

**Minnesota Board of Pharmacy**  
**876<sup>th</sup> Board of Pharmacy Meeting**  
**Wednesday, January 9, 2019**

Statutes, Rules and Guidances

*Temporary Scheduling Order for Syndros (dronabinol oral solution).*

On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(-)-delta-9-transtetrahydrocannabinol (delta-9-THC)] oral solution. Thereafter, the Department of Health and Human Services (HHS) provided the Drug Enforcement Administration (DEA) with a scheduling recommendation that would result in Syndros (and other oral solutions containing dronabinol) being placed in schedule II of the Controlled Substances Act (CSA). The DEA then took action to place FDA-approved products of oral solutions containing dronabinol in schedule II of the CSA. The state has not yet placed Syndros into a state controlled substance schedule.

The Board has the authority to temporarily schedule a substance by issuing an order and publishing it in the *State Register*. (Only when the DEA has taken a scheduling action first). The Executive Director recommends that the Board adopt the Scheduling Order that was provided in the packets of materials distributed for this meeting. It would place dronabinol [(-)-delta-9-transtetrahydrocannabinol (delta-9-THC)] oral solutions into Schedule II.

*Potential scheduling of gabapentin*

At the November 2018 Board meeting, Dr. Katrina Howard gave a presentation concerning this issue. Dr. Wiberg asked the Board to consider authorizing him to go to the legislature with the request to have gabapentin classified as a Schedule 5 controlled substance. After Board discussion and public input from Mr. Kurt Hanna on the global impact of rescheduling gabapentin, Mr. Bialke moved to defer this matter to the next board meeting on January 9, 2019 to allow Dr. Wiberg and Dr. Katrina Howard time to conduct additional research on this topic. Dr. Jassey seconded the motion. The motion passed unanimously.

Since that meeting, Dr. Howard surveyed other states to determine their scheduling of gabapentin. Most of the states that responded have not scheduled gabapentin – but some did state that they have concerns about the abuse of this drug.

In addition, the Minnesota Departments of Human Services (DHS) and of Health (MDH) have provided input to Dr. Wiberg, indicating their support for the scheduling of gabapentin. Letters from both agencies were included in the packet of meeting materials distributed to the Board Members. The letter from MDH nicely summarizes the reasons for scheduling gabapentin:

- Minnesota Department of Health (MDH) conducted an analysis of the State Unintentional Drug Overdose Reporting System (SUDORS) for opioid-involved deaths between July-December 2017. Of the 216 opioid-involved deaths, 14% of the deaths

were found to have a toxicology result positive for gabapentin. Of these deaths, one had gabapentin listed as one of the causes of death.

- Minnesota Poison Control has seen an increase of 44% in calls regarding gabapentin exposure between 2014 (508 calls) to 2017 (722 calls).
- Four states have already reclassified gabapentin as a controlled substance—Kentucky, Virginia, Tennessee, and Michigan.
- Through the Minnesota Board of Pharmacy survey, 46% of pharmacists reported potential gabapentin misuse, including early refill requests, multiple provider episodes, multiple pharmacy episodes, and cash payments.
- Law enforcement has noted an increase in street value of gabapentin, and a growing relationship between methamphetamine use and gabapentin use. Because gabapentin is not currently a controlled substance, law enforcement are currently unable to address diversion.

MDH points out that gabapentin is typically not abused by itself – but is abused together with either opioids or methamphetamine.

The Executive Director requests permission from the Board to include gabapentin in the controlled substance scheduling bill that will be prepared for introduction during the 2019 Session – placing gabapentin into Schedule V.

*CBD from industrial hemp*

#### Provisions in 2018 federal Agricultural Act

When it enacted the 2018 federal Agriculture Bill (Farm Bill), Congress included provisions concerning hemp. Passage of those provisions has generated questions to the Board about the legality of products that contain CBD (and other cannabinoids) extracted from hemp. After enactment of the Farm Bill, the FDA issued a statement regarding the hemp provisions. The statement can be found at:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm>.

The statement confirms that the Farm Bill did not legalize products made with CBD extracted from hemp.

The Farm Bill very explicitly states that none of the provisions of the Food, Drug & Cosmetic Act (FDCA) are pre-empted by the hemp provisions. That effectively means that products containing CBD can't be sold when drug claims are made – unless the product goes through the new drug approval process, the manufacturer is registered by the FDA, and current good manufacturing procedures are followed. In its statement, the FDA also reiterates that CBD can't be sold as a dietary supplement. As long as the FDA holds that CBD can't be sold as a dietary supplement, products that contain CBD that is extracted from hemp and that are sold with the intent that they be used to treat diseases or alter bodily structure and functions are classified as drugs under state law. (Simply excluding such claims from the label doesn't make it legal to sell a product when the seller and the purchaser both understand that the product is intended to be used as a drug). Drugs can't be sold in this state unless they are approved as a drug by the FDA, their labeling is approved by the FDA, and they are manufactured by a FDA-registered and board-licensed manufacturer that is

following current good manufacturing procedures. Unless all of those conditions are met, a drug product is considered to be adulterated and misbranded. It is a crime under state law (a misdemeanor) to sell misbranded and adulterated products.

