October 19, 2016 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Zanna (ex officio), Dr. Gooen, Dr. Marcus, Ms. Olson, Dr. Gochfeld, Dr. Barberio, Dr. Lind (ex officio). Unable to attend: Mr. Schafer Dr. Moynihan, Dr. Moore.
Review of Minutes	Approved	Minutes from June 22, 2016 meeting was reviewed and approved. The approved meeting summary will also be posted on the DURB website at: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report		• DURB Annual Summary for SFY 2016 was placed in the Board members packets. Comments and/suggestions will be due on or before November 30, 2016. • Protocol for direct acting antiretrovirals (DAAs) used in hepatitis C was approved by the Commissioners. • Still awaiting the Commissioners' approval of the DURB Annual Summary for State's Fiscal Year 2015. • Board members reappointment is in progress. • Proposed meeting dates for 2017 is in the meeting packet. The dates are: Wednesday, January 11 Wednesday, April 19 Wednesday, June 21 Wednesday, October 18
Old Business		
(a) Antidepressant drugs utilization	Continue to monitor	The Board reviewed a follow-up report on antidepressant utilization. Although the fee-for-service (FFS) claims showed decline in this drug category, the MCO directors indicated they were not having a similar trend and actually have seen some increase in utilization. Board members concluded that transition of most patients to managed care and possibly FDA warnings on these drugs may have caused the decrease on the FFS plan.
(b) Opioid use in children 11-16 years old		The Board reviewed a follow-up report on children (11-16 years old) receiving opioids. Dr. Marcus was of the opinion that the indications for joint pain and fracture in the report could actually be sickle cell which usually made up for most indications for opioid use for this age group. Since the present report compared the first six months of 2015 and 2016, the Board requested a full year's report for a more representative review.

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(c) Physician-administered drugs report	Include report in future meetings package.	The Board reviewed a report on physician-administered drugs for the month of June 2016. There were a total of 7,418 paid claims at the cost of $586,512. The Board expressed concern on the presence of naloxone on this report and requested a review of the individual claims to determine the circumstances under which they were used. They also requested that this report be a part of the regular drug utilization report for each meeting.
(d) PCSK9 Inhibitors utilization report		The Board reviewed a report on proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors for August 2015 through July 2016. There were 25 claims for 12 recipients during this period. This is below the original estimates for use of these products.
New Business		
(A) Proposed protocol for sofosbuvir/velpatasvir (Epclusa®)	Approved	The Board reviewed and approved a protocol for direct acting antiviral (DAA), sofosbuvir/velpatasvir (Epclusa®), indicated for the treatment of chronic hepatitis C virus, genotypes 1, 2, 3, 4, 5 or 6 infections in adults. Dr. Swee recommended that the protocol should include a recent FDA alert – all hepatitis C patients should be tested for hepatitis B prior to initial treatment. Dr. Gooen also suggested testing at the end of treatment. The protocol will be revised with these recommendations.
(B) Proposed educational newsletter for HIV pre-exposure prophylaxis (PrEP)		The Board reviewed an educational newsletter for HIV pre-exposure prophylaxis, or PrEP. The purpose of the newsletter is to increase public awareness of this preventive method. The Board was concerned about the low utilization of tenofovir/emtricitabine (Truvada®), a drug proven to be effective in the prevention of HIV infection in high risk individuals. Frequent testing during treatment recommended by Dr. Marcus will be clarified in the final version of the newsletter.
(C) Protocol Review 1. Pulmonary arterial hypertension drugs		Dr. Swee inquired about the disparity between the various Plans on this protocol. Sam Currie, R.Ph., director of pharmacy at Horizon, explained that during quarterly assessments, Horizon tweaks its protocols that have more approvals than denials in essence making the PA process less burdensome. Connie Yuen, R.Ph., pharmacy account director with Amerigroup informed the Board that her Plan also has regular assessments of protocols in place but

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<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Opioid-induced constipation drugs

(D)NJ DURB Annual Report for SFY 2016</td><td></td><td>will do a special review of this drug category. Dr. Swee encouraged all the Plans to review their protocols and submit a report of their findings at the next meeting (April 2017).

