MINUTES OF THE DRUG UTILIZATION REVIEW (DUR)
BOARD MEETING
Wednesday, June 1, 2016
1:00 p.m. to 4:00 p.m.
1 W. Wilson Street, Room 751
Madison, WI 53701

DUR Board Members	HPE Staff	DHS Staff
Present:	**Present:**	**Present:**
Robert Factor, MD	Nadine Miller	Kimberly Smithers
Paul Cesarz, RPh	Tom Olson, PharmD	Rachel Currans-Henry
Michael Brown, PharmD	Jacque Nash, PharmD	Tiffany Reilly
Daniel Erickson, MD	Jamie Jones	Lynn Radmer, RPh
Michael Ochowski, RPh	Randy Cullen, MD	Lisa Reese
Robert Breslow, RPh	Diane Lampe	Kristie Chapman
Lora Wiggins, MD		
Hannah Delong, MSN, PMHNP-B		
Absent:		
Ward Brown, MD		
Jake Olson, PharmD		

Welcome and Introductions
Rachel Currans-Henry called the meeting to order at 1:04 p.m. and began with a welcome and thanks to the Board members for their attendance at the meeting. All members, staff, and guests present introduced themselves to the room. 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 March 2, 2015 Meeting Minutes
Rachel walked through the agenda as printed. Prior to this meeting, Board members received the minutes and RDUR Quarterly Report via e-mail and had the opportunity to review each document. The March minutes were then approved with an initial motion from Mike Brown and a second from Paul Cesarz. The motion passed unanimously.

Early Refill Update
Lynn reminded the Board that the early refill (ER) alert was the last of the prospective DUR alerts to be implemented from a project initiated in 2011. The ER alert changes were implemented on April 11, 2016. The alert now monitors all drugs except those restricted by a quantity limit. This has led to a 20 percent increase in the number of alerts. The increase in alerts, however, has not correlated with an increase in provider help center call volume. The alert message returned to providers was modified based on recommendations from the March Board meeting to display the first date the prescription may be refilled without setting the alert message. This replaced the message that informed providers how many days' supply remained on the most recent fill. The Board previously advised to have both the days remaining on the most recent fill and the date the next fill could occur without hitting the alert. Due to character limitations in the message text field, it did not allow for this modification. The next steps for this project will be to determine future reporting needs and further discussion of long-term care place of service claims.

Lock-In Program Update

Recommendations were made and accepted unanimously at the March Board meeting to improve the efficiency of the Lock-In (LI) Program. All modifications associated with those recommendations were implemented during the April RDUR/LI cycle. The first recommendation was an addition of new criteria to focus on member profiles who are receiving high quantities of restricted medications and have a diagnosis history positive for drug poisoning. Jacque discussed the impact of the new criteria addition, noting an average of 450 member hits per cycle with most of these members having no previous intervention history. The first two cycles also revealed that the most frequent poisoning agents were benzodiazepines and opioids. The second recommendation was expected to have the largest impact. The previous criteria looked for a 120-day supply of a restricted medication in the last 90 days, which resulted in large amounts of "low intensity" reviews (e.g., pediatric patients taking both an extended-release and immediate-release stimulant formulation). The recommendation was to increase the threshold for a hit from 120 days to 240 days, which would exclude all of the aforementioned stimulant cases and escalate those cases receiving the highest volume of controlled substances. The criteria modification reduced the total hit volume from 14,000 to 2,600 and increased the intervention rate due to higher intensity reviews. With this program change implementations, the letter volume for the April cycle increased by approximately 1,500 letters. The third recommendation was to remove HIV and antiretrovirals from the negating criteria since advancements in medicine have essentially given this population quality and quantity of life comparable to the general population. The final proposal was to increase the profile history for annual reviews from 12 months to 18 months. The final two proposals are in place; however, the first two cycles have not produced any data regarding the outcomes from these specific changes.

