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Drug Utilization Review Board Meeting Summary November 14, 2018

The Drug Utilization Review (DUR) Board met on Wednesday, November 14, 2018, at 8:30 a.m. in Conference Room B-16, University of Illinois at Chicago College of Pharmacy, 833 S. Wood Street, Chicago, Illinois.

DUR Board members in attendance: Stacie Laff*, MD, Chairperson; Tim Lehan*, BSPHarm; Bedrija Nikocecic*, PharmD; Christopher Schriever, PharmD.

Illinois Department of Healthcare and Family Services (HFS) Representatives: Donna Clay, BSPHarm, Prior Authorization, University of Illinois at Chicago (UIC); Arvind K. Goyal*, MD, Medical Director, Medical Programs, HFS; Mary Lynn Moody, BSPHarm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPHarm, HFS Bureau of Professional and Ancillary Services (BPAS); Patricia Steward*, BSPHarm, BPAS.

Interested parties: Nick Boyer, Otsuka; Shannon Hussey, Immunomedics; Mary Kaneaster, Gilead Sciences; Scott Mills, Sage Therapeutics.

*Attendance via teleconference

Call to Order. Dr. Laff called the meeting to order on November 14, 2018 at 8:33 am. Dr. Laff called for a vote to allow Mr. Lehan and Dr. Nikocecic to call into the meeting due to work commitments that precluded travel to downtown Chicago. The DUR Board members approved attendance via telephone at this meeting.

Agenda, conflict of interest review, and approval of May 16, 2018 meeting minutes. No changes to the September 19, 2018 minutes or the November 14, 2018 agenda. Dr. Schriever made a motion, seconded by Dr. Nikocecic, and the September 19, 2018 minutes and November 14, 2018 agenda were approved. The DUR Board members had no conflicts of interest pertinent to the agenda. Dr. Laff reminded DUR Board members to recuse themselves from discussion if conflicts of interest exist and to provide an updated *Conflict of Interest* form if new conflicts arise.

DUR Board member training. The DUR Board members were asked to complete the *2018 Ethics Training for Appointees to State of Illinois Boards* and submit the Acknowledgment of Participation form to document completion of training by the end of November. Mr. Lehan requested the training packet to be resent since he had not received it.

DUR Board meeting calendar for 2019. The DUR Board members reviewed the draft meeting schedule for 2019 meetings, which should be posted at the beginning of the new calendar year. Christopher Schriever, PharmD made a motion, seconded by Tim Lehan, BSPHarm, and the DUR Board approved the DUR Board 2019 meeting calendar.

Prospective Drug Utilization Review

Diabetes medications – Four Prescription Policy. Christina Petrykiw, PharmD, notified DUR Board members about the recently released Consensus Report 2018 for management of hyperglycemia in Type 2 diabetes from the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD). The consensus report's evidence-based literature review highlighted studies that evaluated cardiovascular outcomes. The report provides guidance to optimize glycemic control, improve patient outcomes, and decrease cardiovascular and renal complications of Type 2 diabetes. Algorithms and tables facilitate choosing appropriate medications and guide patient-centered care. Pharmacologic recommendations prioritize presence of concomitant diseases, such as atherosclerotic cardiovascular disease (ASCVD), chronic kidney disease (CKD), heart failure, obesity, as well as risk of hypoglycemia and financial coverage of medications. The decision cycle continues to incorporate lifestyle modifications, patient self-management of diabetes, and the understanding that diabetes management involves a continuum of care. The glycosylated hemoglobin (A1c) goal should be individualized. The default A1c goal is less than 7 percent. Medication regimens strive to improve

