MINUTES OF THE DRUG UTILIZATION REVIEW
(DUR) BOARD MEETING
Wednesday, June 7, 2017
1:00 p.m. to 4:00 p.m.
1 W. Wilson Street, Room 751
Madison, WI 53701

DUR Board Members

Present:
Robert Factor, MD
Paul Cesarz, RPh
Jake Olson, PharmD
Daniel Erickson, MD
Michael Ochowski, RPh
Robert Breslow, RPh

Absent:
Ward Brown, MD
Michael Brown, PharmD
Hannah Delong, MSN, PMHNP-B
Lora Wiggins, MD

DXC Staff

Present:
Chally Clegg
Tom Olson, PharmD
Jacque Nash, PharmD
Kristie Chapman
Corinne Eckert
Randy Cullen, MD

DHS Staff

Present:
Kimberly Smithers
Lynn Radmer, RPh
Tiffany Reilly
Casey Himebauch
Lisa Reese
Julie Sager, MD
Jenny Malcore

Welcome and Introductions
Kimberly Smithers called the meeting to order at 1:01 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. 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 1, 2017 Meeting Minutes
Kimberly walked through the agenda as printed. Prior to this meeting, Board members received the draft minutes and RDUR Quarterly Report via e-mail and had the opportunity to review each document. The March minutes were then briefly reviewed and amended with a change in the reporting data on the buprenorphine/benzodiazepine section. The total member count on Cohort 1 for the November run was reported at 414, which was an error and has been updated to 403. The amended March minutes, were approved with an initial motion from **Michael Ochowski** and a second from **Daniel Erickson**. The motion passed unanimously.

Quarterly DUR Reports Update
Lynn reviewed the quarterly reports with the board. The Quarterly Overview report was the first report reviewed. Lynn reminded the Board that members who were identified as having claims in all five drug classes under review were pulled for selected lock-in review, and further discussion of that data would follow later in the meeting, but, as expected, the overall data trend had not changed since the Medicaid population has remained relatively stable. The second report reviewed the prospective DUR alerts both individually and collectively, as requested during the March meeting. The collective report, however, fails to illustrate the significant changes within any individual alert trend due to the widening scale required to combine all alerts. As an example, there was a significant decline in the drug-pregnancy alert, but due to the small overall population affected by this alert, the decline is not seen on the larger scale that incorporates all of the Medicaid population in the combined graph.

Lynn further elaborated on the decline in drug-pregnancy alerts, stating that the large decline was likely due to a module change in First Databank's system as a result of the newly mandated package labeling changes by the FDA. The module changes resulted in fewer drugs being captured under the alert criteria, which resulted in the decline in total drug-pregnancy alerts. First Databank is set to release a new update in July to recapture those previously alerted drugs, so the Board should expect to see an increase in the future. Paul Cesarz asked if this had anything to do with the

Board's previous efforts to decrease the amount of unnecessary alerts; however, Kimberly noted that the timelines did not match.

Place of Service Update

Lynn reminded the Board that the previously discussed nursing home exemptions will be implemented on July 1. The current exemptions for nursing homes that will expire include drug/drug, reported disease, therapeutic duplication, drug/pregnancy, and both types of early refill alerts. Nursing homes will still be exempt from responding to the late refill and three-month supply alerts, which will significantly limit the burden of change, as the three-month supply alert accounts for 36.5% of all alerts in this population. The provider update in June 2017 will inform providers of these upcoming changes. Multiple Board members engaged in conversation regarding the need for early refills and the ultimate destination of the extra dosage units. Possible explanations include destruction and inpatient admissions following recent outpatient refills. Dr. Sager noted that it would be interesting to research what medications were most often hitting the early refill alert. Kimberly concluded that the next step is to bring back individual drug data after the alerts move forward and become active.

