

**Slide 1**

 **Drug Formulary Commission**

**Bureau of Health Care Safety and Quality**

**Department of Public Health**

**December 17, 2015**

* Drug Formulary Commission Statutory Mission

**Opening Remarks**

**Slide 2**

* Schedule II and III Opioid Universe
* Component 1: Drugs Of Heightened Public Health Risk
* Component 2: Drug Formulary Therapeutic Substitutes With Abuse Deterrent Properties
* Component 3: “Cross Walk”

Draft Formulary

* Review of November 5th meeting
	+ Final Monograph
* Monographs of FDA approved abuse deterrent formulations Schedule II opioids
* Update on Data requests

**Slide 3**

 Presentation Agenda

**Therapeutically Equivalent Substitutes FDA Approved ADF Labeling**

**Monograph Review**

**Schedule II Opioids**

**FDA Approved Abuse Deterrent Labeling**

**Slide 4**

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| **List of Medications with Abuse-Deterrent Claims in FDA-Approved Labeling**Therapeutically Equivalent SubstitutesFDA Approved ADF Labeling |
| **Product Name** | **Manufacturer** | **Ingredient(s)** | **Dose Form** | **Method of Abuse Deterrence** |
| Targiniq ER | Purdue | Oxycodone ER and Naloxone | Tablet | Antagonist |
| OxyContin | Purdue | Oxycodone ER | Tablet | Crush-resistant Formulation |
| Hysingla ER | Purdue | Hydrocodone ER | Tablet | Crush-resistant Formulation |
| Embeda | Pfizer | Morphine ER and Naltrexone | Capsule | Antagonist |

**Slide 5**

**Slide 6**

**Therapeutically Equivalent Substitutes**

**Factors for Consideration**

Effectiveness

of itsAbuse -Deterrent Properties

Efficacy/ Effectiveness

Accessibility

Is it Cost

Prohibitive

Per the statute, in considering whether a drug should be placed on the formulary as a therapeutically equivalent substitution, the Commission shall consider:

**Therapeutically Equivalent Substitutes
FDA Approved ADF Labeling**

**Hysingla ER Monograph Review**

* hydrocodone bitartrate
* ADF Property
	+ Crush resistant formulation
	+ Effective against chewing, snorting, injection
* FDA approval November 2014
* FDA ADF labeling approval November 2014
* Available Strengths 20mg, 30mg, 40mg, 60mg, 80mg, 100, 120mg.

**Slide 7**

**Therapeutically Equivalent Substitutes
FDA Approved ADF Labeling**

**Oxycontin CR ADF Monograph Review**

* oxycodone HCL
* ADF Property
	+ physical chemical barrier
	+ effective against injection, snorting
* FDA Approval April 2010
* FDA ADF labeling approved April 2013
* Available Strengths
	+ 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg.

**Slide 8**

**Therapeutically Equivalent Substitutes
FDA Approved ADF Labeling**

**Slide 9**

**Embeda Monograph Review**

* morphine sulfate / naltrexone HCL
* ADF Property
	+ antagonist
	+ effective against crushing, snorting
* FDA Approval August 2013
* FDA ADF Approval October 2014
* Available Strengths 20 /.8, 30/1.2, 50/2, 60/2.4, 80/ 3.2, 100/4mg

**Therapeutically Equivalent Substitutes
FDA Approved ADF Labeling**

**Targiniq ER Monograph Review**

* oxycodone/naloxone
* ADF Property
	+ antagonist
	+ effective against snorting, injection
* FDA approved July 2014
* FDA ADF labeling approval July 2014
* Discontinued

**Slide 10**

**Drug Formulary Commission:
Data Requests**

**Update on Data Requests**

**Slide 11**

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| **Data Requests from Drug Formulary Commission** | **Date of Request** | **Expected Presentation to DFC** |
| High Prescriber Utilizers | 08/06/15 | 11/15/15 |
| Abuse Deterrent or Near Abuse Deterrent Products | 08/06/15 | **Today** |
| High Multiple Provider Episodes Utilizers | 08/06/15 | **Today** |
| Opioid Prescriptions - # of Prescriptions, Solid Quantity, and Solid Quantity per Prescription | 09/08/15 | **Today** |
| Pharmacies with High Number of Individuals who exceed MPE Threshold | 09/08/15 | TBD |
| Frequency of Schedule II and III Drug Products that are also Prescribed with Potentiating Controlled Substance Drugs (Tramadol, Benzodiazepines) | 09/08/15 | TBD |
|  |  |  |
| **Additional Data Provided by Department** | **Date of Request** | **Expected Presentation to DFC** |
| Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics | NA | **Today** |