Benzodiazepines/Buprenorphine Intervention Follow-up Discussion

Lynn Radmer began the discussion with a summary of statistics regarding the number of intervention cases and prescriber feedback. A total of 675 profiles were sent to 275 different prescribers on February 9, 2016, with 457 members identified by the profile reviews. The average number of profiles received per prescriber was 2.5; with one prescriber receiving 29 profiles. At the March Board meeting, Dr. Erickson stated that he would like to see the median of the prescriber data to better demonstrate the distribution. Jamie Jones provided a median of one letter per prescriber for the follow-up discussion. A total of 278 response forms were received, with 98 containing written comments. The overall tone of the comments was positive. There were a total of 391 non-responses. The response form allowed the prescriber to rate the usefulness of the letter; 180 of the 284 (63 percent) response forms received found the intervention either "useful" or "extremely useful."

Jamie performed follow-up data analysis on the members identified for the intervention. There were 119 prescribers that had fewer patients hit the criteria; 62 prescribers did not have any patients hit the criteria. There were a total of 98 members that no longer hit the criteria. Of those 98 members, 31 members had claims only for buprenorphine, 31 members had claims only for benzodiazepines, 9 members had claims but did not hit the criteria, and 27 members had no claims for either agent. Dr. Erickson stated that he would like to see the actual member outcome in correlation with the response type, and Robert Breslow stated he would like to see the correlation between the response type and usefulness ratings. Lynn noted this data would be difficult to obtain since there is not a one to one relationship. Dr. Wiggins noted there was an unintended outcome of members discontinuing their buprenorphine treatment, and Hannah Delong advised that this may be due to the treatment center dropping patients following violation of the treatment contract, which most often includes avoidance of benzodiazepines.

Dr. Cullen performed prescriber outreach phone calls to five outliers who had either responded negatively or not at all. One prescriber wrote a letter expressing the intervention was negatively received. During Dr. Cullen's follow-up call, the prescriber stated "you caught me on a bad day…" then elaborated on the combination of methadone and benzodiazepines which he found to be a bigger area of concern. A second prescriber was concerned that the intervention may increase barriers to opioid dependence treatment. Multiple prescribers stated that they were not concerned with the potential risk of dual therapy due to the low doses of both buprenorphine and benzodiazepines they utilize in practice. There was discussion with the Board that low doses (e.g., 8 mg of buprenorphine per day) are not what is routinely seen on the profile reviews. Dr. Erickson noted that the trial of Selective Serotonin Reuptake

Inhibitors (SSRIs) in his practice rarely succeeds. Dr. Cullen cited a Norwegian trial documenting SSRI efficacy for anxiety and advised that the SSRI is likely not being utilized at a therapeutic level or being switched to a second drug prior to giving up. Hannah Delong cited a National Institutes of Health study documenting the equal efficacy of clonazepam and sertraline at eight weeks with increased efficacy of the SSRI after the eight-week point in treatment. Dr. Cullen received comments from the prescribers he contacted about problems with the Prescription Drug Monitoring Program (PDMP), , and that the intervention letter was helpful because it gave the prescribers an objective piece of evidence to show patients in support of the clinical decision to decrease the patient's benzodiazepine use.

The next step for the benzodiazepines/buprenorphine intervention is to perform additional data analysis after a full wash-out period to exclude potential confounders due to benzodiazepine titrations. The data analysis will include dosing parameters and prescriber detail (e.g., specialty, location).

Benzodiazepines/Methadone Discussion

Lynn informed the Board that this intervention project had been put on hold while awaiting clarification on the legal aspects of disseminating medication assisted treatment (MAT) patient information to non-MAT prescribers. The legal department has cleared the Board to continue with the intervention process. The Board reviewed the existing RDUR criteria that will be used for this intervention. An initial data analysis was conducted based on the criteria model for a 60-day time span from January to March 2016 and identified 322 members with 290 prescribers. Alprazolam and clonazepam were the top benzodiazepines utilized in the preliminary data, with all agents being prescribed in a wide range of doses. The highest doses for each benzodiazepine identified are as follows: lorazepam up to 8 mg/day, alprazolam up to 10 mg/day, diazepam up to 35 mg/day, clonazepam up to 8 mg/day, and temazepam up to 60 mg/day. Dr. Erickson expressed concern that the methadone claim is not reported on the PDMP data, and Rachel responded that the sharing of data among agencies is a necessity that is currently being discussed interdepartmentally. The next steps are to work with Dr. Cullen to develop an initial intervention letter and to design a second phase for follow-up with the methadone treatment centers for the most concerning chronic cases.

