August 10, 2017 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Zanna (ex officio), Dr. Gooen, Dr. Marcus, Dr. Gochfeld, Dr. Moynihan, Dr. Moore, Ms. Olson, Dr. Lind (ex officio) Unable to attend: Mr. Schafer, Dr. Barberio
Public Notice		Dr. Swee read a public notice required at each meeting: In compliance with Chapter 231 of public laws of 1975, notice of this meeting was given by way of filings in the Trenton Times, Star Ledger and Atlantic City Press.
Review of Minutes	Approved	Minutes from April 19, 2017 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 2015 was approved and was published in the New Jersey Register on July 3. • Waiting for the Commissioners to sign off on the DURB annual summary for SFY 2016. • Smoking cessation subcommittee met on May 16. Outcomes from the meeting is included in the current meeting packet. Dr. Tsai from the Department of Health provided information on the incidence of hepatitis C in children (12-17 years old) in New Jersey. Special thanks to Dr. Zanna who made that contact possible. • There is no new information on the reappointment or appointment of board members.
Old Business		
(a) Smoking cessation subcommittee meeting (denials report)		Mr. Azoia, R.Ph., pharmaceutical chief, Medicaid, informed the Board that the Smoking Cessation Subcommittee had a lot of interactions with Dr. Williams and Dr. Steinberg. He, Mr. Azoia, was also in contact with their staff and as a result, a state newsletter (Volume 27, Number 06), was published in July, delineating coverage of these products for all of the MCO plans and fee-for-service; and reconciling billing issues that were identified. Some formulary issues were also addressed. Dr. Swee inquired about the Board's previous request for website update by the Plans. Mr. Currie, R.Ph., pharmacy director for Horizon confirmed that this was done for Horizon. Dr. Marcus informed the Board about a bill signed by the Governor, raising the age to purchase nicotine to 21. He wondered if that would impact the

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(b) Proposed protocol for eteplirsen (Exondys 51®)	Approved	dispensing/coverage of the products. Mr. Azoia and Mr. Currie both indicated that coverage is based on FDA-approved package labeling. The Board reviewed a proposed protocol for eteplirsen, an FDA-approved medication for the treatment of Duchenne muscular dystrophy (DMD). The protocol was tabled at the April meeting because the Board requested that prescriber specialties be specific on the protocol. Dr. Swee inquired if contact was made with the only doctor using the product in the State and if she was ok with the protocol. Sam Emenike, PharmD, with Molina informed the Board that he received an email from Dr. Dastgir, a pediatric neurologist, who suggested the specialists included in the protocol. The Board approved the protocol as written.
New Business		
(A) Proposed protocol for safe and efficient use of deflazacort	Approved	The Board reviewed a proposed protocol for deflazacort (Emflaza®), a recently FDA approved medication also for the treatment of DMD in patients ≥ 5 years of age. The Board approved the protocol as written.
(B) Proposed protocol for the safe and efficient use of nusinersen	Approved	The Board reviewed a proposed protocol for nusinersen (Spinraza®). Dr. Gooen suggested that there should be further review by the Board if substantial use is observed in the future. The protocol was approved as written.
(C) Updated protocol for sofosbuvir (Sovaldi®) to include new indication for children and adolescents	Approved. Will review updated version at the next meeting	After discussion, the Board voted to approve a protocol for sofosbuvir for children and adolescents infected with hepatitis C virus. They however recommended the removal of a requirement that eligible patients should have stage 2 fibrosis (METAVIR 2), and other risk factors specified in section 3 of the adult protocol. They also recommended that the protocol be labeled specifically for patients between 12 and 17 years old. As part of the approval, the Board stipulated the need to revisit the protocol in the October meeting to review any findings in literature regarding fibrosis stage or other risk requirements for this age group or other findings in this area by Dr. Marcus.
(D) Updated protocol for sofosbuvir/ledipasvir (Harvoni®) to include new	Approved. Will review updated version at the next meeting	Same as (C) above.

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<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>indication for children and adolescents</td><td></td><td></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 1st quarter of 2017.

At Dr. Swee's request, Matthew Samuel, PharmD, with United Healthcare promised to review the Plan's "directed intervention" category, breakdown formulary switches and true denials and provide this information at the next meeting. In response to Dr. Marcus' inquiry about Horizon's high "incomplete information" category, Mr. Currie explained that the number comprised of the Plan's effort to collect information from the physicians on behalf of the pharmacies and is inflated when the calls are not returned because the prescribers were not available.

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>0.6</td><td>17</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>35</td></tr>
<tr><td>Amerigroup</td><td>1</td><td>24</td></tr>
<tr><td>Horizon</td><td>1</td><td>35</td></tr>
<tr><td>UHC</td><td>0.9</td><td>50</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>46</td></tr>
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2. Summary of DURB Actions/Recommendations		The Board reviewed a summary of actions from previous meetings (June 2016 thru April 2017).
3(a) DHS/DHSS/MCO Programs Top Drugs Report (b) Physician-administered drugs		The Board reviewed April 2017 report for the top drugs, by dollar amount, claims count, service units and category for fee-for-service plan. They reviewed January 2017 report for MCO top drugs. Dr. Marcus expressed concern about a claim for hereditary angiodema product which seemed to be the same amount in each report. Dr. Swee wondered if anyone had any input on the reason for the rising cost of insulin and the impact on community practice. Dr. Moore informed the Board that hospitals are having problem procuring the new generation insulins because of cost. This has resulted in access issues for some patients. Adherence is a problem with the older generation forms due to multiple injections a day.
4. Medication Information		The following medical information were also included and discussed: (a) Desperate families driven to black market insulin (b) "Superbug" fungus new menace in US hospitals, mostly NY, NJ (c) Death from infections may be masking opioid claims (d) Opioid epidemic may be underestimated, CDC report says (e) FDA: Boxed warning for canagliflozin on amputation risk (f) Why are EpiPens so expensive?

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Follow up items: (a) Pediatric protocol for hepatitis C drugs		(a) The Board requested further review of fibrosis requirements for the treatment of children and adolescents using the two recently approved direct acting antivirals (sofosbuvir and sofosbuvir/ledipasvir) for this population. They also requested that the protocol should reflect the targeted age group (12 – 17 year) old patients only. Dr. Marcus will do further research on this subject.
(b) Directed Intervention review for UHC		(b) The Board requested a breakdown of the "directed intervention" category on PA denials report from United Healthcare. They wanted the Plan to separate formulary switches from true denials.
(C) Drug for hereditary angiodema (HAE)		(c) Dr. Marcus wondered why a drug, Cinryze®, a drug used for HAE was routinely prescribed for a quantity of 20 in the top drugs report.