

**MINUTES OF THE DRUG FORMULARY COMMISSION**

**Meeting of August 6, 2015**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**DRUG FORMULARY COMMISSION  
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH  
Henry I. Bowditch Public Health Council Room, 2<sup>nd</sup> Floor  
250 Washington Street, Boston MA**

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**Docket: Thursday August 6, 2015 12:00 PM**

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**1. ROUTINE ITEMS:**

- a. Welcome and Opening Remarks
- b. Introductions

**2. OFFICE OF GENERAL COUNSEL:**

- a. Open Meeting Law
- b. Ethics & Conflict of Interest
- c. Quorum
- d. Remote Participation (**Vote**)

**3. OVERVIEW OF DRUG FORMULARY COMMISSION**

**4. NEW BUSINESS:**

- a. Discussion of Drug Formulary Commission's Statutory Objectives
- b. Presentation and Discussion Regarding Opiates in Schedules II and III of the Massachusetts Controlled Substances Act

**Drug Formulary Commission**

Presented below is a summary of the meeting, including time-keeping, attendance and votes cast.

**Date of Meeting:** Thursday, August 6, 2015

**Beginning Time:** 12:07 PM

**Ending Time:** 1:53 PM

**Attendance and Summary of Votes:**

<b>Board Member</b>	<b>Attended</b>	<b>Agenda</b>	<b>Item 2d</b>
Dr. Douglas Brandoff	Yes	Yes	Yes
Cheryl Campbell	Yes	Yes	Yes
Ray Campbell III	Yes	Yes	Yes
Dr. Daniel Carr	Yes	Yes	Yes
Joanne Doyle-Petrongolo	Yes	Yes	Yes
Stephen Feldman	Yes	Yes	Yes
Dr. Kenneth Freedman	Yes	Yes	Yes
Dr. Paul Jeffrey	Yes	Yes	Yes
Virginia Lemay	Absent	Absent	Absent
Eric Sheehan	Yes	Not voting	Not voting
Cindy Steinberg	Yes	Yes	Yes
Dr. Jeffrey Supko	Yes	Yes	Yes
Dr. Theoharis Theoharides	Yes	Yes	Yes
Tammy Thomas	Yes	Yes	Yes
<b>Summary</b>	<b>13 Members attended</b>	<b>12 Approved with votes</b>	<b>12 Approved with votes</b>

## **PROCEEDINGS**

A regular meeting of the Drug Formulary Commission (M.G.L. Ch. 17, § 13) was held on Thursday, August 6, 2015 at the Massachusetts Department of Public Health, 250 Washington Street, Henry I. Bowditch Public Health Council Room, 2<sup>nd</sup> Floor, Boston, Massachusetts 02108.

Members present were: Department of Public Health Interim Director of the Bureau of Health Care Safety and Quality, Eric Sheehan (Chair), Dr. Douglas Brandoff, Ms. Cheryl Campbell, Mr. Ray Campbell III, Dr. Daniel Carr, Dr. Joanne Doyle-Petrongolo, Mr. Stephen Feldman, Dr. Kenneth Freedman, Dr. Paul Jeffrey, Ms. Cindy Steinberg, Dr. Jeffrey Supko, Dr. Theoharis Theoharides and Ms. Tammy Thomas.

Absent member was: Dr. Virginia Lemay.

Also in attendance were the following staff from the Department of Public Health: Attorney Kay Doyle, Deputy General Counsel; Suzanne Cray, Director of the Office of Health Care Integration at the Bureau of Health Care Safety and Quality; Jonathan Mundy, Director of the Office of Prescription Monitoring and Drug Control at the Bureau of Health Care Safety and Quality; and David Dunn, Associate Executive Director of the Board of Registration in Pharmacy.

Interim Director Sheehan called the meeting to order at 12:07 PM and made opening remarks before reviewing the agenda and introductions.

Interim Director Sheehan stated that he was representing Department of Public Health Commissioner Dr. Monica Bharel and will serve as her representative as Chair of the Drug Formulary Commission. Interim Director Sheehan explained that opioid abuse is a public health epidemic and the work before this Commission is critical to our efforts to develop solutions aimed at preventing and treating addiction. He explained that Chapter 258 of the Acts of 2014 expanded the Commission's mission, and the Commission is now tasked with preparing a drug formulary of interchangeable drug products for opioids that have a high chance of abuse and/or misuse. To do this work, the Commission will consider the accessibility, cost and effectiveness of the substitute drugs. Additionally, the Commission will review the drug's abuse deterrent technology that could serve as an effective deterrent to abuse and misuse.

