

MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD
MEETING

Wednesday, March 2, 2016
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
Michael Brown, PharmD
Daniel Erickson, MD
Jake Olson, PharmD
Robert Breslow, RPh
Lora Wiggins, MD

Absent:

Michael Ochowski, RPh
Ward Brown, MD
Hannah Delong, MSN, PMHNP-B

HPE Staff

Present:

Jenny Nelson, CPhT
Tom Olson, PharmD
Jacque Nash, PharmD
Jaime Jones

DHS Staff

Present:

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

Welcome and Introductions

Rachel Currans-Henry called the meeting to order at 1:06 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 December 2, 2015 Meeting Minutes

Rachel walked through the agenda as printed, highlighting the Annual Lock-In Review and ADURS Poster summary. 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 December minutes were then approved with an initial motion from Daniel Erickson and a second from Paul Cesarz. 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 and the decision made by the Board to construct an intervention at the September and December meetings. The Board was directed to the copy of the intervention letter in the DUR binders for reference during this discussion. Lynn noted the reference section on page two of the intervention letter highlighting providers were supplied with alternative treatment recommendations for chronic anxiety via established, well-regarded practice care guidelines, as well as the Baltimore Report.

A summary of preliminary statistics regarding the number of intervention cases and initial prescriber feedback was presented to the Board as follows: a total of 675 profiles were sent to 275 different prescribers on February 9, 2016. The average number of profiles received per prescriber was 2.5 with one prescriber receiving 29 profiles. Dr. Erickson stated that he would like to see the median of the prescriber data to better demonstrate the distribution. To date, a total of 202 response forms have been received with 67 containing written comments. The overall tone of the comments is positive, and most providers are indicating an unawareness of the dual therapy use and that they intend to make positive changes to the patients' prescription profiles going forward.

The next steps in the intervention process are to continue data collection for presentation at the next Board meeting, develop with Dr. Cullen and Dr. Maskel follow-up intervention plans for the outlying prescribers, and begin to look for trends in dose de-escalations as a result of the intervention. Robert Breslow inquired as to how many patients were seeing more than one prescriber, and Jacqueline Nash noted approximately 50% of profiles in the initial review process involved more than one prescriber. Dr. Erickson also recommended referencing the PDMP in a follow-up letter to ensure prescribers are aware of its potential to deter dual therapy from unaware providers.

Benzodiazepines/Methadone Discussion

The next agenda item was an extension of the benzodiazepine/buprenorphine discussion. Lynn Radmer clarified that this intervention's target will only be methadone formulations used in opioid addiction treatment rather than standard methadone for pain use. An initial data set was displayed for the Board illustrating how many members are currently using both a Medication Assisted Treatment (MAT) methadone formulation and a benzodiazepine concomitantly in the last 30 days, which resulted in 303 members. A 30-day window for concomitant use was chosen, as opposed to a 60-day window, due to the higher potential for overdose with methadone compared to buprenorphine and the consistency with the existing HID criteria that will be used to conduct the intervention.

A difference between this intervention and the buprenorphine data set is the fact that most cases involve multiple prescribers, (whereas some buprenorphine cases involved only one prescriber for both agents). Methadone is prescribed by (presumably) an opioid treatment center, while benzodiazepines are often prescribed by a separate prescriber or prescribers. Having multiple prescribers involved presents a greater potential for any provider to be unaware of another provider due to patient dishonesty, deficiencies of the PDMP, or a combination of both. Dr. Wiggins noted that urine drug screens are not reliable in this situation because of their inconsistency in picking up benzodiazepine use. Lynn noted that this intervention will be more complex due to the number of prescribers involved, and she indicated a second phase will be required to work more closely with the MAT Centers to develop plans for limiting the occurrences of chronic concomitant use. Jake Olson stated that despite the complexities, this is not an area of pharmacy and prescribing practice that the Board should overlook because of its obvious importance on a national level. Jake mentioned that 41 states have recently petitioned the FDA to add black box warnings to both opioids and benzodiazepine agents advising against dual therapy, which lends support to the Board's current emphasis on this drug therapy issue. Rachel Currans-Henry advised the Board that this topic is in line with the broader initiative to implement better coordination and collaboration between HMOs and methadone clinics. There was discussion regarding an automatic Lock-In policy for MAT users; however, Lynn reminded the Board that the current administrative code likely does not allow for that. Robert Breslow advised that such a policy may deter MAT use altogether. Lynn noted that today's conversation has generated a lot of great ideas for inclusion into the process. The next steps are to work with Dr. Cullen to develop an initial intervention letter, and then design a second phase of close follow up with the methadone treatment centers for the most concerning chronic cases.

