MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
Wednesday, December 2, 2015
1:00 p.m. to 4:00 p.m.
1 W. Wilson Street, Room 630
Madison, WI 53701

DUR Board Members

Present:

Robert Factor, MD
Paul Cesarz, RPh
Michael Brown, PharmD
Daniel Erickson, MD
Jake Olson, PharmD
Michael Ochowski, RPh
Lora Wiggins, MD

Absent:

Robert Breslow, RPh
Ward Brown, MD
Hannah Delong, MSN, PMHNP-B

HP Staff

Present:

Jenny Nelson, CPhT
Tom Olson, PharmD
Jacque Nash, PharmD
Chally Clegg

DHS Staff

Present:

Kimberly Smithers
Kelsey Gmeinder
Rachel Currans-Henry
Tiffany Reilly
Lynn Radmer, RPh
Lisa Reese

Welcome and Introductions

Rachel Currans-Henry called the meeting to order at 1:12 p.m., and began with a welcome and thanks to the Board members for their attendance at the meeting. The members were reminded of the meeting materials in their respective binders for reference and review. A quorum of members attended the meeting.

Review of the Agenda and Board Materials and Approval of September 2, 2015 Meeting Minutes

Rachel walked through the agenda as printed, highlighting the guest speakers' presentation and its relevance to current Board topics of discussion. Prior to this meeting, Board members received the minutes and RDUR Quarterly Report via e-mail and had the opportunity to review each document. Rachel briefly reviewed highlights of the minutes from the last meeting, advising the Board of one change to the final September minutes after the e-mail distribution. The 204 unit quantity limit group was clarified as 60 mg codeine and butalbital products. The September minutes were then approved with a motion from **Paul Cesarz** and a second from **Mike Brown**. The motion passed unanimously.

Benzodiazepines/Buprenorphine Discussion

Lynn Radmer reminded the Board of Dr. Cullen and Dr. Maskel's presentation regarding the risk of overdose and death in concomitant use of benzodiazepines and buprenorphine at the September DUR Board meeting, where the Board made the decision to construct an intervention. Health Information Designs turned on the concomitant benzodiazepine and buprenorphine RDUR criteria in September to perform an informational analysis. A total of 479 patients were identified as chronic users of dual benzodiazepine and buprenorphine therapy, which is consistent with previous data reviewed. Dr. Cullen has been working with other providers to draft a clinical message for an educational intervention in the form of an RDUR letter customized with the State's specific message. The letter will be sent to all prescribers with patients utilizing both medications chronically. Currently the letter is being finalized with references to support the cautionary prescribing language. Lynn has received approval from the authors of "The Baltimore Report" to use as a citation in the RDUR letter. Distribution of the intervention letter is targeted for January to February 2016.

Opioid Treatment Programs

The next agenda item included guest presentations from organizations within DHS. The first speaker was Camille Rodriguez from the Bureau of Community Health Promotion, which is responsible for the development of federal grant programs. Camille serves as the Director of the Bureau of Community Health and the Injury and Violence Prevention Program, which received a federal grant through the CDC in October 2015, entitled "Prescription Drug Overdose Prevention." The grant is funded at one million dollars over the next four years with the ultimate objective of reducing overdose deaths by 10 percent. Since 2004, the number of unintentional overdose deaths has doubled, and 77 percent of those deaths are in people 30 years of age or older with the average being 43 years old and male. The strategies to meet the overall objective include PDMP enhancement, provider education, naloxone distribution, and proper medication disposal. Camille emphasized that the goal is not to take away access to pain relief but to address the complications of providing the needed relief while minimizing the incidence of overdose.

The next speakers were Joyce Allen and Andrea Jacobson from the Bureau of Prevention Recovery and Treatment, which operates under the Division of Mental Health and Substance Abuse Services. The Bureau of Prevention Recovery and Treatment oversees all of the Opioid Treatment Programs (OTP) in Wisconsin and is the State's liaison between the DEA, SAMHSA, and the Justice Department on all matters of opioid treatment. The services provided by the OTPs include methadone dispensing, counseling (a minimum number of monthly sessions is required), mental healthcare, and general healthcare, though the providers are not authorized to prescribe outside of the addiction treatment protocol. Andrea provided a summary of the certification requirements for treatment programs:

- Certified to prescribe methadone for addiction only
- Adult treatment only
- Known duration of addiction ≥ 1 year
- Voluntary enrollment
- Priority treatment for the following cases: pregnancy, mental health, communicable disease/infection
- Upon enrollment, patients must sign a release of information and take a photo for identity verification, and the clinic must upload the photo to the treatment program's registry

Andrea noted there are multiple policies in place to prevent diversion. Both SAMHSA and the State authority must approve all clinic treatment greater than 50 miles from a patient's place of residence and any take-home requests outside of regulation. Patients are allowed one take-home dose for every 90 days of treatment completed. The initial 90 days begins with one take-home dose and advances every three months to a maximum of 6 take-home doses with a maximum of 13 take-home doses after completion of two years of treatment. To directly enable diversion monitoring, all methadone dispensed is in a liquid formulation, patients must bring all bottles to every call back (both scheduled and unannounced), and submit to urine drug screens and blood testing. The current clinic enrollment status and daily dosing is uploaded with the patient's photo ID to the central registry.

Dr. Erickson asked for any budget estimates, and Joyce advised that, although that data was not directly available, medication-assisted treatment is low in cost-benefit analyses. Andrea noted the cost per patient for medication dosing is low, and the total enrollment is close to 6,000 members. All of the certified Opioid Treatment Programs are private and for-profit organizations that are regulated by the State authority.

In addition to the OTPs, Representative Nygren has worked to pass the Heroin Opiate Prevention and Education (H.O.P.E.) legislation, which will provide two million dollars per year for three treatment centers in northern Wisconsin, where there is a lack of opioid treatment access. The Community Activated Recovery Enhancement (C.A.R.E) grant was awarded from SAMHSA in August to establish treatment centers in Sauk and Columbia counties, which are also underserved areas.

Dr. Erickson stated that having the data available in further detail would help enable the board to direct their

future efforts towards interventions that would be most effective.

Updates

- **Follow Up on Prospective DUR Three-Month Alert**
  In 2013, the Board recommended modifying the Three-Month Supply policy to include only DAPO and permissive NS alerts. Pre-implementation data presented to the Board in 2014 demonstrated a high volume of claims that included both a permissive NS alert and another Prospective DUR alert. It was found that pharmacies could override all Prospective DUR alerts on a claim by responding to the permissive NS alert only. In 2014, the Board recommended modifying the functionality where pharmacies could no longer override all Prospective DUR alerts by responding to a permissive NS alert. The modification was implemented in August 2015. Data comparing September 2014 to September 2015 shows a significant decrease in the number of combination alerts. The early refill (ER) alert is a high-frequency combination alert, and Lynn notified the Board that changes to the ER functionality are in development for early 2016. Jake Olson added that the new combination alerts are much more clinically relevant and useful. It is important to note that pharmacies still receive the NS informational alerts; however, the alert is no longer halting the claim.

- **Quantity Limits for Short-Acting Opioids**
  Lynn reminded the Board that the quantity limit relates to short-acting opioids. Current quantity limits are based on maximum recommended doses of the non-opioid agent present in the product. Currently, there are three quantity limit groups that we want to combine into one quantity limit grouping: 204 (60 mg codeine and butalbital products), 408, and 544 (both 408 and 544 contain combination hydrocodone and oxycodone products). Members may receive up to the quantity limit within each group. The Board voted to approve a quantity limit of 336 units and to keep the current exceptions to the policy available via DAPO overrides (lost, stolen, vacation, natural disaster, therapy changes, malignancies, palliative care and sickle cell) in place.

  After further data analysis, it was discovered that keeping the 204 unit group separate it would result in fewer members being detected by the quantity limit if the codeine/butalbital product is not grouped in with all other short-acting opioids. Also, the 336 unit was discussed previously by the Board based on a 28-day prescription supply; however, a review of claims data shows the majority of prescribers write in 30-day supply increments (144,734 versus 13,723 prescriptions). Based on days' supply analysis, quantity limits of 330 and 360 units per 30 days were proposed to the Board with an implementation timeline of January 1, 2016. There was discussion that 330 units is not practical since prescribers rarely write for 11 units per day but that 360 was still too high given the opioid abuse public health issues. Lynn reminded the Board that 360 is an initial conservative starting measure and that the ultimate goal is to move closer to the 272 tramadol quantity limit so that all of the short-acting products may be grouped together. **Daniel Erickson** motioned to approve the recommendation as written at 360 units, and **Lora Wiggins** seconded the motion. **Michael Ochowski** opposed the motion voicing a concern with including the 204 quantity limit in with the 360 quantity limit, allowing a greater days' supply for the 204 quantity limit drugs.