Focused Interventions

Trinity

Jacque began the focused interventions discussion with a summary of the Trinity intervention. In January 2017, standard criteria and letters were used for this intervention to look for any member receiving carisoprodol, an opioid, and a benzodiazepine for 60 days within the last 90 days. A total of 59 members hit the criteria and 80 letters were generated, which indicated one prescriber in the majority of cases. The Board agreed that one prescriber of all three drugs is not the ideal scenario due to the severity of interaction. If one prescriber is aware of the severity and still writing all three prescriptions, the intervention outcome tends to be less positive, which is indicated by the feedback. Prescribers stated the benefits outweighed the risk or the risk was probably insignificant. Those cases involving more than one prescriber were more likely to respond with statements indicating a possible change in therapy. Board members were concerned with this data. Lynn reminded them that Soma is currently non-preferred on the PDL, and Jacque noted the low total member count of 59 compared to the larger intervention groups currently under review and relative to the total Medicaid population. Jenny Malcore, from the Secretary's office, spoke to the Board regarding the PDMP prescriber mandate that went into effect April 1, 2017. Jenny suggested the Board wait to see what type of impact this legislation has on prescriber habits surrounding the trinity discussion, especially considering the new functionality that will include a trinity alert when prescribers check the PDMP as required. The team will monitor and collect data post-April 1 and bring back further information before finalizing the next course of action.

Overutilization of Albuterol

The second focused intervention ran during the January 2017 RDUR cycle looked at members filling excessive prescriptions for short-acting beta agonist inhalers in the absence of any long-term asthma controller medications. Any member with a chronic lung disease other than asthma was excluded from this intervention. A total of 429 cases were identified, resulting in 545 total letters. Jacque noted that the provider feedback on this intervention appeared much more positive in comparison to the Trinity intervention. Most prescribers indicated a plan for either patient follow-up to discuss adherence and/or therapy modification or referral for a specialist consultation. Jacque also advised that an effort was made to exclude emergency department providers when identifiable, which could also be a contributing factor to more detailed feedback. The Board would like to see the distribution between pediatric and adult cases, and this data will be brought back for the September meeting.

Codeine Use

Codeine use in pediatrics was addressed with a focused intervention; however, it was addressed using a custom letter for the State of Wisconsin. The development of this intervention came from the previously-discussed topics surrounding opioid use in childhood and its relation to increased abuse and addiction in adulthood. At the March meeting, Dr. Wiggins and Dr. Sager presented peer-reviewed literature documenting a 33% increase in the risk of future opioid misuse following opioid use prior to high school graduation, and proposed a three days' supply limitation on all dental codeine prescriptions and possibly three days for any opioid use in children. The Board voted to proceed with this focused intervention prior to establishing formal days' supply limitations.

During the intervention cycle, the FDA released new guidelines increasing the age of contraindication for codeine use from 6 to 12 years of age. The new guidelines were incorporated into the intervention criteria and letter, replacing out-of-date information. The custom letter included three separate statements regarding the overall caution for use due to highly variable CYP2D6 metabolism, the contraindication of codeine in pediatrics for pain after tonsillectomy and/or adenoidectomy, and the final absolute contraindication for any codeine use in children younger than 12 years of age.

There were a total of 370 cases identified. The distribution between antitussive and analgesic use was 37% to 63%, respectively. Tylenol #3 and codeine with guaifenesin were the top two medications prescribed. The letters will be mailed by the middle of June, and further information, such as provider feedback and any changes to prescribing habits, will be brought back to the September meeting to discuss next steps.

Five Drug Classes

As previously discussed above, DUR alerts and drug class usage trends are being monitored on the Quarterly Overview Report for members with multiple drug classes at the same time. Members who had a prescription in each of the five monitored drug classes were reviewed for the Lock-In program during the April 2017 RDUR cycle. A total of 11 member profiles were reviewed. Two profiles had been reviewed during the March 2017 cycle and were sent a warning letter. Of the nine remaining profiles, one profile was suppressed due to a previous alert and review in the last 90 days, four profiles generated an alert letter, three profiles generated a warning letter, and one member was locked in. Of note, three of the members had also received buprenorphine/benzodiazepine letters previously. These profiles were typical lock-in reviews, and monitoring the drug class usage is another method to increase the efficiency of the Lock-In program. On an ongoing basis, members who receive all five of the monitored drug classes will be reviewed for the Lock-In program.

