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**Minutes of the Drug Formulary Commission**

**Meeting of Thursday, July 14, 2016**

Henry I. Bowditch Public Health Council Room, 2nd Floor

250 Washington Street

Boston, MA 02114

**Date of Meeting:** Thursday, July 14, 2016

**Beginning Time:** 9:06 AM

**Ending Time:** 10:51 AM

**Advisory Council Members Present:** The following (11) appointed members of the Drug Formulary Commission attended on July 14, 2016, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Interim Director of the Bureau Health Care Safety and Quality, Eric Sheehan (Chair); Dr. Douglas Brandoff; Dr. Daniel Carr; William deGroot; Dr. Joanne Doyle-Petrongolo; Stephen Feldman, Dr. Paul Jeffrey; Dr. Virginia Lemay; Tammy Thomas and Dr. Alexander Walker.

**1. Welcome and Introductions**

Department of Public Health (DPH) Bureau of Health Care Safety and Quality Interim Director Chair Eric Sheehan called the meeting to order at 9:06 AM.

Mr. Sheehan reminded the attendees that this is a recorded, public hearing, and confirmed that no one in audience was recording.

Mr. Sheehan began with a membership announcement. He noted that Ray Campbell was selected as the new Executive Director of the Center for Health Information and Analysis, recognizing his exceptional work in the world of health care policy and his diverse experience, including his notable efforts on this commission. Mr. Sheehan congratulated him on this achievement, and introduced William de Groot, who was appointed in his place. Mr. Sheehan asked the members to join him in welcoming Mr. deGroot as the newest member of the Drug Formulary Commission.

Mr. Sheehan summarized the June 2, 2016 meeting. He noted that the Commission at its last meeting assessed non-opioid pain relievers in answer to the legislative charge to create a list for publication. He noted that the members reconsidered and rejected Zohydro ER as a List B drug; approved Hysingla ER as a chemically equivalent substitute for Zohydro ER; determined that the ADP efficacy of Oxaydo was a category 3, rather than a category 2; and rejected Oxaydo as a chemically equivalent substitute for Oxycodone IR, capsule, Roxicodone, tablet, and Oxycodone IR, tablet, which is a generic of Roxicodone.

Mr. Sheehan called for approval of the minutes from the June 2, 2016 meeting. Minor typographical changes were offered by the members.

* + Motion to approve: Mr. Feldman
  + Second: Dr. Jeffrey
  + All in favor: 10 in favor; 0 opposed; 1 abstention.

Cindy Steinberg abstained as she was not present at the June 2nd meeting.

**2. Non-Opioid Pain Management List**

Mr. Sheehan outlined the requirements of Chapter 52 of the Acts of 2016*, An Act Relative to Substance Use, Treatment, Education and Prevention,* that the Drug Formulary Commission, by September 1, 2016, 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.

Following the discussion from the June 2nd meeting, including member suggestions for introductory language and reformatting, the staff returned with an amended draft of the non-opioid pain management list for the Commission’s review and approval. Mr. Sheehan noted that the new draft was included in the members’ packets and was emailed to the members in advance of the meeting.

Mr. Sheehan noted that following the Commission’s approval, it will be published on the DPH website and distributed to everyone with an MCSR. He noted that the published list could be useful for prescribers, faced with a patient holding a voluntary non-opioid directive, to determine a non-opioid treatment alternative.

Mr. Jonathan Mundy and Dr. Tyson Thompson presented the draft list for the Commission’s review.

Dr. Thompson explained several changes that were made to the previous draft, including the addition of a Corticosteroid class, and reformatting as a table.

Dr. Thompson asked whether the group believed that anti-spasmodics, including dicyclomine should be on the list due to their use for Irritable Bowel Syndrome.

Dr. Walker, Dr. Lemay and Mr. Feldman all agreed that it should not be included.

Mr. Feldman asked that the document include a date, and asked for the source document.

Dr. Thompson stated the source as the Compendia Micromedex.

Mr. Sheehan stated that the document would be dated on the website.