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adherence and persistence of therapy, taking into account patient preferences. Patients not at target A1c levels should be seen at least every 3 months if progress is evident and more frequently initially so education can be provided. Metformin remains the first-line therapy along with lifestyle changes, weight management, and physical activity. If target A1c levels cannot be achieved with optimized metformin therapy, then presence of ASCVD, kidney disease, and heart failure guides choice of the medication to be added to metformin. If these conditions are present, a Glucagon-like Peptide 1 Receptor Agonists (GLP-1 RA) or Sodium-glucose cotransporter 2 inhibitor (SGLT2i) that has demonstrated cardiovascular benefits in clinical trials is recommended. If these conditions are not present, therapy added to metformin can be chosen based on goals to help decrease risk of hypoglycemia, decrease weight gain, or cost considerations. Prior authorization for medications reviewed under the Four Prescription Policy will incorporate the Consensus Report 2018 recommendations. The A1c goal of less than or equal to 7% will be used for non-pregnant adults if no target A1c is determined by the prescriber and patient. Optimized metformin as clinically appropriate will be advocated before addition of other medications for hyperglycemia. Metformin will usually be approved for 1 year. Presence of ASCVD, CKD, or heart failure will guide choice of medications to be added to metformin. In the absence of these conditions, obesity, risk of hypoglycemia, and cost will be considered as needed for individual patients. Second or third agents will be initially approved for 6 months, with provision of the last two recent A1c levels required for renewal. The GLP-1 RA and dipeptidyl peptidase-4 (DPP-4) inhibitors will be considered duplicate therapy consistent with the report recommendations. The prescriber will be asked to choose which medication to use. In terms of injectable therapies, the addition of a GLP-1 RA is preferred over insulin, unless the A1c is 11 percent or greater, at which time insulin therapy is a priority. After addition of a GLP-1 RA to metformin, long-acting insulin, followed by short-acting insulin would be added. The RetroDUR 300 claims review identified metformin underdosing, with many patients filling 500 mg or 1000 mg daily for several months. A letter is proposed to inform prescribers that the RetroDUR 300 review identified metformin underdosing, to request the target and last 2 A1c levels, and to inform the prescriber of the Consensus Report recommendations for glycemic control. Bedrija Nikocecic, PharmD asked whether renal function indices, which could be a reason for lower metformin doses could be requested. Christina Petrykiw, PharmD, noted that with incoming requests, A1c, glomerular filtration rate, body mass index, and presence of ASCVD are requested to help assess appropriateness of metformin and additional therapies. Christopher Schriever, PharmD, recommended adding a statement regarding metformin tolerability which can impact ability to increase doses. Mary Lynn Moody, BSP Pharm, recommended instead of just asking for data, to ask for the reason why the participant is not receiving an optimized metformin dose, while addition of more medications is being considered. Providing a check-box list may facilitate response by prescribers. It is still important to emphasize education about appropriate prescribing to facilitate disease management. Dr. Goyal noted that prescribers do not like prior authorization in general. Prior authorization can play a role with expensive medications or those that require monitoring for appropriate use, but provision of clinical data to the insurer takes away time from patient care. He recommended a 1-2 page educational item, less cumbersome than the report's busy algorithm to educate prescribers. Christina Petrykiw, PharmD, reminded everyone that HFS is charged with prospective and retrospective DUR that at times requires additional clinical information to ensure prescribing is appropriate. Dr. Goyal noted that HFS may be supportive of a provider notice to help improve quality of diabetes management. Audit of select cases may be more effective than requiring collection of data on all patients, given lack of automation and ease of information retrieval in many prescriber practices. Christopher Schriever, PharmD recommended the check box method to help streamline information provision by prescribers. Mary Lynn Moody BSP Pharm, suggested targeting participants who were filling metformin 500 mg daily for a long time since limited therapeutic benefit is achieved with this low dose long-term. Dose titration may take 3-4 months. Education is needed to ensure faster adoption of treatment recommendations, which can take up to 10 years to be incorporated into practice. Dr. Schriever made a motion, seconded by Bedrija Nikocecic, PharmD and the DUR Board members approved the Four Prescription Policy diabetes management process consistent with the Consensus Report recommendations.

Retrospective Drug Utilization Review

Spacer devices. Christina Petrykiw, PharmD, provided an overview of spacer utilization in Fee-for-Service participants. Inhaler technique impacts efficacy of medications. Retrospective studies showed that incorrect inhaler use occurs in up to 68% of patients. Medication adherence decreases when inhalers are difficult to use, multiple inhalers are prescribed and multiple doses taken daily. Spacer devices may improve steroid inhaler technique and efficacy. Several factors impact drug deposition into airways, including disease state and severity, breathing patterns, inhaler technique, medication properties, the propellant, and the particle size. Particles in the 1 – 5 micron range provide clinical effects, getting to the level of the alveoli in the lung. Differences between pressurized metered-dose inhalers (pMDI) and dry-powder inhalers (DPI) were discussed, in particular, type of inspiration and technique difficulties associated with use.

