

# Epilepsy Treatment and Education Task Force

## Summary Notes

Tuesday, August 14<sup>th</sup>, 2012

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### **WELCOME**

The meeting was called to order at 3:15 pm on Tuesday, August 14<sup>th</sup>, 2012, in Room 517 of the Lucas State Office Building in Des Moines, Iowa.

### **PRESENT**

Members of the Task Force present: Chasity Mease, Kevin Harris, Brett Barker, Dr. Moore, Dr. Janus, Geoff Wahl and Dale Todd.

There were also several non-members present, including: Jill Myers-Gadelmann, Roxanne Cogil, Terry Witkowski, Anthony Pudlo, Eric Schutenk, Caitlin Pryor and Andy Spurgen.

### **MINUTES FROM PREVIOUS MEETING**

Dr. Janus made a motion to approve minutes from the July meeting and Geoff Wahl 2<sup>nd</sup> the motion.

### **SUMMARY OF DISCUSSION**

#### Iowa Pharmacy Board Representative – Terry Witkowski, Executive Officer

General Description of Board: The Board consists of 7 members, appointed by Governor. Five members are pharmacists and two are from the general public. They meet twice a year. The Board is charged with regulating controlled substances and licensing pharmacists, interns, students, pharmacy technicians, support clerks. They license and regulate the pharmacies themselves and anyone who prescribes controlled substances, including hospitals and long term care facilities. Wholesalers they do in state and out of state. The Board writes rules to interpret what the legislature writes. The Board writes Chapter 124, Chapter 126, Chapter 155a, sections of Chapter 147, Chapter 172c., and Chapter 657. They regulate and enforce these Chapters.

The Board has had some discussion on generic medications, but it is usually due to an investigation, a patient complaint, ect...

Terry reported that they checked all the complaints from Mar 09 to Jul 12, which is about 800 complaints. Four were related to epilepsy drugs and blood pressure medications. There are two letters of education regarding substitution of an epilepsy drug and the other an anti depressant. One resulted in administrative warning (which is not a formal discipline). One hyperthyroid med. One resulted in formulary disciplinary action (pharmacist and pharmacy) involving Lamictal. Charges against the pharmacy are still pending. They have a total of four involving epilepsy drugs. Out of the 800, she speculates about 5% are out of state.

Compliance officers can and will go out of state to investigate and other cases refer the complaints to their state board. Some out of state customer service issues can be resolved without having to turn over to the other state. The majority of out of state complaints probably get passed on.

Complaints are logged in a central database, including phone calls to compliance officers. Sometimes, however, they are logged as an informational call. If it happens again or they do an inspection, then it gets logged in as an official complaint. Part of the compliance officers' job is education.

The Board has no authority over the insurance companies.

The Board of Pharmacy's complaint form is a one page form with basic information. Terry suggested that possibly they can receive the complaints to log it. If there are a few complaints filed against a pharmacy, that is no guarantee that it will go to disciplinary action, and they could simply need education. If it is a case on education, based on current law, the law says that the prescriber writes brand name necessary and writes substitution not acceptable, and then the pharmacy can't change it without notifying the patient and the prescriber.

There are regulations already in place, so Terry states that legislation is probably not the answer. The issue will be with the 3<sup>rd</sup> party.

#### QUESTIONS FROM TASK FORCE MEMBERS TO TERRY WITOWSKI

Q: As a physician, I don't know how to register a complaint. What is the process for discovered incidences?

A: If you want to file a complaint it needs to be in writing by mail or e-mail. Go to [www.iowa.gov/ibpe](http://www.iowa.gov/ibpe). There is a link under the banner called "File a Complaint", which will open a form to fill out and submit electronically.

Q: I know how to file a complaint, but I usually call the counselors. Does this constitute a formal complaint?

A: Usually it gets communicated to the office and it will get filed as a formal complaint. It is suppose to be communicated to the office to get filed. Sometimes, they can handle it on their own. They try to take major steps to ensure that it won't happen again. The Board will look at everything at the investigation regarding each complaint. "Administrative Warning" is confidential. The intent is to make sure that it stays an isolated mistake. If you get into 2 or 3 of the same thing, then the case goes to Statement of Charges, which is a formal discipline. It goes to a hearing, which is facilitated by an administrative law judge. An asistant attorney general presents the state's case.

Q: What about out of state pharmacy doing a mail order? I was told that the Board of Pharmacy doesn't have any jurisdiction over out of state mail orders.

