Commonwealth of Massachusetts
Department of Public Health

Helping People Lead Healthy Lives In Healthy Communities

105 CMR 720.000:
List of Interchangeable Drug Products
Final Regulatory Amendment Presentation

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Public Health Council
August 9, 2017

Commonwealth of Massachusetts
Department of Public Health

Timeline

8/6/14
Chapter 258 of the Acts of 2014 enacted, new mission for DFC

8/6/15
First meeting of reconstituted DFC

10/15/15
Component 1 Completed: All Schedule II and III opioids placed on HPHR list

3/3/16
Component 2 Completed: Six IAD drug products approved, **Embeda**, **Hysingla ER**, **Nucynta ER**, **Oxaydo**, **Oxycodone ER**, and **OxyContin**

6/2/16
Component 3 Completed: Two IAD drug products found to be Chemically Equivalent Substitutions for six HPHR opioids, **Embeda** and **Hysingla ER**

9/15/16
Xtampza ER approved as additional IAD drug product

11/9/16
Draft Formulary and Regulation presented to PHC

1/19/17
Public Hearing Conducted

3/20/17
Troxyca ER approved as additional IAD drug product

5/18/17
Arymo ER and **Morphabond ER** approved as additional IAD drug products and Chemically Equivalent Substitutions for five HPHR Opioids

7/7/17
Second Public Hearing conducted

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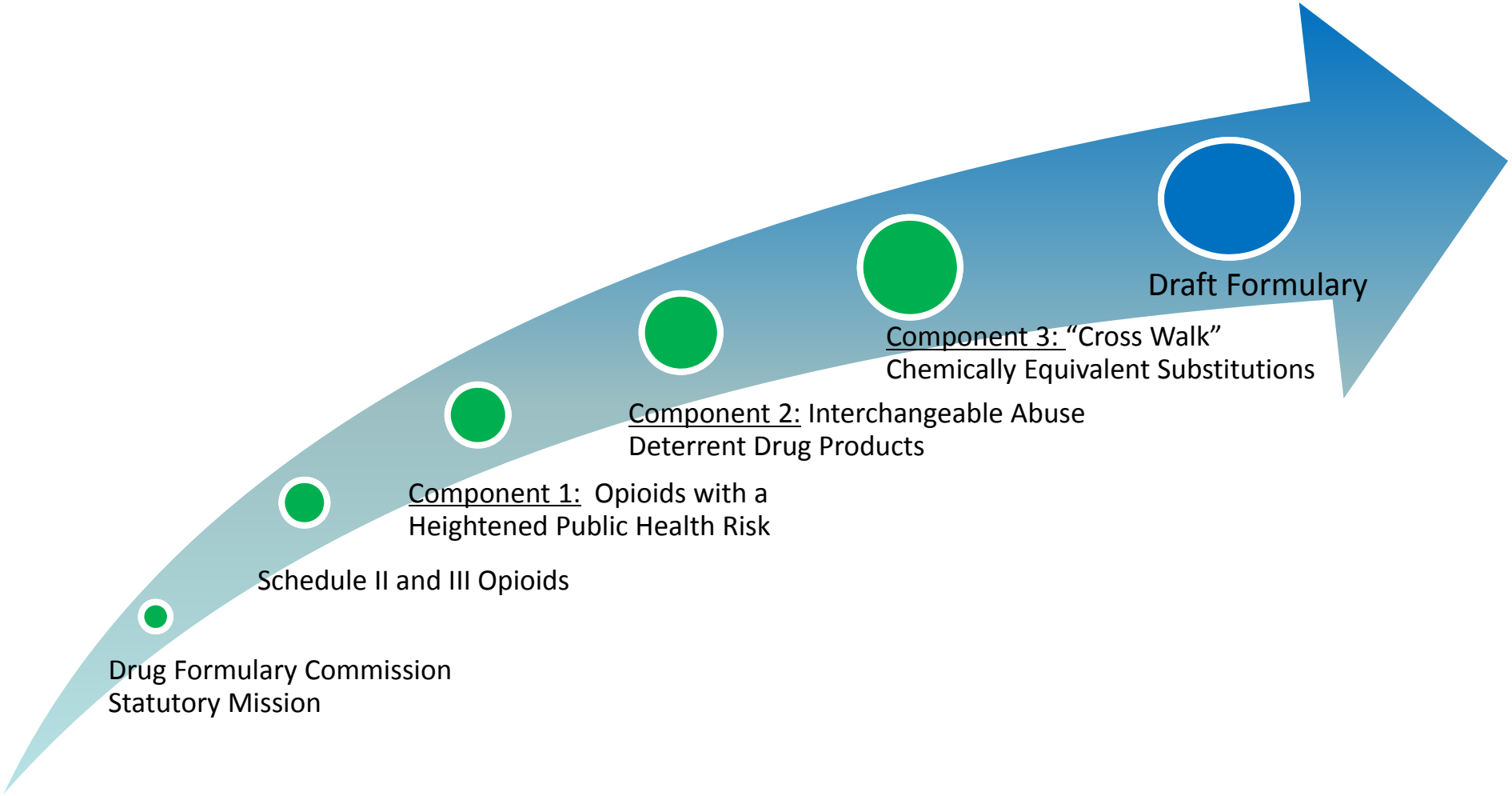
Stages: Evaluation and Review Process Overview



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DFC Approved Interchangeable Abuse Deterrent Drug Products