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The hydrofluoroalkane (HFA) inhalers may increase lung deposition of medications. Appropriate technique delivers up to 15% of the medication dose to the lungs, paralleling nebulized medication deposition. A spacer device increases the volume and space between the inhaler and the mouth, decreases the speed of the aerosol, and decreases the particle size. Spacer characteristics impact the amount of the dose retained by the spacer. A valved holding chamber (VHC) is preferred because it holds the aerosol until an inspiration opens the valve to release the medication into the airway. Spacer devices facilitate less deposition of medication at the back of the throat, thereby decreasing oropharyngeal candidiasis seen with steroid inhaler use. Technique and mask size fit impact spacer efficacy. A DPI is not used with a spacer. Static-free devices may be optimal for HFA inhalers to decrease electrostatic drug loss. Dr. Laff asked why InspirEase was not pictured on slide 17 because many patients ask questions and need frequent replacement of this device. Dr. Petrykiw noted that devices that had pictures available were highlighted. Age-based criteria for masks, spacer devices, and inhalers alone were discussed. HFS spacer coverage was reviewed. Pharmacy claims review identified 9,350 unique participants who filled a steroid-containing inhaler, spacer, or had a prior authorization request from January 2016 through June 2018. Spacers were filled by 4,771 unique participants, resulting in 6,018 fills. More patients filled steroid monotherapy inhalers than combinations with long-acting beta-agonists, which may signal they have milder forms of asthma. Adherence remains a problem with only up to 13% percent of patients filling 11-12 inhalers. The majority of participants have filled only 1 spacer device during the 2.5 year review period. The greatest number of fills were in children 5-11 years of age, adolescents, followed by children less than 4 years of age, although adults also filled spacer devices. More mask devices were filled in the older than 4 age group. Less than a quarter of the participants filling steroids also filled a spacer device. About 50% of the patients filling a spacer filled a steroid, which may be due to third party insurers covering medications and/or the spacer being used to deliver other medications. Dr. Laff noted that in her pediatric practice the spacer would be prescribed with an albuterol inhaler as well. Pharmacists will think of a steroid inhaler with a spacer, rather than other inhalers given guidelines and training that promotes use of spacers with steroid inhalers to decrease potential oral candidiasis. Dr. Nikocec suggested reaching out to the colleges of pharmacy since there appear to be training differences to request inclusion of use of spacers with albuterol in children to facilitate appropriate use. Mary Lynn Moody, BSP Pharm suggested a proactive educational program for pharmacists that provides continuing education regarding asthma that would incorporate discussion of use of appropriate products, such as mask-type VHCs for children. The program can help pharmacists remember to call prescribers when an inhaler prescription presents to check if the prescriber also wishes to have a device filled. Dr. Laff related instances of the wrong device dispensed, for example, an Aerochamber without a mask when the one with a mask was intended. The patient returns to follow-up 2 weeks later and the caregivers express confusion on how to use the device, since it doesn't match the device information provided by the prescriber. Given that effective medication use can decrease Emergency Room visits for asthma, waste of medication due to poor technique, or wrong device or mask size, this was considered a good educational intervention. Dr. Laff noted a mask is used even in children 9 years of age, because the inhaler technique is not easy for children to master. A mask facilitates inhalation, while inhaler mouthpieces are often put completely into the mouth, rendering them practically ineffective. The DPI and Respiclick inhalers are also difficult for children to use and this results in a huge problem for prescribers and families trying to manage asthma. In cases of multiple spacer device fills, the second spacer was filled 7-11 months after the first spacer fill. Review of select prior authorization requests demonstrated that although approved, many patients did not fill their spacer. The sample size was too small to determine whether spacer use improved medication adherence, although a trend toward improved adherence was evident. Reasons for needing a new device include microbial contamination, cracks/damage, or the valve is no longer working. Medical institutions and manufacturers recommend replacement at least after a year of regular use. One suggestion to improve utilization would be to add a spacer/VHC to the inhaled corticosteroid prescription request form being used to encourage first-line therapy use in patients using only montelukast monotherapy. Dr. Laff asked if albuterol can also be added. It was determined that this may not make sense since the given form addresses steroid inhaler use. Staff suggest reaching out to prescribers of participants who fill steroid inhalers, but not spacers to inform of spacer coverage and medication adherence and provide the educational material the DUR Board approved September 2018. Tim Lehan, BSP Pharm noted that pharmacies experience billing issues when spacers reject if patient has a third party insurance. He inquired whether the prior authorization requirement could be removed so that the spacer device could be filled. Medicaid is the secondary payer, thus it is unclear if this prior authorization requirement could be removed. Mary Lynn Moody, BSP Pharm proposed a potential policy of an automatic fill of a spacer with the first fill of an inhaler in children less than a certain age to facilitate spacer use since the device can improve therapeutic effectiveness of the medication. Dr. Schriever noted a disconnect in practice that higher risk patients, such as those who have difficulty with inhaler technique, do not get a spacer. Pharmacist education is needed. Mary Lynn Moody, BSP Pharm suggested this may be a good topic to pilot partnering with the state pharmacy organizations. Dr. Schriever noted that it would also be helpful if all insurers paid for

