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**Massachusetts Department of Public Health
 Minutes of the Drug Formulary Commission
 Meeting of Thursday, December 14, 2017**

Henry I. Bowditch Public Health Council Room, 2nd Floor
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Date of Meeting: Thursday, December 14, 2017
Beginning Time: 9:05 AM
Ending Time: 11:20 AM

Advisory Council Members Present: The following (12) appointed members of the Drug Formulary Commission attended on December 14, 2017, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Bureau of Health Professions Licensure Director James Lavery (Chair); Dr. Douglas Brandoff; Ms. Steinberg Steinberg; Dr. Kenneth Freedman, Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Logan Leslie; Tracey McMillan; Dr. Alec Walker; Dr. Paul Jeffrey; Dr. Virginia Lemay; and Dr. Jeffrey Supko.

1. Welcome and Introductions

James Lavery called the meeting to order at 9:05AM.

Mr. Lavery thanked everyone for being here today, and reminded everyone that the meeting was being recorded. He then asked if anyone was recording, receiving no affirmative response.

Mr. Lavery called for approval of the minutes from the December 14, 2017 meeting. The members requested several corrections be made, then voted to approve as changed.

- Motion to Approve: Dr. Joanne Doyle-Petrongolo
- Second: Dr. Daniel Carr
- In favor: 7; Opposed: 0; Abstentions: Dr. Jeffrey; Dr. Lemay; Ms. Steinberg; Dr. Walker

2. Draft Formulary and Regulation

Mr. Lavery discussed the status of the regulation, as approved by the Public Health Council.

Mr. Lavery stated that Formulary guidance would be distributed at least 30 days prior to filing the regulation with the Secretary of State to assure a smooth implementation and appropriate compliance.

Mr. Lavery noted coordinating efforts and timing with the Division of Insurance, and introduced Ms. McMillan.

Ms. McMillan: DOI has drafted a bulletin and FAQ to provide guidance to the commercial carriers stating the expectation to have systems modified once the regulations are effective.

Ms. McMillan continued that DOI has confirmed that carriers' systems are intact, and once regulations are in effect, they are capable of providing coverage for Formulary drugs.

Ms. Steinberg: Asked what happens to increase cost?

Ms. McMillan: DOI has not done an analysis just yet on that, but has not heard concerns or questions from carriers.

Mr. Lavery: We will discuss cost at the next meeting.

Ms. Steinberg: Clarified that the law says insurers can't pass the cost on to the consumer.

Ms. McMillan: That's correct

Ms. McMillan: Stated the bulletin is not available publicly yet; still under final review.

3. Prescriber Education Program

Before opening discussion on prescriber education, Mr. Lavery announced that the commission would be going into Executive Session to consult with our legal counsel on matters relating to statutory interpretation.

Audience members were led out of the room to a waiting area.

Executive Session ran from 9:22 AM to 10:22 AM.

When the audience returned, Mr. Lavery discussed the goal of finalizing a plan and content for a prescriber education program.

Mr. Lavery stated the plan would include the development of materials that may be reproduced in in-person presentations to large professional groups and licensing boards, live webinars for appointment viewing, and online resources and webinars so busy prescribers can learn anywhere, at any time.

Mr. Lavery stated the content would include a statement of the opioid crisis, DFC achievements, Formulary specifics, and a step-by step process, with flowcharts showing every possible action between writing and dispensing a prescription.

Mr. Lavery noted presentations would end with basic information about timelines, next steps, and other available documents, and would allow for Q and A, which would be recorded for reposting online, so more prescribers might benefit from these additional insights.

Dr. Freedman: Before any webinars begin, a small subcommittee should review the PowerPoint, including nuances related to wording and phrasing

Dr. Jeffrey: Pharmacists should be included in the audience as well.

Mr. Lavery asked if the members would like to have it all in one webinar?

Dr. Jeffrey: stated the core message should be uniform.

Ms. McMillan: Noted that carriers would benefit as well.

Mr. Lavery clarified that all prescribers (NP, PA, DMD) would benefit and will be included.

