 - Many are unable to travel to multiple pharmacies to find someone to fill prescriptions because of pain.
 - Employed patients face loss of wages when they have to take off time to go to multiple pharmacies to fill prescriptions.
- Most pharmacies will not tell callers whether they have specific drugs available to fill prescriptions.
- Being questioned about health histories and drug use within hearing of other pharmacy customers is insulting and embarrassing.
 - Patients feel like they are being treated like criminals.
 - Some patients are too embarrassed to get prescriptions filled because they have been embarrassed and publically shamed by the way they are treated.
 - Dependency on pain medicine to be able to walk or go out in public should not mean being looked at as a drug addict or criminal.

- Patients with chronic pain from disease or injuries face the most scrutiny when trying to fill prescriptions, but cancer patients are also turned away.
- Patients are being told their options are to go to the hospital if they cannot stand the pain, resulting in an increase in hospitalization and increase in healthcare costs.

- Pharmacist / Pharmacy Perspective
 - Testimony

Tim Rogers – Newberry, Fla.

N. Lois Adams – Orlando, Fla.

David Craig – Tampa, Fla.

Dan Buffington – Tampa, Fla.

Kevin Nicholson – Arlington, Va.

Steve Nelson – Okeechobee, Fla.

Bill Napier – Jacksonville, Fla.

J. Roger Accardi – DeBary, Fla.

Steve Ariens – Panama City, Fla.

Jim Kovisto – Jacksonville, Fla.

Bob Parrado – Tampa, Fla.

Melissa Ramba – Florida Retail Federation – Tallahassee, Fla. (Other category)

The speakers described issues they have seen as pharmacists and as patients or caregivers of patients when dealing with refusal to fill pain medications.

Following is a summary of key points, but please listen to the audio for individual stories:

http://ww10.doh.state.fl.us/pub/bop/Audio/Controlled_Substance_Standards_Committee_06092015/

- Pharmacists face a real fear of having business disrupted by prescription drug shortages if the DEA or wholesalers question their filling of patient controlled substances prescriptions.
- Red flags have been identified in Florida rule and as a national effort by industry associations in an effort to reduce abuse of pain medications, but they are outdated and/or are being misused in the refusal to fill issue.
- Use of the PDMP may improve the situation, but it is still a flawed instrument.
- Pharmacists want to help patients but feel that common sense cannot be used with quota systems and threats of enforcement that currently exist.

- Physician Perspective
 - Testimony

Sanford Silverman – Pompano, Fla.

Miguel De La Garza – Tampa, Fla.

John Carrozzella – Kissimmee, Fla.

Harold Cordner – Sebastian, Fla.

Amy Goldstein – American Academy of Pain Management – Sonora, CA. (other category)

The speakers described issues they have seen as physicians whose patients are having trouble filling pain medications.

Following is a summary of key points, but please listen to the audio for individual stories:

http://ww10.doh.state.fl.us/pub/bop/Audio/Controlled_Substance_Standards_Committee_06092015/

- Legitimate pain patients are being further injured when they cannot get prescribed controlled substances filled.
 - Many questioned how corporate policies are affecting the situation and whether drugs are being rationed.
 - Enforcement aggressiveness has caused pharmacists to be overly cautious and deny legitimate patients.
 - Drug addicts have found alternatives, such as heroin, while real patients are dying in pain or even committing suicide because they cannot live in pain.
- Wholesale Distributer Perspective
 - Testimony

Gary Cacciatore – Cardinal Health – Houston, TX

- Distributors don't prescribe or dispense drugs, but they share responsibility for the supply and for keeping controlled substances out of the hands of drug addicts.
- Wholesalers are required to report suspicious orders to the DEA or could lose their DEA registration.
- Thresholds established by wholesaler/distributors are not arbitrary, but based on complex, documented data and algorithms.

3. Issues Identified

Mr. Michael Jackson said he was encouraged that this dialogue was happening. Balance in the healthcare system needs to be found. After the pill mill problems in the mid-2000s led to implementation of Prescription Drug Monitoring Programs, an increase in heavier enforcement has gone too far. Mr. Jackson said education can help, but that the system between pharmacists and physicians needs to be integrated so that more information can be shared.

Dr. Harold Dalton read from the DEA manual about corresponding responsibility. He questioned whether a checklist as some corporate pharmacies have initiated can be substituted for "sound professional judgment." He suggested that the Department of Health provide educational programming.

Dr. Mark Rubenstein told a story of a conversation he had with a pharmacist who asked detailed questions about his treatment of a patient. After answering all of her questions, the pharmacist said she would not fill the prescription, and then refused to give him her name or license number. He said physicians can be disciplined for undertreating pain. He said pharmacists should use proper application of red flags and not corporate policies to determine to whom to dispense. He also advocated for more education, specifically interdisciplinary education. He said the American Medical Association is also working on the problem and is poised to help.

4. Solutions /Recommendations

- Potential Rules Changes
- Potential Legislative Changes
- Collaboration
- Education
- Other

Mr. Meshad said the DEA needs to be asked to participate in the conversation. He said everyone needs to be on similar paths to solutions.

Dr. Michele Weizer said Rule 64B16-27.831 needs to be opened for rule development. It discusses red flags.

Motion: by Dr. Jeffrey Mesaros, to open the rule. Motion carried.

Mr. David Flynn said more discussion is needed on what is not a red flag, such as geography.

Mr. Jeenu Philip said he is a Walgreens supervisor and he has made arrangements for a group of pharmacists and physicians to go to dinner together and talk about the issues. He said pharmacists don't always make the best decisions, but moving toward communication for patient care will help.

Discussion of a consensus document that addresses what everyone should be doing.

Mr. Jackson said not to leave supply out of the discussion. Pharmacists cannot fill prescription if they don't have the drug supply.

Mr. Meshad said he would like to see the Boards of Medicine and Osteopathic Medicine adopt any consensus document as well.

The committee agreed that members would encourage discussion of these issues in other appropriate settings. Mr. Cacciatore said he would add it to the Division of Drugs, Devices and Cosmetics advisory committee that he is on.

At Mr. Philip's suggestion, the committee agreed to review success stories at the next committee meeting.

Ms. Dudley said Susan Langston of the DEA had expressed interest in the committee, but had a conflict with the June meeting. She said she would request Ms. Langston attend the next meeting.

Motion: by Mr. Philip at 5:10 p.m. to adjourn. Motion carried.