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a spacer, which would decrease need for a prior authorization request. This is also another product that can be dispensed, thus revenue for the pharmacy. Dr. Laff reinforced the need for education about knowing whether the inhaler still delivers medication. Patients lack awareness of the counters and continue to use the inhaler even when the counter shows no more medication is left. The situation has improved now that many inhalers have a counter, but patient/caregiver education still needed to ensure medication delivery occurs. Mary Lynn Moody, BSPHarm suggested that HFS do outreach to prescribers of children less than 9 years of age who are filling either albuterol and/or a steroid inhaler to suggest a spacer be filled with a mask to facilitate medication delivery. Also older patients may need a VHC device as well. Staff will work with Dr. Laff to develop this initiative. Dr. Goyal commented that since the data only reflects FFS data, the problem of spacer underutilization would probably be much greater if MCOs were included.

Gabapentin utilization. Christina Petrykiw, PharmD, presented information from pharmacy claims review of Fee-for-Service and Managed Care participants who filled gabapentin from August 19, 2018 through September 25, 2018. The majority of participants (86%) filled one strength of a solid oral dosage form, 13% of participants filled multiple solid oral dosage forms, and 1% of participants filled a liquid formulation alone or with a solid oral dosage. Approximately 8% of participants filling gabapentin multiple times filled both strengths on the same day to make up their daily dose. For the other patients filling multiple gabapentin products during the month, more information from the prescriber needed to determine whether an up- or down- titration or multiple prescribers were prescribing gabapentin. In terms of daily dose for solid oral dosage forms, the most common daily doses for participants filling 1 strength only were 800 mg to 1199 mg daily (26%) or 100 to 399 mg (21%) daily. For those filling multiple strengths to achieve a daily dose, the most common dose was 2700-3199 mg daily followed by 1200 – 1799 mg daily. For liquid gabapentin, the most common daily doses were in the 100 – 799 mg range, with few participants filling more than 1800 mg daily. For FDA-approved indications for postherpetic neuralgia, the maximum dose is 1800 mg. For seizures up to 1800 mg for those 12 years of age and older, is used. Up to 2400 mg may be well tolerated and few patients need 3600 mg for a short duration to manage seizures. For common off-label indications such as diabetic peripheral neuropathy, essential tremor, panic disorder, and social phobia up to 3600 mg daily is used, while other indications such as hot flashes with menopause or breast cancer may use up to 2700 mg daily. For fibromyalgia, nystagmus, orthostatic tremor, neuropathic pain syndromes, and migraine prophylaxis up to 2400 mg may be used. Other indications used a lower maximum daily dose. Nationally gabapentin use tripled between 2002 and 2015. Gabapentin has surpassed pregabalin use, which has stabilized, placing gabapentin in the top 10 most prescribed drugs and in the top 10 by sales volume in 2017. The FDA is evaluating co-prescribing of opioids with gabapentinoids and other CNS depressants. Gabapentinoid misuse, particularly in patients with a history of substance abuse is a concern noted by the European Medicines Agency's Suspected Adverse Drug Reaction database that identified more than 75% adverse events associated with gabapentinoids since 2012. High-risk populations (substance/opioid abuse, psychiatric co-morbidities) warrant abuse monitoring. Doses greater than 3,000 mg daily are considered problematic. Case-controlled studies note increased odds of opioid-related death in persons taking gabapentin compared with those taking opioids alone. A 60% increase in odds of an opioid-related death is seen compared with no gabapentin taken. Risk increases with moderate (900-1799 mg) and high (\geq 1800 mg/day) doses. A Canadian hospital study showed that patients co-prescribed gabapentin and opioids were 49% more likely to experience an opioid-related death. The Canadian gabapentin package insert has been updated with warnings about CNS and respiratory depression with gabapentin use, and warnings about concomitant opioid use that can potentiate the risk of respiratory depression, profound sedation, syncope, and death, and can increase gabapentin concentrations. Patients should be observed for CNS depression and their gabapentin or opioid dose decreased as clinically appropriate. The DUR Board members noticed increased fills of gabapentin total daily