Interim Director Sheehan asked if there were any changes to today's agenda and asked for a motion to approve the agenda. Mr. Campbell made a motion to approve the agenda, and Dr. Theoharides seconded the motion. All voted in favor of the agenda.

Next, Interim Director Sheehan asked the members to introduce themselves.

### **2. OFFICE OF THE GENERAL COUNSEL**

- a. Open Meeting Law
- b. Ethics & Conflict of Interest
- c. Quorum
- d. Remote Participation (Vote)

Attorney Kay Doyle provided a presentation on the Open Meeting Law, Quorum, and Remote Participation.

Interim Director Sheehan asked if there was a motion to accept remote participation as an option for the Commission members. Dr. Freedman made a motion to accept remote participation, and Mr. Feldman seconded the motion. All voted in favor of remote participation.

Attorney Doyle explained the need for members to complete Ethics and Conflict of Interest training. The information to complete this training in PACE, the Commonwealth's training system, will be sent to each member. All training must be completed within 30 days of this meeting and a confirmation should be sent to the Department.

### **3. OVERVIEW OF DRUG FORMULARY COMMISSION**

Interim Director Sheehan stated that since it was the first meeting, it was important for each member to have an understanding of why we are here and the important work that we need to accomplish. Jonathan Mundy, Director of the Office of Prescription Monitoring and Drug Control at the Department of Public Health, presented a brief overview of the Drug Formulary Commission and its statutory objectives, which is noted on the agenda under "New Business".

Mr. Mundy completed this presentation. Interim Director Sheehan thanked Mr. Mundy for the presentation. Interim Director Sheehan opened up the floor for questions.

Dr. Theoharides asked if this was a new Commission to look at opiates or if it was the same as the previous Drug Formulary Commission. Interim Director Sheehan responded that it was the same with an enhanced mission from Chapter 258 to look at Schedule II and III opiates.

Dr. Freedman asked if the purpose was to concentrate on opiates used as medications or are we looking at how they are being used? Mr. Mundy responded that we are going to look at how all the opiates are being used.

Mr. Feldman stated that it would be useful to know what data is available through the Prescription Monitoring Program (PMP) including if refills are captured.

Interim Director Sheehan gave an update on the status of the new online PMP system, including that the RFR will close on August 17.

Dr. Theoharides stated that this will be a cumbersome process that carries a lot of legal implications. We will need assistance from the Department's legal staff. Will the Commission members be covered if there is a lawsuit? That will need to be mandatory for us to do our work. Attorney Doyle stated that there is protection and it can be addressed at a future meeting.

Dr. Carr noted that he would interpret equivalence from the patient perspective. A certain opiate may work for a patient but the formulary states that another one fits. Are we diminishing choices because of a pharmacological perspective? He wished to make the application of the Formulary operational and practical.

Dr. Theoharides stated that pharmacological and clinical substitutions are one side of it but there is also the individual patient that needs to be considered. There are four categories for consideration: 1) pharmacologic substitution; 2) clinical substitutions; 3) individual patient and the variance of the impact of drugs on each person; 4) make up of the enzymes in the liver that breakdown this product. Patient samples can be analyzed to determine whether they do or do not have the 'right' enzymes that allow these opioids to either be metabolized (broken down) or be allowed to stay at higher concentrations. These factors can vary tremendously from patient to patient. This enters only into individual clinical practice but makes a significant difference to individual patients.

Dr. Brandoff stated that there are variations within one patient, depending on the status of the disease and metabolism. Intra-individual capability is important. From a clinical point, how clinicians prescribe and what tools are available when prescribing are equally important considerations. Education of prescribers is important - is that within the Commission's scope and purview?

Interim Director Sheehan responded that we are working on promulgating regulation as part of the FY16 budget to change the requirements for pharmacists to input data into the PMP within 24 hours. We will also ensure PMP data is available for clinicians.