Early Refill Update

Lynn reminded the Board that each of the prospective DUR alerts has been reviewed over the last four years. The early refill alert was the final alert reviewed and modifications were recommended. Recommended changes to the alert are scheduled to be implemented on April 11, 2016. The current functionality of the alert contains a refill threshold of 80% for monitored therapeutic classes that can be overridden by the pharmacy at the point of sale, and prescriptions with less than or equal to a 10-day supply is exempt. The new functionality will include all drugs, except those restricted by a quantity limit, the days' supply exclusion will be decreased from 10 days to 5 days, and the early refill threshold will be tiered based on days' supply (65% for 6-9 days, 80% for 10-34 days, and 85% for 35-100 days). Lisa Reese explained that the controlled substances currently requiring a call to Drug Authorization and Policy Override (DAPO) for an early refill override will still require a call to DAPO with the new update; however, all other early refill updates can still be overridden at the point of sale at the pharmacists' discretion. Lisa advised the Board that the change will result in an overall increased number of alerts because drugs that were not previously monitored by early refill will now be monitored. The alert message will only display how many days remain on the most recent fill. A few pharmacists on the Board advised that they would like to have both the days remaining on the most recent fill and the date the next fill can be filled without hitting the alert. Kimberly Smithers stated that displaying both may not be possible due to NCPDP file format character limitations.

Lock-In Annual Report and Discussion

Jacqueline provided an overview of the Lock-In program's current functionality. The Lock-In Program is designed to target both misuse and abuse of benefits, as well as appropriate clinical prescribing, which is an important distinction, as most providers are initially unaware of each other. The program applies to both fee-for-service and managed-care members and is a five step review process. Jacqueline explained each of the five review steps. In step one, an average of 400 profiles are reviewed each month to determine whether or not an alert letter should be sent. The review criteria looks at number and types of medications, number of prescribers and pharmacies, days' supplies, diagnosis history, and participation in narcotic treatment programs. Step one is the only Lock-In decision made by one pharmacist. Not all profiles receive an alert letter but those that do are suppressed for 90 days. All other steps are reviewed by the Lock-In Sub-Committee, which requires a consensus of three pharmacists for any action. Step two of the process is a warning letter, which is sent to those who have recently received an alert letter and have either not changed or escalated their practices. Step three is the actual Lock-In notice, which also occurs when a member has not changed or escalated their practices after his or her warning. After the Lock-In notice is sent, the member's profile is suppressed for two years during the Lock-in period. Steps four and five are relocking and unlocking respectively. Relocking occurs when a member is still receiving high quantities of restricted medications from his or her Lock-In prescriber without a supporting diagnosis or has had a diagnosis added since the Lock-In indicating the member may be at risk of self-harm (i.e. drug poisoning and suicidal ideation). Steps may be skipped in the process if the pharmacist finds compelling evidence (i.e. concomitant MAT and opioid use or criminal activity).

