October 14, 2015 DURB Meeting Summary

Issue	Page; Tab	Action	Notes
Roll Call			Present: Dr. Swee, Dr. Zanna, Dr. Gochfeld, Mr. Schafer, Dr. Gooen, Dr. Marcus, Dr. Moynihan, Ms. Olson Dr. Lind (ex officio). Unable to attend: Dr. Barberio, Dr. Moore
Review of Minutes	Pages 3-8; Tab 1	Approved	Minutes from June 24, 2015 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	Page 9-10; Tab 2		• The DURB Annual Summary for State's Fiscal Year 2014 has been approved by the Commissioners and will soon be published in NJ State Register. • The DURB Annual Summary for State's Fiscal Year 2015 was included in the package sent to Board members for this meeting. Comments/suggestions should be submitted before November 30, 2015. • Protocols for Sovaldi®, Viekira® and Harvoni® have been approved by the Commissioners.
Old Business			
(a) UHC Response to DURB Follow-up Questions regarding "Directed Interventions"	Page 11; Tab 3		The Board reviewed a response from United Healthcare, which explained that "directed intervention" are claims that are denied after outreach to the physician and he/she agrees to use one of the formulary alternatives suggested by the clinical PA staff.
(b) Current Direct-Acting Antiviral Hepatitis C Drugs by Genotype	Page 12-14; Tab 3	Continue to monitor and update PRN	The Board reviewed an updated version of a chart with current direct acting antiviral drugs for the treatment of hepatitis C. The chart was updated with two recently approved drugs – Daklinza® and Technivie®. Dr. Swee expressed his gratitude to Sam Emenike, PharmD, who had introduced the concept as a way of simplifying the fluid HCV guidelines, and sometimes confusing genotypic coverages. Board members requested presentation of updated version of the chart at the meetings semi-annually. Dr. Marcus requested posting it on the Board's website but Dr. Swee suggested waiting at least six months to watch for new information in the constantly changing field.

October 14, 2015 DURB Meeting Summary

New Business			
(a) Protein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors proposed protocol	Pages 15-20; Tab 4	Tabled for next meeting	The Board reviewed a protocol for protein convertase subtilisin/kexin 9 (PCSK9) inhibitors (Praluent® and Repatha®). These products were recently approved for the treatment of familial hypercholesterolemia (FH) and clinical atherosclerotic cardiovascular disease (ASCVD). Board members raised concern that prescribing privileges were granted to only two specialties – cardiologists and lipid specialists. They decided after a protracted discussion to table the protocol for next meeting while the State and HMOs consider rewording the criteria to allow consultation with other specialties (to be determined) enough for approval. They also wanted clarification on lipidologists (lipid specialists) qualifications, availability in the State of NJ, and patients' access to this specialty on the MCO and fee for service plans.
(b) Daklinza® (daclatasvir) proposed protocol	Pages 21-24; Tab 5	Approved	The Board reviewed and approved a protocol for daclatasvir (Daklinza®), a new product for use with sofosbuvir in the treatment of chronic hepatitis C in patients with genotype 3 infection.
(c) Technivie® (ombitasvir, paritaprevir, and ritonavir) proposed protocol	Pages 25-28; Tab 6	Approved	The Board reviewed and approved a protocol for ombitasvir, paritaprevir, and ritonavir (Technivie®), a new product for the treatment of chronic hepatitis C in patients with genotype 4 infection.
Informational Highlights/Reports			
1. Fee-for-Service/MCO Prior Authorization Report	Pages 29-30; Tab 7	Continue to monitor.	The Board reviewed prior authorization report comparing all MCO plans including FFS for the 2nd quarter of 2015: - The Board again expressed concern about the high denial rate for some of the plans. Ms. Daphnis, pharmacy director with Amerigroup explained that they are able to keep their denials low because they provide updates and information to providers. WellCare's pharmacy director, Ms. Leung, explained to the Board that most of their denials were due to formulary restrictions. The Board concluded that education of the providers would help reduce some of the obstacles, denials. UHC's representative, Ms. Kripalani promised to provide more information to explain the high "other" category in

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<td>their plan's report. Ms. Gauweiler, PharmD, with Horizon, also explained to the Board that most of her plan's non-formulary requests (95%) are changed at the pharmacy level and therefore posed no hindrance to patient care. Ms. Cortina, pharmacy director with Aetna, explained that her plan's high denial rate was due to transition of care for Affordable Care Act (ACA) expansion patients with no prior insurance.
- Percentage of prior authorization requests relative to total claims and denials associated with the PAs are listed below:

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<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td></tr>
<tr><td>FFS</td><td>0.93</td><td>21</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>39</td></tr>
<tr><td>Amerigroup</td><td>1</td><td>18</td></tr>
<tr><td>Horizon</td><td>1</td><td>38</td></tr>
<tr><td>UHC</td><td>0.6</td><td>49.7</td></tr>
<tr><td>WellCare</td><td>1.7</td><td>54.2</td></tr>
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<td>2. Summary of DURB Actions</td>
<td>Page 31-32; Tab 8</td>
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<td>The Board reviewed a summary of actions from previous meetings.</td>
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<td>3. DHS and DHSS Programs Top Drugs Report</td>
<td>Pages 33-52; Tab 9</td>
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<td>The Board reviewed August 2015 report for the top drugs, by dollar amount, claims count, and service units. Except for Harvoni® (for hepatitis C) and aripiprazole (for mental health disorder), HIV drugs made up 80% or $5,878,924 of the top 10 drugs on the list. Dr. Marcus expressed concern about chlorpromazine which moved up 58 points in the ranking. He wondered if this was due to price increase, and requested that the State provide information on anticipated price increases but was told by Mr. Vaccaro that the State was not in position to do that.</td>
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October 14, 2015 DURB Meeting Summary

4. Medication Information	Pages 53-58; Tab 10		The following medical information were also included and discussed: (a) FDA approves first treatment for sexual disorder (b) FDA approves use of opioid pain treatment for some youngsters (c) Number of marijuana dispensaries correlated with abuse, study finds (d) HIV may continue to multiply in patients who are responding well to antiretroviral therapy
Follow up items: (a) Current DAAs for treatment of chronic hepatitis C (b) PCSK9 Inhibitors protocol c) UHC to provide explanation for "other" category		Continue to monitor	(a) Dr. Swee recommended that the summary of hepatitis C drugs by genotype should be reviewed and presented to the Board in six months. (b) i. Dr. Marcus suggested that a flow chart if possible would help to understand the PCSK9 inhibitors protocol. ii. The Board requested more information on lipid specialists including certification if applicable and how many in the US. iii. Dr. Marcus requested that creatine kinase should be included in the PCSK9 protocol as a matrix to determine true muscle pain in patients claiming intolerant to statin. (c) The Board requested that UHC should provide explanation for the category "other" in the quarterly PA denial report.