MINUTES OF THE DRUG UTILIZATION REVIEW (DUR)
BOARD MEETING
Wednesday, September 14, 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	Sean Gartley
Daniel Erickson, MD	Kristie Roller, Pharm D	Lynn Radmer, RPh
Michael Ochowski, RPh	Kristie Chapman	Lisa Reese
Robert Breslow, RPh		Kim Wohler
Lora Wiggins, MD		Rene Eastman
Ward Brown, MD		Julie Sager
Jake Olson, PharmD		Kevin Moore
Absent:		Doug Englebert
Hannah Delong, MSN, PMHNP-B		

Welcome and Introductions
Rachel Currans-Henry called the meeting to order at 1:07 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. Kevin Moore completed the introductions and expressed his gratitude to the Board for their service, reminding them of the importance of their work.

Review of the Agenda and Board Materials and Approval of June 1, 2016 Meeting Minutes
Rachel walked through the agenda as printed, noting that most of the items from the June minutes are being brought back for updates, with the exception of the Preferred Drug List (PDL), the federal guidance and the HOPE Legislation topics. 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 June minutes were approved with an initial motion from **Paul Cesarz** and a second from **Mike Brown**. The motion passed unanimously.

Future DUR Activity Survey Discussion
Kimberly reminded the Board of the initial survey that was sent out via e-mail in July 2015 requesting that members both rank a number of suggested ideas as well as write in miscellaneous topics for Board consideration and/or participation. The number one ranked item was to revise the Pharmacy Services Lock-In Program. Kimberly noted this is already underway with the April 2016 updates. The second item was the development of a provider education newsletter for best practices for chronic non-cancer pain, and the third item was a newsletter for best practices for opioid prescribing in general. There were a number of creative write-in ideas such as focusing on combinations of abuse (e.g., "the trinity," The "trinity" is a drug regimen that includes at least one opioid, a benzodiazepine and carisoprodol.), opioids for migraine treatment, multiple benzodiazepines, excessive albuterol use without a long-term controller, urine drug screens for chronic opioid users, and evaluation of brand medically necessary. Paul Cesarz recommended resending the survey so everyone could refresh on the topics and re-rank their priorities now that significant time has lapsed. Kimberly advised that she would be sending an e-mail in the next couple of weeks with the survey items as well as a more detailed description of some of the write-in ideas.

MTM Evaluation
Sean Gartley presented background on ForwardHealth's Medication Therapy Management (MTM) program, including a comparison to MTM services offered by Medicare Part D and outcome data for the ForwardHealth MTM program.

MTM is "part of a national trend that reimburses pharmacies for value-added services that assist members in

managing their medications." DHS implemented the MTM program on September 1, 2012 as part of the Wisconsin Pharmacy Quality Collaborative (WPQC).

The two tiers of MTM service are Intervention-Based Service (IBS) and Comprehensive Medication Reviews and Assessments (CMR/A). IBS and CMR/A services are strictly voluntary benefits for ForwardHealth members.

The IBS interventions are usually based on one drug or disease state and function as an extension of the patient-to-pharmacist counseling that normally takes place at the counter or register. Examples of an IBS would include counseling on a newly-added medication and use of a pill box

The CMR/A intervention is a complete medication regimen evaluation. This requires a face-to-face private meeting between the member and pharmacist that often lasts 30 minutes but in a fair amount of cases lasts near or over one hour. Members must meet specific qualifications to receive CMR/A services, including meeting one of the following criteria:

- A member takes four or more prescription medications to treat or prevent two or more chronic conditions, one of which must be hypertension, asthma, chronic kidney disease, congestive heart failure, dyslipidemia, Chronic Obstructive Pulmonary Disease or depression.
- The member has diabetes.
- The member requires coordination of care due to multiple prescribers.
- The member has been discharged from the hospital or long-term care setting within the past 14 days.
- The member has health literacy issues as determined by the pharmacist.
- The member has been referred for the MTM services by the prescriber.

CMR/As are limited to 4 per rolling year (including the initial meeting plus three follow-up visits), which can also be overridden due to unforeseen medication management issues.