Dr. Lemay noted the absence of tizanidine (Zanaflex). She believes it should be on the list as many other muscle relaxants are on the list.

Dr. Thompson agreed it could be on the list, but did not include it because it is used for spinal cord injury.

Dr. Doyle-Petrongolo agreed it should be on the list.

Lauren Nelson clarified where it should be placed. Dr. Thompson directed it to be added after orphenadrine, and agreed to look up specific FDA indication for the final list.

Dr. Carr asked that “and headache” be included in the title, because it is treated differently than pain or other ailments.

Mr. Sheehan stated that the title was consistent with the statute, which mandated that the list be for pain management.

Dr. Carr asked if the first sentence in second paragraph could be changed to include “and non-drug interventions for pain and headache”

D. Brandoff agreed that it was reasonable to make it more complete and accurate.

Dr. Walker asked if there were any other areas that we could include, like spasticity?

Dr. Carr claimed that differentiating headache from pain in general would have a positive impact on general public.

Dr. Doyle-Petrongolo respectfully disagreed because there are many other types of pain out there, and the FDA indications clarified enough.

Dr. Jeffrey agreed that headache should be included it in the introductory paragraph.

Mr. Sheehan requested and received a consensus to add “and headache pain” to end of first sentence in 2nd paragraph.

Dr. Carr stated that “Off-label Pain Indication” may not be completely appropriate, and proposed “Off-label Published Experience”.

Mr. De Groot noted that there is wording that the FDA uses that we could incorporate

Mr. Feldman stated that the current title for the column includes an understanding that there was a published trial that supports its use.

Mr. Sheehan asked if it would be appropriate to say “Off-label pain use indication”

Dr. Carr stated his discomfort with the word “indication”

Mr. Feldman suggested saying “Off-Label Use”. The group agreed.

Dr. Carr asked, as long as migraine drugs are on list, would new CGRP antibodies be appropriate?

Dr. Thompson noted that these drugs are in Phase 3, and not yet approved. He agreed they could be included once they are approved.

Dr. Carr requested the cells be merged for drugs in the same therapeutic class, and ensure that a single cell not be split between pages. All agreed.

Ms. Steinberg stated that Amitriptyline should have indication for neuropathic pain and back pain. Group agreed.

Dr. Doyle-Petrongolo asked if antidepressants should be split into sub groups: TCAs, SSRIs, SNRIs, etc. Group agreed.

Dr. Brandoff noted that gabapentin and pregabalin have indication for Chemo induced peripheral neuropathy.

Dr. Lemay recommended including headers on each new page.

Ms. Steinberg asked why neuropathic pain has a parenthetical for cancer pain.

Dr. Thompson explained that it was listed this way in the compendia, but agreed to strike it out.

Mr. Sheehan ensured the members that staff would make the agreed upon edits and asked for a motion to approve list of non-opioid drug products for pain management.

* + Motion to approve: Dr. Walker
  + Second: Dr. Brandoff
  + All in favor: 11 in favor; 0 opposed.

**3. Draft Formulary Guidance**

Mr. Sheehan informed the Commission that, having identified no further pairings for the drugs approved as interchangeable abuse deterrent drug products in Component 3, we have now completed the work necessary for a completed draft Formulary of Chemically Equivalent Substitutions, as was the mission of the commission under section 13 of chapter 17 of the General Laws, as charged in chapter 258 of the acts of 2014.

He stated that the Department would issue draft guidance that will accompany the draft Formulary of Chemically Equivalent Substitutions that will be incorporated into the proposed amendments to 105 CMR 720 for promulgation to the Public Health Council.

He then informed the commission about the process for promulgation of the regulation, and reminded the members that the draft formulary is a tool for prescribers when continuing and initiating the treatment of pain, and that a robust prescriber-patient relationship will give prescribers the option of noting “no substitution” when he or she believes that substituting for a safer alternative is not warranted in light of a cost increase or other individual patient factors.

Mr. Sheehan outlined the process for substituting a HPHR opioid with a chemically equivalent substitution, and proceeded to a discussion of the goals of the draft guidance.