doses of 2400 mg or more. Claims review identified about 2900 participants filling total daily doses 2400 mg or greater. A daily dose of 3600 mg was filled by 418 participants and 27 participants filled a daily dose greater than 3600 mg. The DUR Board reviewed options to ensure appropriate gabapentin dosing, including prior authorization for exceeding a lower dose such as 2400 mg or 2700 mg rather than the current 3600 mg; prior authorization for accumulated quantity of gabapentin per month; RetroDUR for participants also filling medications that depress respiration (drug interaction), for doses greater than 3600 mg, for prescribers whose patients are filling multiple strengths of gabapentin on different days, or those receiving subtherapeutic doses long-term. A RetroDUR gabapentin-focused prescriber letter would address patients filling doses 2400 – 3599 mg, clarify diagnosis, confirm need for high dose, and obtain medical justification for use of the higher doses. If medications that depress respiration, including opioids/benzodiazepines, are being filled the letter should warn of potential increased risk with concomitant therapy. For history of substance abuse, recommending monitoring of gabapentin misuse is applicable. If filling opioids, warning about increased risk of opioid-related death with concomitant therapy as well as potential need to adjust opioid or gabapentin doses is recommended. Donna Clay

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BSP Pharm asked whether the cases of multiple fills of different strengths during the same month were an issue of multiple prescribers. Dr. Petrykiw noted that this would have to be reviewed in the data pulled, since the focus of this review was on total daily dose. Dr. Goyal asked about data regarding alcohol withdrawal use of gabapentin or with concomitant use with benzodiazepines. The DUR Board members stated that combination of gabapentin with medications that depress respiration or increase gabapentin misuse was a greater concern than gabapentin monotherapy and may warrant education, including a HFS provider notice. Dr. Schriever noted that in past year more patients in clinic are requesting gabapentin refills and becoming more adherent with this therapy, unlike their other therapies. Some patients admitted to increased street value of gabapentin. The DUR Board members felt that the Drug Enforcement Agency may with time change gabapentin to a controlled substance, similar to pregabalin.

Education.

FDA Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). Christina Petrykiw, PharmD, updated DUR Board members about the change in the FDA Opioid Analgesics REMS which as of September 2018 includes immediate-release opioid analgesics for outpatient use, in addition to the extended-release and long-acting (ER/LA) opioid analgesics. This change includes 347 opioid analgesics. A Medication guide should be given to the patient and/or caregiver, Patient counseling guides should address safe opioid use, risks of use, as well as appropriate storage and disposal. The REMS programs need to include plans for assessing the effectiveness of the program. The REMS training now includes all health care providers involved in pain management, not just prescribers. The prescriber education must include appropriate pain management for given conditions including opioid alternatives. The FDA may provide guidance on this by March 2019. The FDA has released an Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain available at <https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM620249.pdf>. Prescription opioid product labels are being updated with information about health care provider education via REMS in the boxed warning, warning, and precaution sections. Providing the most current, comprehensive information about appropriate pain management helps ensure prescriptions are written for an appropriate purpose and duration. If overall dispensing of opioids decreases, this can decrease opioid exposure and prevent potential addiction. Other FDA opioid initiatives include an Opioid Policy Steering Committee that is evaluating the need for mandatory opioid education for health care providers; an awarded contract to the National Academies of Sciences, Engineering, and Medicine (NASEM) to develop evidence-based guidelines for appropriate opioid analgesic prescribing for various acute pain conditions; and the Department of Health and Human Services' Five-point strategy to combat the opioid crisis. This strategy includes improved access for prevention, treatment, and recovery services, better data about the opioid epidemic, better evidence-based pain management, targeting of overdose-reversing medications, and better research on pain and addiction.

