

**DUR Committee Agenda
September 8, 2015**

**Office of MaineCare Services, Department of Health and Human Services
Augusta Armory
Augusta, Maine
6:00 to 8:00 pm**

Call to Order: 6:00 pm

Public Comments - Open Session

Old Business:

Approval of Minutes (5 mins)

MaineCare Update (5 mins)

Board member MOU's (10 mins)

Closed Session:

Financial Discussion (20 mins)

New Board Member Introductions/Update (5 mins)

New Business:

- A) Behavior Health Medications (10 mins)
- B) Suboxone and Opiate Reports (10 mins)
- C) PCSK9 Inhibitors (5 mins)
- D) SSDC Updates/ Annual Meeting (10 mins)
- E) New Drug Review (45 mins)
 - Aptensio XR
 - Asmanex HFA
 - Daklinza
 - Entresto
 - Glatopa
 - Invega Trinz Inj
 - Irenka
 - Orkambi
 - Prestalia
 - Rexulti
 - Stiolto Respimat
 - Technivie
- F) FDA Safety Alerts (20 mins)

Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm454141.htm>

Unapproved Prescription Ear Drop (Otic) Products: Not FDA Evaluated for Safety, Effectiveness and Quality

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453430.htm>

Codeine Cough-and-Cold Medicines in Children: Drug Safety Communication - FDA Evaluating Potential Risk of Serious Side Effects

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm>

FDA Issues the Drug Supply Chain Security Act (DSCSA) Implementation: Product Tracing Requirements for Dispensers—Compliance Policy Guidance

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

FDA Drug Safety Communication: FDA reporting permanent skin color changes associated with use of Daytrana patch (methylphenidate transdermal system) for treating ADHD

http://www.fda.gov/Drugs/DrugSafety/ucm452244.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Brintellix (vortioxetine) and Brilinta (ticagrelor): Drug Safety Communication - Name Confusion

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm>

Picato (ingenol mebutate) Gel: Drug Safety Communication - FDA Warns of Severe Adverse Events, Requires Label Changes

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm459311.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Next meeting: October 13th 2015 1-4pm

Adjournment: 8:00 pm