

**DUR Committee Agenda
February 10th, 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 November Minutes (5 mins)
- Psych Work Group Update (5 mins)

MaineCare Update

Closed Session:

- Financial Discussion (10 mins)
- Contracts (10 mins)

New Business:

A) Final Hepatitis C PA Form and Status (10 mins)

B) FDA Safety Alerts (20 mins)

- FDA recommends not using lidocaine to treat teething pain and requires new Boxed Warning (6/26/2014) <http://www.fda.gov/drugs/drugsafety/ucm402240.htm>
- Methylphenidate HCl ER tablets (generic Concerta) made by Mallinckrodt and Kudco: FDA concerns about therapeutic equivalence with 2 generic versions of Concerta tablets (11/13/2014) <http://www.fda.gov/drugs/drugsafety/ucm422568.htm>
- FDA reviews long-term antiplatelet therapy as preliminary trial data shows benefits but a higher risk of non-cardiovascular death (11/16/2014) <http://www.fda.gov/Drugs/DrugSafety/ucm423079.htm>
- FDA warns about case of rare brain infection PML with MS drug Tecfidera (dimethyl fumarate) (11/25/2014) <http://www.fda.gov/Drugs/DrugSafety/ucm424625.htm>
- FDA issues final rule on changes to pregnancy and lactation labeling information for prescription drug and biological products (12/3/2014) <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm425317.htm>
- FDA reporting mental health drug ziprasidone (Geodon) associated with rare but potentially fatal skin reaction (12/11/2014) <http://www.fda.gov/Drugs/DrugSafety/ucm426391.htm>
- FDA has reviewed possible risks of pain medicine use during pregnancy (1/9/2015) <http://www.fda.gov/Drugs/DrugSafety/ucm429117.htm>

D) New Drug Review (40 mins)

Keytruda	Ofev	Esbriet	Hysingla	Onexton	Viekira	Trulicity
Tybost	Plegridy	Akynzeo	Xigduo XR	Lynparza	Afrezza	Belsomra
Mircera	Savaysa	Soolantra	Kerydin	Oralair	Bunavail	Uceris Rectal foam
Uceris Oral tablets		Incruse Ellipta		Arnuity Ellipta		

Next meeting: March 10th 2015 6-8pm

Adjournment: 8:00 pm