Mr. Feldman commented that we should consider this in light of electronic health records and the availability of health data. He stated he is personally aware of one drug which requires diagnosis (for prescription by pharmacists). Otherwise a pharmacist doesn't have diagnostic information or know what the drugs are for. Need to know what is being used to treat addiction in this case.

Ms. Steinberg stated that in Massachusetts there is a requirement that every 2 years, physicians must take 3 hours of CEU in pain management including opioid prescribing. We may want to make a recommendation for training to be provided to educate pharmacists and other prescribers in this area.

Mr. Supko asked what is the first goal for this Commission? What is the agenda/timeline?

Interim Director Sheehan responded stating that our goal is to develop a draft Formulary by early winter. The frequency of meetings from hereon in needs to be discussed. We also need to know what information the Commission members need from the DPH to make decisions.

Mr. Supko asked what is the real objective? To look at the chemical entity of all the drugs and make recommendations for substitutions for everything on the list? Interim Director Sheehan responded to say that is the expectation of the Commission and Mr. Dunn noted that our first step will be to look the drugs with the greatest abuse potential.

Dr. Freedman asked how “concern” should be defined? Abuse or misuse on the basis of what data? He also stated that the Commission will need to have the following data:

- For the past 1-2 years, the number of individuals who died of drug overdose and how many had prescriptions of Schedule II and III prescription drugs. Means to potentially identify frequency and combinations.
- Regarding PMP data, would like to see data on high utilizers, defined as seeing >4 physicians or pharmacists in the same year. We would want to know what such individuals are being prescribed.
- Within the PMP there is not a requirement to report on the prescribing to patients receiving drugs for addiction, such as methadone.

Ms. Steinberg stated that she would like to know if we collect data about overdoses including what drugs are in the individual’s system. Mr. Mundy responded that we can obtain that information.

Dr. Freedman noted that even if we don’t have information for Massachusetts, comparable data from other States as well as national data would be useful.

Mr. Feldman asked what is on the table for consideration by the Commission and what isn’t. The way that prescriptions are filled could be looked at.

Dr. Doyle-Petrongolo stated that access is an issue for patients. We should look at the barriers for obtaining prescription drugs. Regarding the timeframe, when is the timeframe in winter, because winter is long. Interim Director Sheehan responded that our goal is to produce a draft by early winter.

Mr. Campbell asked if there any resources available to the Drug Formulary Commission – if we thought other experts would be helpful. Or is it just the members of this Commission? Interim Director Sheehan responded by saying that we will follow-up on the consideration of external experts, but the intention is for DPH staff to be available too.

Dr. Jeffrey asked what products are considered to be abuse deterrent or near abuse deterrent? We will need a strategy for determining which drugs are high risk. Some are a high likelihood for abuse but we will need guidance on what we should substitute with.

Dr. Theoharides stated that we have such a diverse background, we need to compile list which will be difficult. A document listing different drugs and deterrents, given equivalence and given the abuse potential, would be helpful to provide a starting point. They do not all have the same therapeutic or biological equivalence. Some may be equivalent in terms of one aspect (abuse potential) but not in terms of another (therapeutic properties).

Dr. Carr commented that the word “equivalence” is often expressed in pharmacological terms which is a bottom up approach. We may want to consider a top-down approach to assessing risk and take a departure from the current approach.

#### **4. NEW BUSINESS**

Interim Director Sheehan asked the commission members to comment on the potential barriers to meeting our goal that you see in your respective fields.

Dr. Brandoff commented that all drugs have abuse potential, it’s more the medium in which they are prescribed that is important. He suggested we need a denominator to use to determine the scope and which drugs are taken in an abusive way and how many are taken as intended. We need continued access for those who take the medication as intended.

Interim Director Sheehan stated that an important role of the Drug Formulary Commission is to categorize abuse deterrence – that does not mean abuse proof. We will look at everyone’s expertise to educate and train the public.

Dr. Doyle-Petrongolo commented that we should consider quantities of what is being prescribed. We need guidelines for what is being prescribed for doctors.

Mr. Campbell noted that lots of data is being discussed. I hope we can make it part of our mission to educate the public. Providing context around data and understanding the privacy concerns of certain data requests can be very helpful. Also, do we have the ability to get data from CHIA? Interim Director Sheehan responded stating that we are looking at ways to get data out more effectively and will follow-up on obtaining data from CHIA.