Federal Agency Opioid Guidance and HOPE Legislation Discussion

Tom listed several of the recent federal publications discussing opioid prescribing and abuse. The list of recent publications includes the Presidential Memorandum, *Addressing Prescription Drug Abuse and Heroin Use*; National Institutes of Health (NIH) National Pain Strategy; FDA Opioid Action Plan; *CDC Guideline for Prescribing Opioids for Chronic Pain*; and the CMS Bulletin, *Best Practices for Addressing Prescription Opioid Overdoses, Misuse, and Addiction*. Tom began with a summary of the Presidential Memorandum and the NIH publication. The Presidential Memorandum was the first publication released on October 21, 2015.The focus is to direct the agencies within the Executive branch to develop policies and procedures for addressing opioid abuse. The Memorandum identified three priority areas: policy, federal prescriber training, and improving access to MAT and modernizing benefit design. The policy section directs agencies to develop policies for provider training and increased MAT access. Training of federal prescribers is specifically directed to providers who work at the federal level. The third section is directed towards agencies that directly provide health care services to conduct formulary reviews and identify any existing barriers to MAT and to increase access.

Tom also summarized the NIH's National Pain Strategy, which was published in March 2016. The NIH's primary function is to serve as the nation's medical research agency; thus, the National Pain Strategy recognizes the lack of adequate evidence-based guidance and provides goals for the development of further supporting data. The NIH supports developing patient-centered care based on a biopsychosocial model, reducing barriers to MAT, and increasing public awareness to reduce the stigma of opioid abuse treatment.

The third federal item discussed was the FDA's Opioid Action Plan, which was released on February 4, 2016. The Opioid Action Plan contains specific areas of activity aimed to support the policy direction set forth by the Presidential Memorandum. The recommendations include: convene an advisory committee for the review of new drug agent applications without abuse-deterrent formulations (ADF) as well as any new pediatric labeling, developing new warning labels for immediate-release opioid formulations for abuse potential, updating Risk Evaluation and Mitigation

Strategy (REMS) Programs, expanding ADFs and post-market study requirements concerning the long-term impact of extended-release opioid use, support for other treatment options outside of opioids, and reassessing the overall risk-benefit approval framework for opioid use. The action items are intended to be carried out by the FDA with the intent of reducing opioid abuse potential at the drug approval and labeling steps.

Jacque provided a comparison of the CDC guidelines for prescribing opioids and the CMS bulletin, *Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction*. The target audience for the CDC is the prescriber population versus the state health plans for the CMS bulletin. The CDC is also an evidence-based traditional guideline (though the evidence is significantly lacking); whereas, the CMS bulletin is a recommendation piece with a few specific ideas for the states but no direct guidance. The CDC "provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end of life care" and is intended to provide clarity among all of the other previously-discussed federal publications. The aim of the guideline is to give prescribers a set of specific steps to follow in the treatment of chronic pain that will ultimately support the prevention of opioid abuse. The CDC guideline is divided into three areas of priority with 12 recommendations. The first section discusses when to initiate and/or continue opioid use and defines chronic pain as that continuing for greater than three months. The specific recommendations of section one include: having a full treatment plan, including a discontinuation date in mind from the onset, beginning with non-opioid treatment and ensuring that the patient is aware of the potential risks for development of dependence and abuse. Section two discusses dosage selection, duration, follow-up, and discontinuation. The recommendations of section two include: starting with immediate-release formulations, prescribing the lowest-effective dose with avoidance of greater than 90 morphine equivalents per day if possible, only treating acute pain for three to seven days, and evaluating the risk-benefit ratio within one month of initiation and every three months thereafter. Section three addresses the risk assessment and recommends PDMP monitoring no less than every three months, naloxone availability as needed, urine drug screens at least annually (the only patient-specific recommendation in the guideline), and offering MAT when appropriate. Jacque then offered possible ways to utilize the CDC guidelines with the DUR Board, which could include provider education through interventions and dissemination of the guideline, as well as future lowering of the opioid quantity limits based on the daily morphine equivalent recommendations.