Dr. Doyle-Petrongolo stated that physicians she works with want very simple, very basic guidance: for example “you are not required to switch oxycodone to Oxaydo.”

Mr. Feldman agreed and emphasized using SureScripts for e-prescribing. He suggested a change on page three from “not intended to supercede patient-prescriber relationship.” He also advocated for electronic schedule II prescriptions.

Mr. deGroot suggested speaking with NY, which has implemented e-prescribing for schedule II prescriptions.

Dr. Carr asked if it was possible to break up the definition for chemically equivalent substitutions into bullets.

Mr. Sheehan stated that the definition was approved by the commission and had to remain exactly the same.

Mr. Feldman suggested this be broken down into pieces, because it is not easy to look at.

Mr. Sheehan stated that he, Ms. Nelson and others presented this to the commissioner who agreed it should be easier to read

Ms. Nelson assured the members that guidance would be multifaceted. There will be more than just this circular letter.

D. Brandoff emphasized how transformative an effect this is going to have on those delivering and receiving care. The degree of enormity of this is so important. We all are engaged in this, what it’s going to force is mindful prescribing and dispensing

D. Carr asked if this commission is authorized to produce a patient version of this with FAQs. Thinking of pain, when you think about equivalence, maybe under guidance there should be a disclaimer that this document is not about equianalgesic calculations.

Mr. Feldman agreed that it would have an incredible impact but that we haven’t talked about what measures we can come up with to measure what’s going on in relation to this. We need to have data to know how well or poor of a job it’s doing.

Mr. Sheehan reminded the commission that we have PMP data that shows what’s been filled and picked up.

Mr. Feldman noted that if an abuse deterrent is prescribed, we don’t know from the PMP what the process behind it was. Did this program impact the MD to prescribe the abuse deterrent drug?

Mr. Mundy noted that we will have ability to look at changes in therapy.

Mr. Feldman agreed that we would see the change but not know why.

Mr. Sheehan agreed we would never know why a patient got a certain drug, and suggested this was a whole new area we may not have jurisdiction over.

Mr. Feldman suggested there could be something in Surescript, if you write for something that could be substituted there could be a pop up for that.

Dr. Doyle-Petrongolo agreed that the institutions could provide the data, “Are you switching because you were mandated?”

Mr. Sheehan stated that he greatly appreciates the suggestion. Our data world is evolving. Our statute precludes us from doing a lot of things and how we collect them. I appreciate everyone’s thoughts on the draft guidance.

**4. Next Steps**

Mr. Sheehan informed the commission that we anticipated publishing the Draft Formulary, Regulations and Guidance by the first of the year, and that it would be updated each year thereafter.

He informed the members that meetings would be monthly, on the third Thursday each month. He also told them that there would be no meeting in August since they were able to complete the non-opioid drug list.

Dr. Doyle-Petrongolo noted that the February and April meetings fell during school vacation weeks.

Mr. Sheehan laid out the review process for new ADP drugs on the market.

Dr. Thompson informed the members that Vantrela ER has gone through advisory committee and been approved, and SequesetOx has a July 14th PDUFA (anticipated FDA approval) date.

Mr. Sheehan announced that Mr. Mundy was leaving the Department to go back to clinical pharmacy work. His clinical knowledge and expertise will be missed. This will be Jon’s last DFC meeting.

Mr. Mundy made some brief remarks, indicating that he has done a lot of things that he is proud of to make pharmacy better, but this is this first time he has been involved in something that will have such a large scope of impact. The experience has been outstanding.

Having no further business before the Commission, Mr. Sheehan asked for a motion to adjourn.

* + Motion: Dr. Brandoff
  + Second: Mr. Feldman
  + All in favor: Unanimous

The Drug Formulary Commission meeting concluded at 10:51PM.

**Documents Presented to DFC at the *July 14, 2016* Meeting**

* DFC Minutes from June 2, 2016
* DFC PowerPoint presentation
* Draft Non-Opioid Pain Management List
* Draft Formulary Guidance

Documents can be found at: <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/drug-formulary-commission.html>