July 18, 2018 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Zanna (ex officio), Dr. Barberio, Dr. Gochfeld, Dr. Moynihan, Dr. Marcus, Dr. Moore, Ms. Olson, Dr. Gooen, Unable to attend: Mr. Schafer, Dr. Lind (ex-officio)
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 July 18, 2018 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		• The direct acting antivirals (DAAs) protocol has been updated to remove METAVIR F2 fibrosis requirement for approval. • Naltrexone (Vivitrol®) protocol has been updated to remove "tried and failed oral naltrexone" requirement. • We are awaiting commissioners' signatures for approved protocols for opioid-induced constipation products, Ranexa®, and Nuedexta®. • Most recently updated protocol for DAAs used in hepatitis C treatment (addition of newer drugs and hepatitis B required tests) was signed off by the Commissioners. • Morphine milligram equivalents factor table in the DURB's MME newsletter was updated with cautionary alert as requested by the Board. • Dr. Swee inquired about the recent recall of valsartan products, an angiotensin receptor blocker. Mr. Azoia, pharmaceutical chief for the State responded that the pharmacies were responsible for pulling these products off the shelves as they are notified by the drug distributors, who were usually, by policy alerted by the manufacturers with the NDC numbers of impacted products.
Old Business		
(a) Updated protocol for ranolazine (Ranexa®)		The Board was updated on the changes made to the ranolazine protocol approved by the Board at the April meeting – removal of the language "tried, failed and/or intolerant" to nitrate. The Board accepted and approved the change.

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(b) Updated protocol for naltrexone injection (Vivitrol®)		The Board reviewed the changes made to the naltrexone injection protocol also approved by the Board at the January meeting. DMAHS had removed the requirement for trial and failure of oral naltrexone prior to use of injectable naltrexone.
(c) Updated protocol for direct acting antivirals (DAAs) in the treatment of hepatitis C		The Board reviewed an updated copy of the protocol for direct acting antivirals used in the treatment of hepatitis C patients. The change was the State's removal of the requirement that patient should have stage 2 fibrosis or METAVIR F2 to qualify for treatment with these agents. The State therefore expanded coverage. Dr. Moynihan wondered how often prescribers would need to consult with specialty physicians prior to managing patients on these medications. She was informed that one consultation is enough. The Board approved the updated protocol.
(d) Update on gabapentin/opioid combination letter		The Board reviewed a summary report of the responses from practitioners who received letters to justify the concomitant use of opioids and gabapentin. A total of 180 letters were sent. Sixty-one (34%) were returned which included 3 discontinuations of opioids, promise to discontinue opioid (2), and other responses (52). Dr. Swee wanted an outcomes report before the Board could take further action on the subject.
New Business		
(A) Proposed protocol for safe and use of opioids	Approved with suggested changes	The Board reviewed a proposed protocol for opioids. Dr. Barberio was concerned that limiting patients to one short-acting opioid (SAO) and one long-acting opioid (LAO) will be problematic for some of her patients. The Board recommended amending these sections of the protocol to read: no more than two SAOs and no more than two LAOs respectively. [Proposed protocol wording for SAOs: no more than two opioid analgesics concurrently; consisting of one SAO and one LAO. For LAOs: no more than one LAO and one SAO concurrently.] Dr. Barberio also raised concern with the protocol's proposed requirement that a titration plan is in place for either opioid or benzodiazepine when used concurrently. The Board recommended that patients on this combination should be monitored closely. Ms. Olson, APN, MS, suggested that this concession may loosen up the protocol to prescribers who may not monitor their patients closely and continue to provide them with indefinite use of the

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		combo.
(B) Proposed edit for opioids >120 morphine milligrams equivalents (MME)	Approved	The Board reviewed and approved a proposal to prospectively review opioids > 120 MME/day.
(C) Proposed educational newsletter for metformin	Approved	The Board reviewed and approved a proposed educational newsletter intended to encourage prescribers to use metformin as first-line treatment for patients with type 2 diabetes. Dr. Barberio expressed concern that she does not get newsletters from the State. Mr. Azoia explained that as a non-billing Medicaid provider, she may not be on the distribution list but her billing service is and may be getting the mailings. Sam Emenike, PharmD., suggested that going forward, he will email all approved newsletters directly to all the Board members. Dr. Gochfeld asked if the current system (sending information to the billing service) could be changed. Mr. Vaccaro, R.Ph., went on to explain that in late 2018, providers will be able to access information from the State via a new portal.
(D) Medication-Assisted Treatment (MAT) products		Dr. Berman, an addiction psychiatrist addressed the Board about his concern with pre-authorization requirements for naltrexone injection (Vivitrol®). He wanted the Board to help streamline the process so that patients are given the treatment they need without going through a protracted PA process. The Board had received letters from patient advocates on this subject. Dr. Swee suggested the formation of a subcommittee to review the process. The subcommittee will be comprised of Dr. Berman, Dr. Barberio, Dr. Gochfeld, Sam Currie, R.Ph., Dr. Marcus, and Ed Vaccaro, R.Ph.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	The Board reviewed prior authorization denial report comparing all MCO plans including FFS for the 1st quarter of 2018. Dr. Swee called on Matt Samuel, PharmD, director of pharmacy with United Healthcare to explain the procedure for processing "non-formulary" drug requests in their plan. Dr. Samuel explained that for UHC, it is the responsibility of the prescriber to evaluate formulary alternatives and change the medication(s) for their

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<table>
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<tr><td></td><td></td><td>patients versus other plans where the pharmacies contact the prescriber and initiate this process. Dr. Moynihan inquired if the (non-formulary) drug would be considered after the prescriber provides justification for choosing that product. Dr. Samuel responded that the plan only covers alternative products provided for those products.
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>0.5</td><td>17</td></tr>
<tr><td>Aetna</td><td>1</td><td>35</td></tr>
<tr><td>Amerigroup</td><td>1</td><td>25</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>35</td></tr>
<tr><td>UHC</td><td>0.8</td><td>53</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>49</td></tr>
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<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of actions from previous meetings (August 2017 thru April 2018).</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>The Board reviewed April 2018 report for the top drugs, by dollar amount, claims count, service units and category for fee-for-service plan. This was compared to the report for February 2018. They also reviewed March 2018 report for MCO top drugs. Dr. Marcus wanted to know why the anti-hemophilia drugs were reported in units, his main concern being the high number of units reported during this period relative to the claims. Mr. Azoia explained the process of prescribing and billing of these products. Linda Gooen, PharmD., suggested that the Board should review the impact of various approved protocols utilization.</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Some medical information was presented and discussed.</td></tr>
<tr><td>Follow up items:</td><td></td><td>- Update the Board on the discussions and findings from the MAT drugs subcommittee meeting.
- Update the Board on the status of the metformin newsletter</td></tr>
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