Dr. Carr stated that Blue Cross/Blue Shield had an advisory panel on guidelines for prescription of opioids post-surgery. He stated that he will submit those as reference.

Dr. Jeffrey commented that we want to understand our task. Is it correct that we need to produce a document with lists of drugs to be published with the intention of directing pharmacists to substitute drugs? I want to confirm that is what we are about. Did I describe our task correctly? Interim Director Sheehan responded by saying that was a good summary of our charge. I am aware this is a lot of work. My goal as Chair is to ensure I provide enough data and information to complete this work.

Mr. Feldman noted that we will need evidence to back-up what drugs are put on the lists.

Dr. Brandoff asked if Interim Director Sheehan could talk about the logistics of the meetings and expectations.

Interim Director Sheehan responded by recommending a meeting of the Drug Formulary Commission on the first Thursday of every month moving forward and that meetings take place for three hours. Are there any thoughts from the Commission members on this recommendation?

Dr. Theoharides asked if there could be sub-committees? I don't think we can get this done meeting once a month. Mr. Dunn responded stating that the Board of Pharmacy has subcommittees which have broken down into separate topics, some meet more frequently than others. Interim Director Sheehan stated that we will discuss this further at the next meeting.

Dr. Freedman stated that he preferred meetings to take place first thing in the morning or last thing in the afternoon. Dr. Doyle-Petrongolo agreed. Interim Director Sheehan responded stating that Mr. Mundy would send options out for the next meeting.

Dr. Carr commented about equivalence – using the example of Oxycodone, hypothetically lots of different ones get swept under this generic category: oxycodone hydrochloride. Will our charge be to look at the different ones and say “this person wouldn't necessarily need Oxycodone for that – that can be replaced with what we deem to be an equivalent amount of morphine”? Mr. Mundy responded stating that we will get information that is needed – through literature searches and other State programs.

Interim Director Sheehan asked the members if Commission members could provide us with guidance on what challenges have been experienced or foreseen potential barriers to completing this task ahead of us.

Mr. Feldman stated that the biggest challenge is with patients – patients need pain medication first. How will the list be implemented?

Dr. Doyle-Petrongolo commented that we know that we need to do a list but can we think about an algorithm? The pharmacist is likely to get caught in the middle. Mr. Dunn responded that we will research that approach.

Interim Director Sheehan stated that the statute requires four things to be taken into consideration: effectiveness/efficacy of the drug, access, cost and effectiveness of the abuse-deterrence program. Mr. Mundy commented that our process will be similar to a formulary developed in a hospital setting, but different to meet our needs.

Mr. Feldman asked if we will have a preferred list of substitutes or will it be a “cannot use” list? Mr. Mundy stated that we will review and get back to the Commission on that question.

Dr. Carr asked if the work related to the Commission has been completed previously by an insurer, other state, etc. Mr. Mundy responded stating that we don't know but will research and get back to the Commission.

Mr. Feldman asked if hospital formularies are different than insurer formularies. We need to consider the differences.

Dr. Theoharides asked how the Commission should communicate if we want to help staff. We have data that can be helpful. Attorney Doyle responded saying that all information should be submitted to Mr. Mundy and staff will determine how to distribute.

Ms. Steinberg noted that she would like to have clarification around the language in the statute and in the charge.

Interim Director Sheehan noted that our next steps are:

- Email the members with dates for the next meeting.
- Members need to sign the acknowledgment of receipt of the Open Meeting Law Guide and submit to staff.
- You will get a handout on Ethics training. Once completed, please send your certification to staff.

Interim Director Sheehan asked for a motion to adjourn. Dr. Supko made the motion to adjourn and Mr. Feldman seconded.

The meeting adjourned at 1:55 PM on a motion by and passed unanimously without discussion.

LIST OF DOCUMENTS PRESENTED TO THE DRUG FORMULARY COMMISSION FOR THIS MEETING:

1. Docket of the meeting.
2. Copies of all power point presentations (emailed upon conclusion of the meeting).
3. Copies of the August 3, 2015, press release on the Commission.
4. Copies of the Attorney General's Open Meeting Law Guide and instructions on how to access PACE for Ethics and Conflict of Interest training.
5. Reimbursement information.

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Interim Director Eric Sheehan, Chair