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| **List of Medications with Abuse-Deterrent Claims in FDA-Approved Labeling** |
| **Product Name** | **Manufacturer** | **Ingredient(s)** | **Dose Form** | **Method of Abuse Deterrence** | **Notes** |
| Targiniq ER | Purdue | Oxycodone ER and Naloxone | Tablet | Antagonist | ----- |
| OxyContin | Purdue | Oxycodone ER | Tablet | Crush-resistant formulation | ----- |
| Hysingla ER | Purdue | Hydrocodone ER | Tablet | Crush-resistant formulation | ----- |
| Embeda | Pfizer | Morphine ER and Naltrexone | Capsule | Antagonist | ----- |

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| **List of Medications with Abuse-Deterrent Claims but not within FDA-Approved Labeling** |
| **Product Name** | **Manufacturer** | **Ingredient(s)** | **Dose Form** | **Method of Abuse Deterrence** | **Notes** |
| Opana ER | Endo |  |  | Crush-resistant formulation | No Label |
| Oxaydo | Egalet | Oxycodone ER | Tablet | Aversion Technology with assumed ADF properties | Label contains language from Human Abuse Liability (HAL) study (but not in accordance with FDA guideline standard) |
| Nucynta ER | Jannsen | Tapentadol | Tablet | Crush-resistant formulation | No Label |
| Zohydro | Pernix Therapeutics | Hydrocodone ER | Capsule | Reformation with BeadTek Technology (indistinguishable mix of inactive, active IR, and active ER beads) designed to be ADF | No current ADF |
| Zubsolv | Orexo | Buprenorphine and Naloxone | Sublingual Tablet | Antagonist | For medication-assisted treatment, designed to deter IV abuse; No label |

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| **Schedule II and III Opioid Drug Products Associated with Individuals with Specified Multiple Provider Episode Threshold** |
| Generic Cross Reference Name | # Prescriptions | Solid Quantity | Unique Individuals | Average Daily MME\*/Individual | Solid Quantity/Solid Rx | Avg Days Supply | % Individuals Received Opioid\*\* |
| Oxycodone Hydrochloride | 774 | 36,391 | 137 | 398.1 | 48.5 | 9.7 | 67.2 |
| Acetaminophen/Oxycodone Hydrochloride | 515 | 14,418 | 122 | 170.5 | 28.0 | 6.5 | 59.8 |
| Buprenorphine/Naloxone | 262 | 4,003 | 37 |  ---- | 15.3 | 8.5 | 18.1 |
| Acetaminophen/Hydrocodone Bitartrate | 207 | 4,846 | 80 | 70.5 | 23.4 | 5.8 | 39.2 |
| HYDROmorphone hydrochloride | 170 | 10,412 | 44 | 412.9 | 62.7 | 7.4 | 21.6 |
| Morphine Sulfate | 126 | 5,241 | 32 | 354.1 | 51.9 | 14.2 | 15.7 |
| Fentanyl | 73 | 517 | 17 | 124.0 | 7.1 | 17.7 | 8.3 |
| Acetaminophen/Codeine Phosphate | 41 | 806 | 26 | 241.3 | 19.7 | 4.0 | 12.7 |
| Methadone Hydrochloride | 36 | 2,500 | 12 | 232.5 | 80.6 | 19.0 | 5.9 |
| Buprenorphine Hydrochloride | 12 | 167 | 2 | 654.3 | 13.9 | 10.5 | 1.0 |
| Codeine Sulfate | 8 | 409 | 3 | 37.9 | 51.1 | 13.6 | 1.5 |
| Aspirin/Oxycodone Hydrochloride | 4 | 102 | 1 | 134.4 | 25.5 | 5.8 | 0.5 |
| Hydrocodone Bitartrate/Ibuprofen | 3 | 24 | 3 | 30.0 | 8.0 | 2.0 | 1.5 |
| Buprenorphine | 2 | 5 | 2 | 9.6 | 2.5 | 15.5 | 1.0 |
| Meperidine Hydrochloride | 1 | 32 | 1 | 40.0 | 32.0 | 4.0 | 0.5 |
| Oxymorphone Hydrochloride | 1 | 60 | 1 | 90.0 | 60.0 | 30.0 | 0.5 |
| Totals | 2,237 | 79,937 | 204 | 605.1 | 36.7 | 8.9 |  ---- |
| \*Morphine Milligram Equivalent |  |  |  |  |  |  |   |
| \*\* This represents the percent of individuals who received the specific opioid drug product within that corresponding row |   |
| (e.g., 67.2 percent of the 204 individuals who met the MPE threshold received at least one oxycodone hydrochloride prescription) |
|  ---- Buprenorphine/Naloxone (Brand name is Suboxone) is used for substance abuse treatment; OPMDC is reviewing the scientific  |
| literature regarding adding MME for this drug product and will update information as soon as the review is completed. |   |
| Number of unique individuals identified who met the 5&5 over 3 month (April-June, 2015) criteria = 204 |   |   |