Opioid Use in Children

Lynn reminded the Board of their previous decision to focus on opioid use in children and began with a review of child members receiving an acute, sub-acute or chronic days' supply of opioids, by prescriber specialty. The definition for each duration of therapy are as follows: "acute" is defined as less than or equal to 3 days of opioids, "sub-acute" is defined as 4 to 14 days of opioids, and "chronic" is defined as greater than 14 days of opioids. The State of Wisconsin has a low overall total of chronic pediatric opioid users. Also, the rate of emergency medicine and Otolaryngologists prescribing dropped significantly during the fourth quarter, which could be attributed to a lower rate of tonsillectomy during the holiday season. As expected, specialists (most notably Otolaryngology) make up the highest proportion of sub-acute opioid prescribers.

The data discussion led to a proposal for another focused intervention regarding the FDA's newest warning for the use of tramadol in children. Lynn summarized the warning, which recommends avoiding tramadol in adolescents (12–18 years of age) who are obese, have obstructive sleep apnea, or have severe lung disease and contraindicates use for pain in any child under 12 years of age or those under 18 years of age being treated for pain after removal of tonsils and/or adenoids. According to preliminary data, this criteria would affect about 100 children in the State of Wisconsin, with about 10% of those children being under 12 years of age. With this information, Lynn then proposed a focused intervention on all children younger than 18 receiving tramadol. Jake Olson stated that in his practice some pediatric neurologists are likely prescribing tramadol in chronic headache cases, so intervening on those causes concern. Dr. Erickson advised that a better approach might be to offer alternative treatments rather than a straightforward alert letter. In response to these concerns, Dr. Sager recited the data from the Washington Report documenting a 33% increase in the risk of opioid abuse as an adult when prescribed in adolescence. Dr. Sager also advised that after looking into the implementation of a 3-7 days' supply limitation, there was not enough supporting data to indicate that it could be operationalized without significant burden on families with legitimate chronic needs. The proposal was then brought back to the table for a focused intervention on all children and adolescents under 18 years of age using tramadol. **Mike Ochowski** favored the motion, and **Daniel Erickson** seconded. The motion passed unanimously.

Benzodiazepines Discussion

Buprenorphine

Lynn gave a recap of the buprenorphine/benzodiazepine intervention timeline. To date, three cohorts have been

established and sent phase I letters. All three cohorts are suppressed for one year from the date of the phase I letter. Cohort 1 has also been sent a phase II letter, which uses a more lenient criteria overlap of 60 days for each medication (as opposed to 30 days of buprenorphine and 15 days of benzodiazepine) to identify those members who are taking both medications together more frequently. Roughly half (212 out of 403) of Cohort 1 members met the phase II criteria.

Each quarter a new cohort of members will be identified, sent a phase I letter, and then suppressed for one year. The same cohort will then be run under the phase II criteria at a later date, and affected members will then be intervened on a second time. With this recurring cycle, a statistics associated with each cohort will be reported in the DUR binders and updates will be presented to the Board as needed. Of note, with each successive phase I run, the cohort has decreased in size from 403 members initially to 90 members currently.

Methadone

The Division of Medicaid Services collaborated with the Division of Care and Treatment Services to draft a letter for a pilot program. The letter will be piloted at one methadone treatment center before going statewide and will be used to alert the methadone prescriber of any member also receiving a benzodiazepine. This method was chosen due to the privacy laws prohibiting any dissemination of a member's participation in a medication assisted therapy (MAT) program to another provider The State uncovered billing issues with the methadone treatment centers and is working to correct the claims. The pilot will begin once the billing issues have been resolved.