The Board requested the presence of a WellCare representative at the next meeting to explain the step therapy process which requires the trial and failure of MiraLax, a product with recent FDA warning (neuropsychiatric events) in order to qualify for alternative therapy. They had a similar request for Amerigroup.

Dr. Swee reminded board members to review the NJDURB annual report for SFY 2016 included in the package mailed earlier to members. He instructed them to read through it and send comments to Sam Emenike, PharmD on or before November 30, 2016. Ed Vaccaro, R.Ph. and Dalia Hanna, PharmD contributed to the writing of the annual report.</td></tr>
<tr><td>Informational Highlights/Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report</td><td>Continue to monitor.</td><td>The Board reviewed prior authorization denial report comparing all MCO plans including FFS for the 2nd quarter of 2016.

Percentage of prior authorization requests relative to total claims and denials associated with the PAs are listed below:
<table>
<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td></tr>
<tr><td>FFS</td><td>0.7</td><td>19.6</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>32</td></tr>
<tr><td>Amerigroup</td><td>1</td><td>13.6</td></tr>
<tr><td>Horizon</td><td>1</td><td>44</td></tr>
<tr><td>UHC</td><td>0.8</td><td>47.5</td></tr>
<tr><td>WellCare</td><td>1</td><td>45.9</td></tr>
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2. Summary of DURB Actions		The Board reviewed a summary of actions from previous meetings (October 2015 thru June 2016). Dr. Marcus inquired about the status of forwarding a list of dentists prescribing for 30 days opioid to Medicaid Fraud Department (MFD). He was informed that the Division was waiting for an updated report before involving MFD. Dr. Swee instructed emphasized the importance of completing this process when the report is available.
3. DHS and DHSS Programs Top Drugs Report		The Board reviewed August 2016 report for the top drugs, by dollar amount, claims count, and service units. Dr. Marcus commented on Daraprim®, an old medication that has garnered national attention for the 5000% increase in price.

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4. Medication Information		The following medical information were also included and discussed: (a) Opioid deaths in New Jersey. This information, from NJ Medical Examiner's office showed 723 total drug-related deaths from January 1 2015 to June 2015. Although some of the cases were positive for multiple drugs there were 415 deaths attributed to heroin, 24 (morphine), 159 (cocaine), 150 (fentanyl), 121 (oxycodone), and 44 (methadone). (b) Opioid overdoses falling at centers adhering to guidelines (c) New York sets 7-day limit on initial opioid prescriptions (d) 'America's other drug problem': Giving the elderly too many prescriptions (e) Giving High Risk Gay Men A Daily PrEP Pill could Reduce Number of New HIV Cases By A Third Over Next Decade Dr. Gochfeld informed the Board that her colleagues in addiction therapy expressed concern about the delays in treatment associated with prior authorization for buprenorphine. Dr. Swee mentioned that there will be a discussion about this subject and nicotine replacement therapy (NRT) at the January 2017 meeting. He has plans to invite one of the authorities on the subject of NRTs to talk for a few minutes at the meeting. Dr. Gochfeld also pledged to invite someone to speak on addiction treatment.

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Follow up items: (a) Opioids for children report		(a) The Board requested a full year's report (Jan – Dec 2016) for review at the next meeting.
(b) Naloxone patients from physician-administered drugs report		(b) The Board requested a review of patients receiving naloxone as physician-administered drug for circumstances, including actual site of administration and for what indication. They also requested that physician-administered drugs report be part of each meeting package.
(c) Review of protocols by all plans.		(c) Dr. Swee requested that all Plans review their protocols and provide a report of plans to streamline them relative to approvals. The goal is to remove any barriers posed by prior authorization when determined that approval rate for the product/category is high.
(d) Opioid-induced constipation.		(d) Dr. Swee requested that WellCare representative be invited to the next meeting to explain why they require that patients try and fail Miralax® prior to alternative products when there is an FDA warning about the former. Connie Yuen, with Amerigroup will also present the Board with an explanation as to why her Plan has the same requirement.
(e) Chantix® and buprenorphine speakers		(e) Dr. Swee will arrange for a speaker (Jill Williams) to speak on NRTs at the January meeting. Dr. Gochfeld also pledged to invite a speaker on the subject of addiction therapy.