The CMS bulletin's purpose is to highlight emerging Medicaid strategies for preventing opioid-related harms and it contains multiple recommendations for state health organizations. Some of the recommendations have already been undertaken by the State of Wisconsin and others are ongoing. The first recommendation was to make methadone (for pain treatment) non-preferred on the PDL; Rachel confirmed for the Board that this was done at the May PDL meeting and will take effect July 1, 2016. The second recommendation was to provide provider education to improve opioid prescribing and dispensing and practices. Other recommendations were to have prior authorization criteria for chronic long-acting opioid use at high doses; increasing access to the PDMP; utilization of patient-restriction programs; increase the use of naloxone and to expand coverage and treatment of substance use disorders.
Lastly, Tiffany summarized the HOPE legislation. Representative John Nygren introduced the first set of seven bills in 2013 and during the 2015-2016 legislation session, introduced 10 additional bills. The various bills are designed to provide immunity for those seeking treatment, expand access to treatment, align State and federal regulations, and provide increased training for law enforcement and first responders. Tiffany provided details of a few of the most notable bills for the Board. The 2013 Wisconsin Acts 199 and 200 respectively require a patient to provide photo identification when picking up a schedule II or III controlled substance and provide naloxone training to first responders. The 2015 115 Act allows for purchase of naloxone via standing order, and Act 266 shortened the PDMP submission timeframe from seven days to 24 hours. Most notably, Act 388 allocates $2 million each fiscal year for treatment and diversion programs. Lynn reminded the Board of the recent quantity limit implementation and the ongoing buprenorphine/methadone/benzodiazepines interventions. Paul Cesarz stated he has seen a reduction in both the quantity and treatment duration in practice since the CDC guidelines were published.

PDL Update

Rachel outlined the changes made during the May 11, 2016 Pharmacy Prior Authorization Advisory Committee (PAC) meeting. There were a total of 52 drug classes reviewed, with the majority having no major changes. The hepatitis C

class will have modifications made to the PDL class. Harvoni will remain non-preferred, but Daklinza, Technivie, and Zepatier will be added as preferred to the PDL. All drugs in the hepatitis C class require clinical prior authorization. Drugs in the PCSK9 class are non-preferred. Health outcomes data on these agents is currently unavailable. As previously mentioned, methadone tablets and methadone solution will be made non-preferred in the analgesic, opioid long-acting class. Methadone dispersible tablets and methadone concentrate will be added as preferred to the opioid dependency agents- methadone class. Naloxone (syringe and vial) and Narcan spray will be added as preferred to the opioid dependency agents-rescue agent class. Naltrexone tablets and Vivitrol injection will be added to the opioid dependency and alcohol abuse/dependency agent treatment class as preferred agents.

MTM Evaluation

This agenda item was delayed for a future meeting due to time constraints. Paul Cesarz and Robert Breslow expressed interest if outcomes data and a comparison to Medicare Part D MTM could be discussed.

Future Topics

It was suggested that the Board revisit the DUR activity survey that was previously postponed in the September 2015 meeting. This agenda item will be brought back for discussion at a future Board meeting.

Adjournment

Paul Cesarz motioned to adjourn. Mike Ochowski seconded the motion. The meeting adjourned at 3:58 p.m. Upcoming meetings are on the following Wednesdays: September 14, 2016; December 7, 2016; and March 1, 2017.

Guests: Julie Sager, MD (OIG); Chris Stanfield (Supernus); Jerod Downing (Perdue); Scott Mills (Allergan); Jennifer Wilbanks (Otsuka); Nick Boyer (Otsuka); Elizabeth Plouff (UCB); Dawn Bina (Novo Nordisk); Randi Lewandowski (Teva); Nick Penzetta (Teva); Rob Kincaid (Teva); Andrea Jacobson (BPTR); A. Ernst (BPTR).