Robert Breslow recommended an intermediate level of intervention be considered, as some single drug or single disease interventions are extremely significant on the cost-savings side yet do not require the time-intensity of a CMR/A. Robert Breslow also recommended the consideration of CMR/A services to be provided via telephone given the inability of some patients to keep their appointments. Mike Brown commented that the current certification requirement (WPQC) applies to the pharmacy or clinic, which excludes clinical pharmacists who are operating independently of another biller or place of service to provide CMR/A services (provision of CMR/A services requires accreditation by Wisconsin Quality Collaborative Practice and provision of the IBS services does not require accreditation).

Medicare Part D's MTM program is similar in some ways compared to ForwardHealth's MTM program. To qualify for Medicare Part D's MTM program, members must be taking multiple medications, have multiple disease states, and be likely to incur a predetermined annual pharmacy cost (roughly $3,500 for 2016). Similar to ForwardHealth's MTM program, Medicare Part D members may opt-out of the MTM program.

There are differences between Medicaid and Medicare Part D's MTM programs. Medicare Part D requires MTM for all Medicare sponsors while Medicaid does not (the State of Wisconsin chose to offer MTM services but other states do not), and Medicare Part D allows the Case Management Reviews to be done via telehealth by any qualified provider (which in Medicare Part D's case may include physicians, registered nurses and others in addition to pharmacists). The MTM program has recently become a component of each Medicare Part D plan's star rating with the completion rate contributing to the overall STAR score of the plan.

Sean presented the following data for the ForwardHealth MTM program, including data from the implementation of the program in September 2012 through the end of April 2016:

- 99,226 paid claims
- 63,823 members served
- 578 pharmacies billed
- IBS over $2.3 million in paid claims
- CMR/A over $260,000 in paid claims

ForwardHealth evaluated the impact of MTM on claims cost per member per year for the time period beginning September 1, 2012 through June 30, 2015. The findings include:

- The overall medical costs for ForwardHealth members receiving MTM services (IBS or CMR/A) was $556 more per-member per-year compared to a controlled group.
- Within the medical costs for ForwardHealth members receiving MTM services, inpatient costs were $102 less per-member per-year compared to a controlled group.
- The overall medical costs for ForwardHealth members receiving CMR/A services was $1,139 more per-member per-year compared to a controlled group.
- Within the medical costs for ForwardHealth members receiving CMR/A services, inpatient costs were $524 less per-member per-year compared to a controlled group.
- For both populations receiving MTM services as well as those receiving only CMR/A services, the number of inpatient claims compared to the control group was the same. Therefore, the level of care, number of days spent in the hospital, severity of condition and/or other factors may contribute to the lower inpatient costs for MTM recipients.

Mike Brown pointed out that the patient population in question does have chronic diseases of progression, which inherently lends itself to cost increases over time, so watching the trends over time will be interesting Rachel advised that the full MTM report, detailing the results and formation of the control group will be sent to the committee when it is released.

DUR Alerts Update and Long-term Care Place of Service Discussion

DUR Alerts Update

Lynn reminded the Board that the last of the DUR alert system modifications, early refill, went live on April 11, 2016. The team has analyzed some claims data to determine any impact resulting from the changes to the alert. There has been no significant change identified. Lynn did want to notify the Board that the quarterly reports provided in the meeting materials now include all claim types (e.g., professional and institutional) as opposed to just the pharmacy point-of-sale claims previously provided.

LTC Place of Service Discussion

The long-term care (LTC) place of service topic was brought back for discussion with the overall goal of removing most of the DUR alert exemptions from nursing homes. Kimberly indicated that these exemptions were implemented when prospective DUR was implemented at a time when billing strategies and overall medical operations were significantly different; thus, the exemptions are somewhat outdated. The current DUR alerts for nursing home place of service are informational only: drug/drug, reported disease, therapeutic duplication, drug/pregnancy, early refill, early refill (DAPO), late refill, and three-month supply. In data analysis, the team discovered that only about 40% of claims coded as nursing home place of service could be verified as such; thus, the majority of these DUR alert exempt claims most likely are not being billed for the correct place of service. ForwardHealth published a provider update in June 2015 reminding providers to use the correct place of service codes. The overall impact on nursing home claims was analyzed and only 13.63% of nursing home claims in June 2016 had a DUR alert on them, indicating a minor impact to daily operations. The largest volume of alerts came from three-month supply and early refill at 39% and 28%, respectively. An early refill analysis revealed that the alert was rendered when approximately 50% of the current fill should have remained. The Board was concerned with this amount of perceived waste. The proposal, based on data, was to remove all exemptions from the nursing home place of service except the three-month supply and late refill alerts, as the three-month supply would pose an undo disruption to operations and late refill may not be relevant in this population. The DUR summary reports will be updated overtime to provide more information. These reports will be brought back at a future Board meeting. **Dan Erickson** motioned to pass the proposed changes and **Mike Brown** seconded it. The motion passed unanimously.