A: The Board does have jurisdiction, but it is limited. They don't have jurisdiction over generic substitution section. One of the letters of education they sent out was in relation to a non-resident pharmacy.

Q: What does a pharmacy board consider DAW? If I write a prescription to use the same Generic manufacturer for one year, is it a violation?

A: You should cite the name of the manufacturer you want to use. The pharmacists say they can't do it. You CAN file a complaint if DAW isn't being followed. The code is very clear. The DAW must be followed. You have to use certain words with certain third parties and Medicare/Medicaid. PPAS out of WI Audit support for independent pharmacy. Says be careful using DAW. It is in the fine print. The pharmacies are getting hit hard with the 3<sup>rd</sup> party audits, especially on the fine print in the contracts. Prescriptions that need to be refilled come back on a fax. They put in the generic name on the sheet and not the brand. It gets switched and the doctor doesn't realize it. Terry says the DEA is taking a hard stance on this and will probably be changed. The DEAs stance is that the pharmacists is not the agent of the prescriber, therefore cannot generate a prescription form for the prescriber. The prescriber should generate the prescription. This will be changing. Terry recommends generating a new prescription.

Q: If physicians should start filing formal complaints, how do we do that, but don't get people (pharmacists) into trouble? How can we do that to get an idea of what the numbers are?

A: Less than 10 percent of complaints end up with formal discipline. There is an issue with out of state code. She says that they can't enforce that with the way the code reads now. We need DAW clarification on prescriptions.

Q: Does the Board understand the sensitivity to the population of people with epilepsy?

A: Terry reports that they understand that the law is there and no one should be substituting because the law is in place. The Board recognizes that and it should be sufficient. The pharmacy corporate entity has a contract

and they receive what they send them. That doesn't mean that they can't get it. It may take jumping through hoops to get it. The attitude is that they don't have time to fight with corporate offices, especially if they don't understand the big issue. If they believe there is no difference between Brand A and Brand B and they are therapeutic equivalent, they believe what they are substituting is the same thing. If pharmacists are operating under substitution laws (FDA redbook), two drugs which can be interchanged and if they don't have any personal knowledge or experience with a person with epilepsy, they may not be aware that they are not the same equivalency. Pharmacies don't take into account drug interactions. Look at absorption rates with food and without food. The fillers and additives are not the same and are absorbed differently. 80-120% confidence interval. The difference in spectrum is enough to throw somebody off. Kumadin, thyroid disease, anti-thyrythmics and anticonvulsants are examples. There are a lot of pharmacy companies who don't recognize the spectrum. The FDA is a flawed system and does need improved. A few well publicized complaints to the Board should solve these issues. Suggestion to put the CE in a quarterly newsletter. Issues should lead to discussions with education to all the pharmacists.

Q: How does compliance offers feel about these issues?

A: Non-resident pharmacies have to comply with the home state. There is recourse that you can file a complaint with the home state. The Board of Iowa will refer complaints to other states if they can't do anything. If we can get the word out to the neurologists, the Board will accept and investigate those complaints, which will be helpful. They are investigated and a report is made. If a complaint is filed, it is always logged. If someone informally talks to a compliance officer, that isn't always logged. If it is logged, it is tracked. Make the DAW clear. Terry's personal suggestion is to hand-write whatever you do. Write: "brand medically necessary". For DAW, write: "name of brand only" and "name of manufacturer". There is a pill identification website to find out name of manufacturers. A pharmacist should be able to get whatever brand is requested. The bigger issue is with mail order pharmacies, as they say they can't get a certain brand. Pharmacies can say they don't or refuse to fill certain prescriptions. The Board will take information verbally or recommend you file a complaint. Debbie Jorgensen logs all the complaints

#### Update on handouts to Pharmacists

Chasity hasn't heard back, but has handed out CE piece.

#### Concerns of Task Force Members

- 1.) Complaints – Needs to be logged. Patterns emerge. The recommendation is that everything should be logged, including phone calls.
- 2.) Complaints need to be filed. It takes too long to file a complaint.
- 3.) Closing out-of-state loophole.
- 4.) Education gap – outdated models about bioequivalence.

#### CLOSING

Dale is going to draft a letter on recommendations to the Board of Pharmacy.

#### **ADJOURNMENT**

There was an abrupt departure from the meeting, due to a fire alarm in the building, so the task force members quickly dispersed.

The next meeting will be on September 11<sup>th</sup> at 3:00 p.m. in Room 517 in the Lucas Building.