Product Name	Ingredient(s)	Dose Form	Method of Abuse Deterrence	Date DFC Approved as Potential Substitute
Hysingla ER®	Hydrocodone ER	Tablet	Crush-resistant Formulation	December 17, 2015
OxyContin®	Oxycodone ER	Tablet	Crush-resistant Formulation	January 7, 2016
Embeda®	Morphine Sulfate ER and Naltrexone	Capsule	Antagonist	January 7, 2016
Oxaydo®	Oxycodone IR	Tablet	Aversion technology with assumed ADF properties	February 4, 2016
Nucynta ER®	Tapentadol	Tablet	Crush-resistant formulation	February 4, 2016
Xtampza ER®	Oxycodone ER	Capsule	DETERx® Physical/chemical barrier	September 15, 2016
Troxyca ER®	Oxycodone ER and Naltrexone	Capsule	Agonist/Antagonist	March 20, 2017
Arymo ER®	Morphine Sulfate ER	Tablet	Guardian® Physical/chemical barrier	May 18, 2017
Morphabond ER®	Morphine Sulfate ER	Tablet	SentryBond® Physical/chemical barrier	May 18, 2017

ER or Extended Release is a mechanism to prolong absorption of a drug to allow longer dosing intervals and minimize fluctuations in serum drug levels.
IR or Immediate Release indicates the release of the active ingredient within a small period of time, typically less than 30 minutes.
All decisions of the Drug Formulary Commission may be reconsidered upon receipt of new, relevant evidence.

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Thank You

The Department would like to acknowledge Dr. Tyson Thompson, PharmD, our consultant pharmacist, and all the members of the Drug Formulary Commission for their dedication and hard work in developing the nation's first Formulary of Chemically Equivalent Substitutions and their substantial contribution to the fight against opioid abuse and misuse in the Commonwealth.

Current Commission Members

Dr. Shihab U. Ahmed
Dr. Douglas Brandoff
Cheryl Campbell
Dr. Daniel Carr
Dr. Joanne Doyle Petrongolo
Stephen Feldman, Rph
Dr. Kenneth Freedman
Dr. Paul Jeffrey
Dr. Virginia Lemay
Logan Leslie
Tracey McMillan
Cindy Steinberg
Dr. Jeffrey Supko
Dr. Theoharis Theoharides
Dr. Alexander Walker

Background

- The purpose of this presentation is to request final promulgation by the Public Health Council of the proposed revisions to 105 CMR 720.000, *List of Interchangeable Drug Products.*

- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562.

- This regulation establishes a drug formulary, or list of interchangeable drug products, based on recommendations of the statutorily established Drug Formulary Commission (DFC).

Background

- Chapter 258 of the Acts of 2014 changed the mandate of the Drug Formulary Commission to expand its responsibilities and tasked it with preparing a drug formulary of substitutions for Schedule II or III opioids that have a heightened level of public health risk due to the drugs' potential for abuse and misuse.

- Once the formulary is adopted by regulation:
  - Prescribers may choose to prescribe the abuse-deterrent opioids in place of other opioids.
  - Pursuant to statute, where an opioid with a heightened level of public health risk has been prescribed without a notation of "dispense as written", pharmacists must dispense an interchangeable abuse-deterrent product if one exists.
  - DPH will issue guidance and engage in outreach and education to convey these changes.

Highlights of Preliminary Review

On November 9, 2016, the Department presented to the Public Health Council proposed revisions to 105 CMR 720.000, *List of Interchangeable Drug Products*. Specific preliminary revisions included:

- Changing the title of the regulation from "List of Interchangeable Drug Products" to "Drug Formulary Commission";
- Updating the references to interchangeable drug products;
- Removing the outdated list of generic drugs; and
- Including the drug formulary of chemically equivalent substitutions for opioids with a heightened public health risk.

Post-Comment Review

As a result of the comments received during the public comment period, including the public hearings on January 19 and July 7, 2017, DPH recommends further revisions to 105 CMR 720.000. The further revisions will achieve the following:

- Add a definition for "Commission" as the term is used throughout the regulation but was not specifically defined;
- For consistency, replace all instances of "the United States Food and Drug Administration" with the term "FDA";
- For clarity, include the complete spelling of the drug "Acetaminophen" in the chart of generic Schedule III opioid drug products; and
- Amend the formulary of interchangeable abuse-deterrent drug products for opioids with heightened public health risk to clarify that each listed strength applies to all listed drug products.

Post-Comment Review: Interchangeable Abuse-Deterrent Drug Products

Since the regulation amendment process began, the Drug Formulary Commission has approved several additional interchangeable abuse-deterrent drug products, including:

- Morphabond ER and Arymo ER, both of which have listed substitutes; and
- Xtampza ER and Troxyca ER, which have no approved substitutes at this time.

Implementation

While commenters' concerns over implementation did not require any change to the regulation, staff is addressing those concerns outside of the regulation itself.

- Guidance will be issued to provide clear instructions to pharmacists on proper dispensing of abuse deterrent opioids that have been identified as chemically equivalent substitutions for HPHR opioids.

- Staff is also developing a robust education effort to ensure prescribers have the tools to provide patients with the most appropriate medications to meet their individual needs.

- Once the regulation becomes effective, data collection through MassPAT and other agencies that monitor cost trends will begin to determine the success of and barriers to implementation.

Conclusion/Next Steps

- Staff requests the Public Health Council approve the proposed regulations for promulgation.
- Following Public Health Council approval, the Department will file the amended regulation with the Secretary of the Commonwealth for final enactment.
- Pharmacist and prescriber guidance will be issued. Education of prescribers will be ongoing.

Additional Information

- Thank you for the opportunity to present this information today.

- For more information on 105 CMR 720.000, *List of Interchangeable Drug Products,* please find the relevant statutory language (M.G.L. c. 17 § 13 and M.G.L. c. 112 § 12D) and the full current regulation here:

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter17/Section13
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12D
http://www.mass.gov/eohhs/docs/dph/regs/105cmr720.pdf