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| **CY 2014 Schedule II Opioid Drug Products** |
| **Generic Cross Reference Name** | **# Prescriptions** | **Solid Quantity** | **Solid Quantity/Prescription** |
| Oxycodone Hydrochloride | 1,101,386 | 81,304,480 | 75 |
| Acetaminophen/Oxycodone Hydrochloride | 1,059,097 | 57,987,696 | 55 |
| Acetaminophen/Hydrocodone Bitartrate | 1,032,335 | 50,780,350 | 49 |
| Morphine Sulfate | 237,275 | 12,679,749 | 69 |
| Hydromorphone hydrochloride | 125,331 | 8,761,164 | 72 |
| Fentanyl | 120,614 | 1,220,203 | 10 |
| Methadone Hydrochloride | 94,266 | 12,114,376 | 134 |
| Hydrocodone Bitartrate/Ibuprofen | 18,135 | 902,161 | 50 |
| Tapentadol Hydrochloride | 9,646 | 756,144 | 78 |
| Oxymorphone Hydrochloride | 9,269 | 766,224 | 83 |
| Codeine Sulfate | 6,805 | 548,995 | 81 |
| Meperidine Hydrochloride | 4,031 | 206,538 | 68 |
| Fentanyl Citrate | 1,028 | 98,592 | 97 |
| Levorphanol Tartrate | 544 | 103,940 | 191 |
| Aspirin/Oxycodone Hydrochloride | 500 | 35,404 | 71 |
| Belladonna Alkaloids/Opium Alkaloids | 261 | 6,699 | 26 |
| Hydrocodone Bitartrate | 29 | 1,560 | 54 |
| Ibuprofen/Oxycodone Hydrochloride | 12 | 412 | 34 |
| Note: Morphine Sulfate/Naltrexone Hydrochloride (EMBEDA®) was not reported to the MA PMP in CY 2014 |

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| **CY 2014 Schedule III Opioid Drug Products** |
| **Generic Cross Reference Name** | **# Prescriptions** | **Solid Quantity** | **Solid Quantity/Prescription** |
| Buprenorphine/Naloxone | 548,579 | 16,816,603 | 31 |
| Acetaminophen/Codeine Phosphate | 241,402 | 9,053,029 | 38 |
| Buprenorphine Hydrochloride | 28,290 | 871,528 | 31 |
| APAP/Butalbital/Caff/Codeine Phos | 9,565 | 450,441 | 47 |
| Buprenorphine | 8,892 | 35,622 | 4 |
| Aspirin/Butalbital/Caffeine/Codeine Phosphate | 3,848 | 214,538 | 56 |
| Aspirin/Carisoprodol/Codeine Phosphate | 61 | 5,400 | 89 |
| Acetaminophen/Caffeine/Dihydrocodeine Bitartrate | 10 | 399 | 40 |
| Aspirin/Caffeine/Dihydrocodeine Bitartrate | 4 | 480 | 120 |
| **Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics**  |
| **Product Name** | **GCR Name** | **Form** |
| AVINZA | Morphine Sulfate | Capsules - Extended Release  |
| BUTRANS | Buprenorphine | Patch - Extended Release |
| DURAGESIC | Fentanyl | Patch - Extended Release |
| EXALGO | Hydromorphone hydrochloride | Tablet - Extended Release |
| FENTANYL TRANSDERMAL SYSTEM | Fentanyl | Patch - Extended Release |
| KADIAN | Morphine Sulfate | Capsules - Extended Release  |
| MORPHINE SUPHATE | Morphine Sulfate | Capsules - Extended Release  |
| MORPHINE SUPHATE | Morphine Sulfate | Capsules - Extended Release (24 hours) |
| MORPHINE SUPHATE | Morphine Sulfate | Tablet - Extended Release |
| MS CONTIN | Morphine Sulfate | Tablet - Extended Release |
| \*NOVAPLUS FENTANYL | Fentanyl | Patch - Extended Release |
| NUCYNTA ER | Tapentadol Hydrochloride | Tablet - Extended Release |
| OPANA ER | Oxymorphone Hydrochloride | Tablet - Extended Release |
| OXYCODONE HYDROCHLORIDE | Oxycodone Hydrochloride | Tablet - Extended Release  |
| OXYCONTIN | Oxycodone Hydrochloride | Capsules - Extended Release  |
| OXYMORPHONE HYDROCHLORIDE | Oxymorphone Hydrochloride | Tablet - Extended Release |
| ZOHYDRO ER | Hydrocodone Bitartrate | Capsules - Extended Release  |
| \*Not included on the FDA REMS list, but are ER/LA opioid drug products |

**Meeting Summary**

* Meeting Recap
* Review of takeaways
* Next steps

**Slide 19**