In short, the sale of most products that contain CBD, extracted from any type of cannabis plant, remains illegal under both federal and state law. The exceptions would be FDA-approved drugs, such as the recently approved Epidiolex – and the products allowed to be sold under state law by the manufacturers that are regulated by the Minnesota Department of Health, Office of Medical Cannabis.

The FDA statement does say that the agency will hold a public hearing and will take new steps to evaluate whether it should pursue the process it would have to follow to allow a pharmaceutical ingredient (like CBD) to be sold as a dietary supplement. From the statement, it appears that the process would involve issuing a regulation – which can take months or even years – and presumably that process won't start until after the FDA makes a decision about whether or not to pursue the action at all. If at some point in the future the FDA does allow CBD to be sold as a dietary supplement, the Board will, of course, need to revisit the issue. In addition, the Minnesota legislature may address this issue during the upcoming legislative session and may act to make the sale of such products legal under state law – although it would remain illegal under federal law.

As licensees of the Board of Pharmacy, pharmacists and pharmacies, drug wholesalers, and drug manufacturers can't violate federal and state law related to drugs or the practice of pharmacy. Consequently, they are advised against stocking and selling products that contain CBD (or other cannabinoids) – except for products approved by the FDA as drugs – within any space licensed by the Board.

These comments do not apply to the use of CBD in foods – since that is not under this Board's jurisdiction.

#### Principles for potential state legislation

The Minnesota Legislature may address this issue during the upcoming session. As of the date on which this document was finalized (January 4, 2019) the Executive Director had not been contacted to provide technical assistance on any bills related to this issue. The Executive Director asks the Board to consider endorsing the following principles so that he can convey the consensus of the Board if legislation is introduced. If the Legislature acts to make such products legal under state law, even though such products are illegal under federal law, it might wish to:

- Prohibit the sale of any product containing a cannabinoid other than CBD. Products containing CBG (the precursor to both CBD and THC) are already being marketed. Without this prohibition, there may be a proliferation of the sale of products containing any of the hundreds of cannabinoids found in the cannabis sativa plant. While there has been research conducted involving CBD the vast majority of the other cannabinoids have not been well-researched. Allowing the sale of products containing other cannabinoids would place the public at risk.
- Establish testing requirements for:

- Verifying the quantity or percentage of CBD found in the product.
- Verify that the product does not contain more than trace amounts, if any, of fertilizers, pesticides, herbicides, or heavy metals.
- Establish labeling requirements that:
  - Prohibit making any treatment or structure and function claims that have not been approved by the FDA;
  - Require the quantity or percentage of CBD to be listed;
  - Require the listing of the manufacturer of the product, as well as the address of the manufacturer.
- Clearly state that products that don't meet these requirements are adulterated and misbranded and therefore subject to the authority of the Board of Pharmacy to issue embargos and cease-and-desist orders.

### *Potential legislation for 2019 Session*

The Executive Director will provide information about potential 2019 legislation for which the Board will probably be asked to provide input. Other individuals have asked to provide information as well. Some proposed bills have been included in the packet of meeting materials supplied to the Board Members.

1. Board sponsored legislation
  - ◆ Non-controversial general policy and potentially controversial general policy – these contain language that the Board has already authorized the Executive Director to try to get enacted. (Conforming state law to federal law in the area of drug wholesaling, veterinary compounding, compounding standards, etc).
  - ◆ Controlled substance scheduling – this is the Board's annual bill to make changes to the controlled substance schedules found in statutes.
  - ◆ Prescription Monitoring Program – will be explained by PMP Manager Barb Carter during the PMP Update.
2. Other potential legislation
  - ◆ Medication repository – **Rowan Mahon, Randal Seiffert, and others**
  - ◆ Counterfeit drugs and illicit online pharmacies – proposed by NABP.
  - ◆ Minnesota Pharmacy Alliance scope of practice - **Michelle Aytay**
  - ◆ Opioid abuse – last session several legislators requested that the Executive Director provide technical assistance concerning issues such as quantity limits for opioid prescriptions, a 30-day time-frame after the issuance of an opioid prescription during which it could be filled, etc.
  - ◆ Pharmacy benefit managers – a variety of bills were introduced last session (prohibiting gag clauses)
  - ◆ Prescription drug access and prices
    - Drugs from Canada – legislative staffers have indicated that some members may be interested in pursuing legislation to allow drugs to be obtained from Canada
    - Other programs

### *Update on rule-making*

The Pharmacy Surveyors have been conducting background research and some have begun the preparation of first drafts of potential rule changes. That process is likely to take at least several more months. Once those drafts have been prepared and edited by the Executive Director, they will be presented to the Board at one of its public business meetings so that the Members can provide input. Also at that time, the Executive Director will ask the Board to start the open appointments process for establishing rules advisory committees.