Stimulants Discussion

Lynn began the stimulant discussion with graphs showing both the number and percentages of adults and children taking stimulants above preset quantity thresholds of 34, 68, 102, and 136. These thresholds were based on a 34-day supply with the ultimate goal of implementing a stimulant quantity limit, excluding narcolepsy. Lynn proposed a 136-unit quantity limit as a conservative approach only affecting 3% of adults and 1% of children. To support this proposal, Jacque and Dr. Cullen presented member profile data. Jacque reviewed eight methamphetamine profiles through the Lock-In selected review process. The profiles were chosen due to excessive stimulant quantities. The quantity range was 120 methamphetamine tablets to 360 methamphetamine tablets per month, and most members were also receiving a benzodiazepine from a second prescriber. Lock-in alert letters were sent for four profiles, one member was already suppressed, two members had lost coverage, and one pediatric profile appeared to be a complicated mental health case not warranting further action. Both Jacque and Dr. Cullen reviewed high-quantity dextroamphetamine and methylphenidate profiles, with Dr. Cullen engaging in peer-to-peer follow-up via phone consult. The common trend among these profiles was a lack of extended-release trials, use of high-dose benzodiazepines and sedative mood stabilizers, and significant mental health diagnoses. The most concerning profile carried a quantity of 540 methylphenidate 20 mg tablets per 30 days. Upon provider follow-up, Dr. Cullen discovered that the provider felt helpless and did not know how to handle this patient who came into the office on that dose for over 10 years. The ability to "blame Medicaid" for having to reduce dosages was a common theme among Dr. Cullen's calls and seemed well-received by providers looking for an option to push back against patient demands.

Robert Breslow voiced his concern for putting the pharmacist in a compromising situation by implementing quantity limits and suggested an educational intervention. Dr. Sager advised that stimulants are a great drug class for limitations due to their lack of physical impact when taken away (i.e., no physical withdrawal). In addition, multiple Board members agreed that four units per day is generous and not clinically necessary in most cases. Dr. Sager also pushed for the quantity limit due to the high cost, stating that stimulants are currently the State's highest drug class spend, and usage among adult members continues to rise, with a 2,000 member increase in the fourth quarter of 2016 alone. Dr. Erickson favored the quantity limit but also the need for an educational piece at some point to ultimately shift the curve to less usage, which is the best solution to the overall problem.

In an effort to wrap up the discussion an initial straw poll was taken and final ideas collected from the Board. The topic will be brought back to the September meeting. The goal for implementation is January 2018 to coordinate with any stimulant updates coming from the November PAC meeting. Dr. Erickson, Mike Ochowski, Jake Olson, and Dr. Factor all indicated agreement with a quantity limit of four units per day in conjunction with an educational piece to lower overall usage.

Pharmacy Utilization Data

Kimberly summarized the pharmacy utilization trends for the last five years. Total gross paid costs have increased 13%, while net costs decreased 4% due to growth in rebate collection of 20% over the same time period. This also resulted in a net decrease in price per member per month (PMPM). Drug utilization by type showed an increase in specialty by both net paid per claim and claim volume, while non-specialty stayed about the same. Specialty drugs has also increased annually as a percent of net paid amount for all claims, though non-specialty still holds the majority of the cost.

Preferred Drug List Update

The PAC meeting was held in May and all updates will take effect July 1, 2017. Fifty-two drug classes were reviewed. Hepatitis C will have a criteria change only, with preferred drugs remaining the same. The other most notable class was opioid dependency. Testimony was heard surrounding the controversy over Suboxone film availability to patients and its role in diversion. As a result of the testimony and discussion, the committee added Zubsolv to the PDL. As a final closing question, Dr. Erickson asked how often naloxone is being prescribed in the State, and though Kimberly could say use has increased, no definitive answer could be given, so this will also be researched and brought back in September.

Adjournment

Daniel Erickson motioned to adjourn. The meeting adjourned at 4:11 p.m. Upcoming meetings are on the following Wednesdays: September 13, 2017; December 6, 2017; and March 7, 2018.

Guests: Danielle Leonard, Johnson & Johnson; Nick Boyer, Otuska; Lisa Gronneberg, Biogen; Carly Greenhoe, Skywalk RX; Craig Haubach, Merck; Lester Lachuk, Care Wisconsin; Richard Mueller, Community Care; Dean G, Pfizer; Dawn Bina, NovoNordisk.