After reviewing the existing program and criteria, Jacqueline presented statistics for the 2015 calendar year. All case and letter totals increased significantly from 2014 to 2015, due to an increase in the total number of profile hits on the Lock-In criteria. A total of 975 alert cases resulted in 3,151 alert letters in 2015, which is an increase from 2014 totals of 612 and 1,626 respectively. The same trend was noticed for warning cases with 121 cases in 2015 and 83 cases in 2014. Lock-In case load rose from 22 cases in 2014 to 34 cases in 2015, but the biggest increase was seen in relock cases, as 19 were relocked in 2015 compared with only 2 in 2014. The Selected Review volume and source percentages remained the same between 2014 and 2015. The Lock-In program has a high efficacy rate indicated by the positive provider feedback.

Recommendations were made for improving the efficiency of the program. The interventions made are effective; however, the percentage of interventions compared with the total number of criteria hits is low, which indicates a high frequency of case rejection due to a lack of significant evidence of misuse and/or abuse. The first proposal was an addition of new criteria. The proposed criteria would include profiles of members who receive large quantities of restricted medications and have a recent drug poisoning diagnosis. This criteria addition would ensure that profiles with poisoning diagnoses are reviewed ahead of others that are only hitting due to large opioid quantities. When a member hits on more than one criteria, the profile contains a higher risk score; escalating the member for review. The second proposal was expected to have the largest impact. The existing criteria look for a 120-day supply of restricted medication in the last 90 days, which increases the amounts of "low intensity" reviews (i.e. pediatric patients taking both an extended-release and immediate-release stimulant formulation). The recommendation is to increase the threshold for a hit from 120 days to 240 days, which will exclude all of the aforementioned stimulant cases and escalate those cases receiving the highest volume of controlled substances. Mike Brown suggested a pilot of this idea, but Lynn informed the Board that the Core team had already piloted this change in the February retrospective DUR cycle. Jacqueline stated the pilot resulted in a decrease of hit volume from 14,000 to 2,600 and significantly increased the intervention rate due to higher intensity reviews. 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. Jacqueline explained that without PDMP data, the extra 6 months of data would be beneficial in determining when to relock or unlock a member. Daniel Erickson motioned to approve all proposals, and Lora Wiggins seconded. The motion passed unanimously.

ADURS Meeting Update and Poster

Lynn directed everyone's attention to the poster at the back of the room. The American Drug Utilization Review Society (ADURS) met at the end of February for its annual convention in Scottsdale, Arizona. At the poster presentation, Lynn presented a summary of the stimulant dosing in children and adolescents intervention, previously undertaken by the Board. Dr. Cullen and Dr. Maskel collaborated with the Core DUR team to create the poster. Dr. Cullen has also written

an abstract about the intervention that he has submitted to the American Academy of Child and Adolescent Psychiatry (AACAP). The data analytics team from HPE conducted an in-depth statistical analysis on the intervention data as a requirement for the AACAP submission and found statistical significance between the pre- and post-intervention data sets. Overall, the reception from the other states at ADURS was very positive, with a few states indicating that they would be interested in following Wisconsin's model.

Lynn highlighted some topics of discussion from the ADURS meeting. Fourteen hours of continuing education were distributed among topics of new drugs, diabetes and hyperlipidemia treatment guideline updates, opioid overdose and abuse-deterrent formulations, the States' Roundtable, and upcoming CMS regulations. John Coster represented CMS and discussed the new annual report, as well as the proposed MCO rules, which do not significantly impact Wisconsin due to its pharmacy benefit carve-out. Lynn noted an important upcoming discussion will be in regard to methadone for pain use and its status on the PDL. CMS has encouraged states to remove methadone from their PDLs as preferred due to a higher rate of involvement in opioid overdose-related deaths. The next PDL meeting is scheduled in May and opioid analgesics are on the agenda for review. This topic will be revisited at the June DUR Board meeting.

Adjournment

Jake Olson motioned to adjourn. Mike Brown seconded the motion. The meeting adjourned at 3:57 p.m. Upcoming meetings are on the following Wednesdays: June 1, 2016; September 14, 2016; and December 7, 2016.

Guests: Nick Boyer (Otsuka); Kevin Gallagher (AstraZeneca); Scott Mills (Allergan); Mark Borkovec (Upsher-Smith)