Pharmacy Services Lock-In Program Update

Jacque reminded the Board of the previously-approved program updates. Recommendations for improving the efficiency of the Lock-In (LI) Program were made and accepted unanimously at the March Board meeting. All of the modifications were implemented in the April cycle. The first proposal was the addition of new criteria to highlight profiles of members who are receiving high quantities of restricted medications with a diagnosis history positive for poisoning. Jacque discussed the impact of the new criteria addition, noting an average of 450 member hits per cycle

with most members having no previous interventions. The first two cycles also revealed that the most frequent poisoning agents were benzodiazepines and opioids, which is of great concern given the Board's current focus. Since the initial April cycle, the total number of members hitting on the new poisoning criteria has dropped by approximately 200 profiles, indicating a significant intervention volume on these members without additional members being added to the criteria pool. The second proposal 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 drastically reduced the total hit volume from 15,620 to 1,681 between cycles for June 2015 and June 2016 and significantly increased the intervention rate due to higher intensity reviews. The impact of both the new criteria addition and the increased days' supply are noted when looking at case volume trends from January to June of this year. The January lock-in case volume was low due to the buprenorphine/benzodiazepine intervention, which prevented any lock-in intervention on a member receiving an letter, and the February and March cycles are a baseline standard prior to the proposal implementations. Although the implementations took place in April, the review selection was not made in time to target the new additions. The most significant change in case volume began in May and continued into June when the profile selection included only the high-risk group from the new criteria addition and the remaining profiles needed to obtain 400 profile reviews came from the high-risk standard lock-in criteria. The most notable change is a 50% increase in total lock-in case volume, which means 50% more members' providers are receiving letters notifying them of a potentially dangerous situation and/or misuse and abuse. Dr. Erickson would like to know if there is any data regarding follow-up on the members hitting the poisoning criteria and receiving help. Jacque advised that the reviews have shown some members transitioning to Suboxone treatment after receiving the initial alert letter. The third proposal 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. Both of the final two proposals are in place; however, the first four cycles have not produced any outcomes data regarding these specific changes, other than the observation of a handful of members on highly active antiretrovirals therapy (HAART) receiving lock-in alert letters for apparent misuse of opioid agents.

Short-acting Opioid Quantity Limit Discussion

Tom reminded the Board of the quantity limit implemented on January 1, 2016 for all short-acting opioids. The quantity limit was set at 360 and was based on the maximum standard dosing for a short-acting formulation of two units every four hours as needed. This topic was brought back to today's meeting to highlight some year-to-date claims data comparing both the number of total claims and number of overrides from March, April, and May 2015 to the same months in 2016. The total number of claims dropped by 11.4% from 2015 to 2016, with the number of quantity limit hits increasing from 252 to 757, which created an increase in overrides from 6 to 15. The Board did not perceive these changes as significant and felt this data even confirmed that a quantity limit of 360 is still too high. A consensus was made to bring this back for discussion at a later date for a possible reduction and continued data analysis. The Board would like to also see if the total downward trend in total claims is happening with the extended-release opioids as well.

