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Massachusetts Department of Public Health
Minutes of the Drug Formulary Commission
Meeting of Thursday, August 17, 2017
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street
Boston, MA 02114

Date of Meeting: **Thursday, August 17, 2017**
Beginning Time: 9:06 AM
Ending Time: 10:04 AM

Advisory Council Members Present: The following (11) appointed members of the Drug Formulary Commission attended on December 15, 2016, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Bureau of Health Care Safety and Quality Director Eric Sheehan (Chair); Dr. Douglas Brandoff; Cheryl Campbell; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Stephen Feldman, Dr. Kenneth Freedman; Dr. Paul Jeffrey; Tracey McMillan; Cindy Steinberg; and Dr. Theoharis Theoharides.

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1. Welcome and Introductions

Eric Sheehan called the meeting to order at 9:06AM

Mr. Sheehan 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. Sheehan began the meeting by recapping the May 18th meeting. At this meeting, the Commission approved Morphabond ER and Arymo ER as IAD drug products, and five non-abuse deterrent Morphine ER drug products as substitutes for both. Commission staff also presented the timeline for continued review of the proposed amendments to 105 CMR 720, including the first draft formulary.

Next, Mr. Sheehan called for approval of the minutes from the May 18, 2017 meeting.

- Motion to Approve: Dr. Theoharides
- Second: Mr. Feldman
- All in favor: 10; Opposed: 0; Abstentions: Ms. Campbell

2. Non-Opioid Pain Management List

Mr. Sheehan introduced the next agenda item. The STEP Act added a requirement for the Commission to publish, distribute, and update annually a list of FDA approved, non-opioid drug products that are effective pain management alternatives and have a lesser potential for abuse than Schedule II and III opioid drug products, the first of which was distributed and published by the Department with the commission's insight and discussion in July 2016.

Mr. Sheehan announced that the Commission would do its annual review of this list today, with the goal of approving it for publication on the DPH website and distribution to all prescribers and interested parties. This published list may be useful for prescribers, faced with a patient holding a voluntary non-opioid directive, as part of the robust patient-prescriber relationship, to determine a non-opioid treatment alternative.

Mr. Sheehan introduced Dr. Tyson Thompson to review the current list.

Dr. Thompson went through the list; including an explanation of the basic elements.

Dr. Carr suggested adding a sentence relative to an exemption for injectable regional anesthesia.

Dr. Brandoff stated that he knows of a group of patients in hospital that have been in a study and thinks the Commission is trying to impact pain management. These principles are relevant to patients and prescribers. If this can be a tool for inpatient providers to use and curtail those that may immediately jump to an opioid then there is relevance.

Mr. Sheehan asked Dr. Carr to restate the goal of adding this sentence. He stated that prescribers are an intended stakeholder and he wouldn't want them to be deterred from using the list.

Dr. Carr stated that the end goal of the sentence is that drugs that are given as part of regional anesthesia, if appropriate, can be injected, and you may not need anything else. He doesn't want to overlook this practice, although it is a specialized area. He also doesn't want to discourage the use of the list but knows that there is a lot out there.

Dr. Brandoff suggested maybe using the term "techniques" in the statement.

Dr. Carr agreed that would achieve the goal.

Ms. Campbell noted that saying the list is "not intended to encompass," then we will not be meeting the statute. She asked if language could be added to stay within the statute.

Dr. Freedman stated that he doesn't think we need a lot of this; that it may not be necessary.

Dr. Doyle-Petrongolo suggested, from a provider perspective, that they will look at what else they can use for treating their patients. The majority of this will likely be from the ambulatory side. It is good to start while the patient is in-house but as is, without the new statement, is good.

Mr. Sheehan asked the members, before we move on, in light of the discussion, is there a consensus to remove the added statement.

Dr. Carr stated he was happy to withdraw the statement. He agreed that it was a good point that if you are trained in anesthesia, you will likely not consult this list.

Dr. Brandoff stated he was comfortable taking out the sentence.

Ms. Steinberg stated that we have said that there are different uses for the medications. She would want to add some conditions.

Dr. Thompson agreed that drugs are used for those conditions but didn't want to not have a resource to back it up. The information in the conditions column was pulled from the drug manufacturer.

Dr. Doyle-Petrongolo understood he is trying to be consistent with his sources.

Ms. Steinberg asked if it was appropriate to use our expertise based on what we know it is used for. She stated she would hate for it not to be used for ways it could be used.

Dr. Doyle-Petrongolo thinks in professional judgment, it would be used.

Ms. Steinberg agreed to move forward with what people think.

Dr. Carr stated, similar to the earlier point, that it may be helpful, and adding a statement may help to support cross over based on a prescriber's judgment. It's enough to have them listed in these categories to give the prescriber info to try it.

Dr. Jeffrey agreed it could include language to address off-label use of the medication for the condition of neuropathy.

Dr. Carr asserted that these categories are not meant to be binding. It's not yes they do work or no they don't.

Dr. Jeffrey noted that the table is set up from the therapeutic class perspective. An alternative is to do it by classification. He suggested we could find out how many times it is being viewed online.

Ms. Steinberg agreed that it could also be a helpful tool for patients and would be more accessible for patients if set up differently.

Mr. Sheehan stated that we could look at doing a different non-opioid list targeted to patients to make it easier for them to digest.