FDA Animal Veterinary Resources for veterinarians who stock and administer opioids. The DUR Board members had noted increased use of opioids by pet owners obtaining opioids for their pets. Now new FDA animal veterinary resources for veterinarians who stock and administer opioids are available. Veterinarians must adhere to state opioid prescribing regulations, which 15 states, including Illinois, have in place. Veterinarians must report dispensing of opioids and controlled substances to patients, have limits on quantities that may be prescribed at one time, and limit duration of opioid therapy. Colorado and Maine require verification of the pet owner's past medication history before dispensing opioids or writing an opioid prescription. Veterinarians must also follow federal opioid prescribing regulations, including contacting the local DEA with questions regarding current regulations and filing stolen medication reports with the DEA and local police departments. Pet owners must be made aware of opioid alternatives, receive training about safe storage and disposal of opioids, and education about management of a pet overdose due to fentanyl and other opioids. The University of Illinois College of Veterinary Medicine provides an emergency hotline for canine overdoses. Veterinarians must have a Safety Plan in place and know signs of opioid abuse to help identify veterinary shopping. Brochures to educate about diversion prevention have been developed.

The DUR Board members supported providing links to the reviewed documents on the DUR Board Education Webpage. Dr. Goyal noted that the Illinois Department of Financial and Professional Regulation has incorporated the Federation of State Medical Boards' Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain into the Rules for the Administration of the Medical Practice Act in Illinois effective July 6, 2018. These published standards differ somewhat from the FDA and CDC opioid prescribing guidelines. Dr. Goyal informed the DUR Board members that with the next medical license renewal cycle, 3 hours of

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continuing education about opioids will be required. The Illinois Public Health grant is developing a 3-hour opioid continuing education offering. Other physician organizations, including the Illinois State Medical Society, are developing opioid prescribing continuing education. Illinois is one of 11 states that received a grant to address maternal opiate use that leads to neonatal abstinence syndrome. Mary Lynn Moody, BSPHarm, noted that the College of Pharmacy with the Illinois Prescription Monitoring Program received a Centers for Disease Control and Prevention (CDC) grant for academic detailing related to opioid prescribing. The pilot study was conducted in the Chicago area, the current phase of the study is in rural Illinois, and Northern Illinois will be next. Dr. Laff noted that it would be wonderful to have something that addresses addictive behavior and mental health funding because this starts early - in the pediatric population.

Future agenda items. Dr. Laff noted that medical marijuana is being used for pain and asked whether that may be topic for discussion. Patty Steward, BSPHarm, noted that medical marijuana is not approved by the FDA, and since this is not an approved medication, HFS does not cover it. Dr. Laff noted that marijuana overuse is an issue and seen a lot in pregnant mothers. Dr. Schriever said that it is being used a lot in high schools and daily use is resulting in cognitive impairment. When it is legalized, Dr. Laff notes, the perception is that it is safe, yet that is not necessarily true. Dr. Goyal informed everyone that in states that legalized recreational marijuana, it has become the main medication implicated in car accidents, having surpassed alcohol. Sleep deprivation is the second most common cause of auto accidents.

Public comments. Dr. Laff noted that public comments should pertain to the day's agenda. No public comments made.

Adjournment. Christopher Schriever, PharmD, made a motion, seconded by Tim Lehan, BSPHarm, and Dr. Laff adjourned the DUR Board meeting at 10:09 am.

Meeting summary prepared by Christina A. Petrykiw, PharmD, CDE.

Approved February 20, 2019 by the Illinois Drug Utilization Review Board.