Benzodiazepines/Buprenorphine Intervention Follow-up Discussion

Lynn Radmer began the discussion with an introduction of the FDA's new black box warnings on both opioids and benzodiazepines with emphasis on the statement from the FDA that the warning is not currently on medication assisted treatment (MAT) products but is being further reviewed; this lends support to the timeliness of the Board's intervention and overall importance. A total of 675 profiles were sent to 275 different prescribers, with 457 members identified by the profile reviews. The team performed follow-up data analysis on the same member pool identified in the intervention, and the results are as follows: for the months of March and June 2016, 70 and 159 members, respectively, no longer hit the criteria. In June, there was an equal discontinuation rate of the benzodiazepine, buprenorphine, and both drugs among those that dropped off the criteria. Post-intervention analysis of the criteria as a whole from the initial project implementation through June 2016 reveals that as those members receiving an intervention drop off, new members begin hitting the criteria, which indicates the need for an ongoing cycle of intervention for this specific focus. Thus, the team's proposal is to rerun the focused intervention every six months, sending an alert letter to all new members hitting the criteria. Mike Brown then expressed some concern that due to the volume of new members showing up, the population may be better served by a three-month intervention cycle, which would catch potentially-

dangerous situations sooner and hopefully prevent serious consequences. There appeared to be a consensus among the Board and team for this rationale. Lynn then modified the proposal to every three months; however, Dr. Erickson suggested an amendment for sending additional alert letters beyond the initial intervention. Lynn advised that the there is a second phase planned for the entire project whereby a second alert letter will be sent focusing on another aspect of the combination therapy. The plan is to follow up on providers who continue to prescribe high-dose benzodiazepines along with buprenorphine, which is consistent with the new black box warning advising use of the lowest effective dose possible. With this new information, Dr. Erickson withdrew his amendment, and Kimberly requested an official vote on the proposal. **Mike Brown** motioned to approve the proposal as modified with a cycle of every three months, and **Jake Olson** seconded. There were no objections. Robert Breslow recommended that the Board consider adding language regarding the FDA's black box warning to the follow-up letter for the second phase intervention.

High-dose Benzodiazepines Intervention Discussion

The next agenda item was an extension of the benzodiazepine/buprenorphine discussion. As previously discussed, phase two of the intervention involves identifying cases that continue to hit the benzodiazepine/buprenorphine criteria and are utilizing high-dose benzodiazepines, which will be a threshold, established with the help of psychiatrists Dr. Cullen and Dr. Maskel. The team also performed analysis of the members still hitting the criteria stratifying the benzodiazepine doses. The threshold for high dose was set at greater than 3 mg for alprazolam, clonazepam, and lorazepam, and 5 mg for diazepam for evaluation purposes. Lynn and Tom presented the data for the Board and advised that the next steps are to meet with the psychiatry consultants to develop a targeted letter. Mike Brown expressed some concern that by sending a letter with this focus, the Board may be implying that low-dose benzodiazepine use is "okay" when the goal is to stop as much combination use as possible. Lynn stated the goal does remain to stop the use as much as possible and that the intent of this second phase is to target those cases in which the provider's views are not in line with the intervention goal and have no intent to limit combination use. The Board's secondary focus is if we cannot stop the use, a lower dose is safer than a high dose and is consistent with the FDA black box warning. Robert Breslow recommended including language that supports the slow taper off the benzodiazepine so that the letter is not perceived as an inappropriate intervention in those cases where members are on a slow taper but are still hitting the criteria.

Benzodiazepines/Methadone Discussion

The final agenda item was a review of data analyzing how many members currently hit on the existing benzodiazepine/methadone criteria as well as a detailed look at the spread of low- versus high-dose benzodiazepine use among this group. The number of members in the criteria is at its highest of 307 when the data is run as a minimum 30 days' supply. The split among low versus high benzodiazepine dosing closely resembles that seen in the buprenorphine intervention. The next step in the intervention process is to work with the Division of Care and Treatment Services (DCTS) and Opioid Treatment Programs to discuss the data findings and to develop a plan.

Adjournment

Mike Ochowski motioned to adjourn. **Paul Cesarz** seconded the motion. The meeting adjourned at 4:17 p.m. Upcoming meetings are on the following Wednesdays: December 7, 2016; March 1, 2017; June 7, 2017; and September 13, 2017.

Guests: Elizabeth Ariano (Indivor); Danielle Laurent (PSW); Dawn Bina (Novo Nordisk); Jennifer Wilbanks (Otsuka); Nick Boyer (Otsuka); Dean Groth (Pfizer); Bonnie Kase (ZS); Daniel DeZee (ZS)