Dr. Jeffrey expressed that we may be going down a bit of a rabbit hole and may not want to add on here that it is being used for other purposes.

Dr. Freedman agreed, stating he did not think that we should go down this road. I acknowledge that the medication could be used for other purposes but this list is going to significantly expand if we go down this road. The statement covers that the list is not all-inclusive.

Ms. Campbell reminded members that the statute says a list based on FDA information.

Mr. Feldman asked if we should add the source of the information.

Dr. Thompson agreed that would be fine.

Dr. Jeffrey stated that adding the source reinforces not adding the off-label conditions.

Staff added source info and neuropathy at the end of chemotherapy

Mr. Sheehan requested a motion to approve the list as amended.

- Motion to Approve: Dr. Theoharides
- Second: Dr. Jeffrey
- All in favor: 11; Opposed: 0; Abstentions: 0

3. Draft Formulary and Regulation

Mr. Sheehan announced the exiting news that the Public Health Council approved 105 CMR 720 for promulgation on August 9, 2017. He stated that the officially titled "Drug Formulary Commission" regulation would be filed with the Secretary of State in the next few weeks, to coordinate with the distribution of prescriber and pharmacist guidance, assuring a smooth implementation and appropriate compliance.

Mr. Sheehan stated that DPH will also continue its review of the draft guidance to prescribers and pharmacists, and in response to feedback previously provided by the Commission, we are closely looking at options for when the prescriber may be unavailable to authorize a new prescription for a chemically equivalent substitution or a notation for "No Substitution". He noted the Commission's concerns about patient access to pain management when a prescriber is not immediately available and told them DPH was identifying potential remedies for that eventuality.

Mr. Sheehan announced that the development of prescriber education will be on the agenda for discussion at future meetings and asserted that the commission's transition from the Bureau of Health Care Safety and Quality to the Bureau of Health Professions Licensure will provide additional opportunities to coordinate member expertise with relevant professional boards in crafting and implementing this education. He then asked if there were any questions.

Dr. Jeffrey asked if there were any further thoughts on timing.

Lauren Nelson stated that the guidance would be ready soon and distribution would be timed with the filing of the regulation.

Ms. Steinberg asked about the process for roll-out. She also asked how DPH would educate or notify all these practitioners.

Mr. Sheehan outlined that the guidance gets distributed through stakeholders, boards, and MCSR holders; and that this lines up well for the Bureau of Health Professions Licensure because the licensure boards, except BORIM and Podiatry, are under BHPL.

Ms. Steinberg asked when it officially becomes law.

Ms. Nelson answered that it would become law once it is filed with the Secretary of State and has an effective date. It becomes effective the day that the Secretary of State says that it's filed.

4. Next Steps

Mr. Sheehan updated the Commission on the drug product pipeline. While there are no abuse deterrent drug products ready for evaluation today, there are still a few, as mentioned in May, that may be ready for presentation in the coming months, including FDA approved Vantrela ER® and RoxyBond®. He noted that there are some yet-to-be-named drugs in development and alerted the Commission that, 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.

Mr. Sheehan also reminded the Commission that 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. Sheehan thanked the Commission members for their thoughtful comments and questions.

Today, the Commission approved the updated Non-Opioid Pain Management List. As noted, this will be an annual responsibility for the commission, due to be published by September 1st of each year.

Mr. Sheehan noted that staff would be in touch with updates related to the effective date of the regulation and the distribution of the guidance, and reminded the Commission that while we anticipate monthly meetings to continue to be held on the 3rd Thursday of each month, from 9:00-12:00PM in this room, the September 21st meeting would be cancelled. Mr. Sheehan urged members to please stay tuned for meeting news, including doodle polls, and stated that we would confirm quorums as far in advance as possible, and if a scheduled meeting must be cancelled for lack of information to present or any other reason, we expect to notify you at the previous month's meeting, if at all possible.

Mr. Sheehan reminded members that this was his last meeting as Chair of the Drug Formulary Commission, as the operation of the Drug Formulary Commission will be shifting to the Bureau of Health Professions Licensure. He noted that many aspects of the Commission will remain unchanged as a result of this move. Meetings will continue on the same schedule in this same

room, and several faces you recognize, like Tyson Thompson and Lauren Nelson, will remain involved going forward.

Mr. Sheehan announced that James Lavery, the Bureau Director at BHPL, will be the new Chair of the DFC, and brought him up for moment to introduce himself again and answer any questions you may have.

Mr. James Lavery introduced himself to the members and introduced David Young as the new director of the Drug Control Program.

Dr. Carr stated, on behalf of the members, that he wanted to acknowledge the leadership of Eric Sheehan and dedication of Lauren, Suzanne and Tyson.

Members unanimously affirmed.

Mr. Sheehan thanked Mr. Lavery and the members and stated, on behalf of BHCSQ, especially Suzanne, Lauren and myself, that we consider it an honor and privilege to work with this dedicated Commission and wish you nothing but the greatest success in your continued efforts to stem the tide of dangerous opioid abuse and misuse through this work.

Mr. Sheehan asked for any final discussion or questions then called for a motion to adjourn.

- Motion to Adjourn: Dr. Brandoff
- Second: Ms. Campbell
- All in favor: Unanimous