Dr. Carr: Stated that a clear and prominent purpose, relating to the specific law should be stated. For example, chemically equivalent was used, meaning formulation of a molecule replaced with a different formulation of the same molecule. Terminology must be specific.

Dr. Doyle-Petrongolo: Pharmacists should be included in title of education program. Also, we should reach out to neighboring state prescribers/pharmacists.

Dr. Lemay: Asked how long the presentation would be?

Mr. Lavery said it would likely be 45 minutes – 1 hour live (30 min online)

Dr. Lemay: Reiterated the importance of the guidance going out at least 30 days in advance.

Ms. Steinberg: Asked if there would be patient education?

Mr. Lavery responded that the primary focus must be on prescribers and pharmacists. Hopefully prescribers will educate their patients. Then we will work with patient groups.

Dr. Walker: Continuing Medical Education credits would be ideal.

Dr. Carr: Professional societies have great info for this.

Dr. Carr: There should be a phrase or catch phrase that cues mental awareness for drug formulary commission.

Dr. Freeman: Co-pays should be addressed.

4. Cost Impact Review

Mr. Lavery stated that DFC staff would like to invite experts to speak on the question “what does it mean for an abuse deterrent substitute to be cost-prohibitive?” He asked the members to describe the particular areas related to cost they would like to hear about.

Dr. Jeffrey: We need a concrete threshold, a defined value threshold, a wow factor. This should be part of the conversation.

Joanne: Insurance, particularly Medicare Part D, should be represented.

Dr. Thompson: Currently, cost is based on the wholesale acquisition costs , distilled cost per milligram. Milligram dispensed per entire year. And compared at 50, 75, and 100% for abuse deterrent substitution.

Dr. Carr: Pfizer has a report with significant value based wholesale knowledge. Tufts Center for Study of Drug Development has knowledge in pharmacoeconomics.

Dr. Jeffrey: We should include a federal agency for healthcare research and quality, like FDA.

Ms. Nelson asked the members if there were other costs, non-monetary?

Ms. Steinberg: Noted administrative costs.

Ms. Nelson suggested the Coalition of ADF Manufacturers, or a group doing similar work, like Governor Baker's Opioid Task Force, or NIH.

Dr. Jeffrey: We need a budgetary framework, and concept of value, and consistency.

Dr. Freeman: Agreed we don't have expertise in this room, but it's useful to have guidance on the topic. We should hear from a couple different entities, including the Harvard group on pharmacoepidemiology.

Ms. Steinberg: The Chapter 55 overdose data would add value.

Dr. Carr: We should discuss health related quality of life. Precise estimates would be difficult, but it would be important to figure out the impact of pain and opioids and different formulations. These could be considered secondary costs.

Ms. Nelson reiterated the basic question what did the legislature mean DFC to look at when they said "is the substitution cost prohibitive?"
She also recommended CHIA and HPC.

5. Next Steps

Mr. Lavery asked Dr. Thompson for an update on IADs.

Dr. Thompson stated that Roxybond (oxycodone IR) would likely be ready for evaluation at the next meeting, and that he was still watching Vantrela ER (hydrocodone ER).

Dr. Thompson noted that the pipeline for approval is very full. He stated that NKATR-181 is interesting; the chemical entity crosses the blood-brain barrier more slowly so that the molecule is less euphoric. This is a novel molecule. He will watch closely.

Mr. Lavery reminded member that the Formulary is a fluid document. As the FDA continues to review and approve drugs with ADP properties, and more of these drug products are brought to the US market, the Commission will need to determine how these drugs may interact on the Formulary. Also, if information comes to light at any time to potentially change the evaluation of an existing drug product on the formulary, the product can be added to the agenda for reconsideration.

Mr. Lavery thanked the Commission members for their thoughtful comments and questions. He will update the committee as he learns about the roll out date.

Ms. Nelson stated that they will resend an email to get a quorum call for the next meeting, which would be in late January or early February.

Mr. Lavery asked for any final discussion or questions, and hearing none, then called for a motion to adjourn.

- Motion to Adjourn: Dr. Doyle-Petrongolo
- Second: Dr. Carr
- All in favor: Unanimous at 11:20 AM.