PDL Update

Rachel Currans-Henry provided a PDL update, noting that 41 drug classes were reviewed and hepatitis C was discussed but not brought up for a formal recommendation. Effective January 1, 2016, antipsychotic injectable formulations will be added to the PDL to maximize supplemental rebate eligibility. The addition of the injectable formulations to the PDL will not change any of the current policy for providers billing these products by HCPCS code. A vote was taken to enable the addition of generic aripiprazole as a preferred drug on the PDL when it becomes cost-effective. Stimulants are the highest cost-driving drug class on the PDL; thus, new-start patients will now be required to complete step therapy requirements via Vyvanse and a second preferred agent prior to trying an amphetamine product, which will be converted to a non-preferred status. Members who were taking amphetamine formulations (as identified from claims history) during the six months prior to January 1, 2016, and are still actively taking an amphetamine formulation will be grandfathered. For these members a prior

authorization is not required until further notice.

The Department held a hepatitis C clinical discussion inviting the top prescribers of hepatitis C medications to participate. Ideas were discussed on how to further broaden the criteria to treat high priority patients, including HIV co-infections, renal transplants, and utilizing a spectrum of fibrosis staging techniques. In response to the CMS letter addressing states' hepatitis C prior authorization criteria, Rachel presented cost analysis and calculated that, assuming 60 percent of infected patients were at least an F2 fibrosis stage and all of them were treated, this would entail a 100 million dollar investment with a return (in decreased medical costs) of only 16.4 million dollars.

Government Accountability Office Report
Jake Olson and Tiffany Reilly presented the Government Accountability Office (GAO) Report in conjunction with State data. Jake stated that the GAO Report was presented at a National Association of Community Pharmacists (NCPA) meeting, and the content could be useful in directing future DUR activity. The Report analyzed data from Arizona, Florida, Michigan, and New Jersey during fiscal year 2011. The four states were chosen based on the highest spend status. The Report objectives were to identify fraudulent or abusive prescribing activities and evaluate the extent of oversight, policies, controls, and processes in place at the state level. Potential control policies not included in the GAO Report include the Lock-In program, which Wisconsin employs, and the prohibition of automatic refills. Wisconsin allows automatic refills and states in handbook topic number 11597 prescriptions dispensed must be picked up by the member or a member representative and if not picked up be returned to Medicaid and the medication be returned to pharmacy stock.

Two areas of the GAO Report were directly compared to Wisconsin via state data. One potentially fraudulent activity includes patients receiving more than 365 days' worth of medication in a year's time. Tiffany presented data for all drugs; only 731 of 880,000 members received greater than a 480 days' supply in 365 days, which equates to less than 1percent. The GAO also looked at potential "doctor shopping," in which patients may be seeing five or more prescribers to obtain the same medications. The use of antipsychotics, most notably quetiapine, to either enhance the effects of other drugs or serve as a method of self-detox are increasingly on the rise according to the American Academy of Addiction Psychiatry. For the State of Wisconsin, Tiffany found less than 1percent of members are seeing greater than five prescribers for antipsychotics. Tiffany concluded, for both areas of interest, that the State of Wisconsin does not see either of these as an area of concern at this time.

Future DUR Activity Survey Discussion
Due to time constraints, Kimberly Smithers conveyed to the Board that she would distribute the results of the Future DUR Activity Survey via an e-mail and encouraged feedback from the Board regarding both the recommendations provided in the survey results and new ideas for future meeting discussion.

Adjournment
Paul Cesarz motioned to adjourn. **Mike Brown** seconded the motion. The meeting adjourned at 4:02 p.m. Upcoming meetings are on the following Wednesdays: March 2, 2016; June 1, 2016; September 14, 2016; and December 7, 2016.

Guests: Mike Healy (Gilead), Scott Mills (Allergan), Sarah Nelson (Skywalk), Randi Lewandowski (Teva), Jocelyn Good (Pfizer), Keith McCoy (Pfizer), A. Elizabeth Plouff (UCB)