ATTENDEES

**Board Members Present:** Kenneth Fisher, R.Ph. (Chair); Richard Gannon, Pharm.D.; Keith Lyke R.Ph., Bhupesh Mangla, M.D., Ram Illindala, M.D.; Angela Moemeka, M.D., F.A.A.P

**Ex-Officio Non-Voting Member Present:** Heather L. Kissinger, Pharm. D. (HID – DUR Board Coordinator and Secretary), James Zakszewski, R.Ph.

**Guests:** Ellen Arce, R.Ph. (EDS), Wendy Pollinger (Eli-Lilly); Daniel Martin (Amgen), Nick Rebholz (OMJPI), Liz Pujolas (MedImmune)

INTRODUCTORY BUSINESS
- Ken Fisher called the meeting to order at 6:45 p.m.

OLD BUSINESS

A. Previous Meeting Minutes
- The June 2009 DUR Board meeting minutes were approved by all members with the following changes:
  - Page 11, second section, third bullet Bhupesh Mangla requested the sentence be revised to read: “…ACEI controlled blood pressure better for Type I diabetics and ARBs controlled blood pressure better for Type II diabetics when used for renal protection and management of congestive heart failure in these patients.
  - Page 13, fourth bullet, Rich Gannon requested criteria 25 to be tabled indefinitely until further investigation could be performed. Heather Kissinger stated she would put together a new section for criteria that were tabled indefinitely so that the Board could review them periodically as new information is released.

B. Follow-up from Previous Meeting
- The Board reviewed the section titled “Follow-up from the June 2009 DUR Board Meeting.”
  - Follow-up 1. A request was made to create a new criterion regarding the interaction between fluvoxamine and the select statins due to fluvoxamine’s strong inhibition of 3A4.
September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

- Heather Kissinger stated that the new criterion could be found in section 8.
- Follow-up 2, a request was made that zolpidem be added to the list of generic sedative/hypnotics used to treat insomnia to Criteria 2792 (alert message: Clinical trials have not shown Ambien CR (zolpidem controlled-release) to be superior to other sedative/hypnotics for the treatment of insomnia. If no contraindications are present consider prescribing a less expensive generic sedative/hypnotic agent before prescribing a brand name product. Generic sedative/hypnotic options include zolpidem, estazolam, flurazepam, temazepam, and triazolam.) It was further requested that zolpidem be the first generic sedative/hypnotic listed in the alert message prior to all other options.
- Heather Kissinger stated that this change was made.
- Follow-up 3, a request was made during the March 2009 DUR meeting to know how many patients were receiving a prescription for a dopaminergic agent and also receiving a prescription for long term high dose metoclopramide. A search was built using the new metoclopramide criteria

**Metoclopramide / Black Box Warning**
Alert Message: Chronic and high-dose use of metoclopramide has been linked to tardive dyskinesia even after the drug is discontinued. These adverse effects are rarely reversible and have no known treatment. The patients at greatest risk are the elderly, especially older women, patients who have been on the drug for a long time and patients taking higher doses. The chronic use of metoclopramide should be avoided in all but rare cases where the benefit outweighs the risk and patients should be informed of the risk.

Conflict Code: TA - Therapeutic Appropriateness *(Black Box Warning)*

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<tr>
<th>Drugs/Diseases</th>
<th>Util A</th>
<th>Util B</th>
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<tr>
<td>Metoclopramide</td>
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References:

- There were **1748** patients who hit on the metoclopramide / black box warning criteria during the 5/5/09 ICER. There were **1901** patients who received a dopaminergic agent between 2/24/09 and 4/24/09. A cross reference search was conducted between the metoclopramide patients and patients who received a dopaminergic agent between 4/1/09 and 6/1/09. **39** patients were found...
Connecticut Medical Assistance Pharmacy Program
Drug Utilization Review (DUR) Program
DUR Board Meeting

September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

to have received both a dopaminergic agent in conjunction with chronic high dose metoclopramide.

- An additional Request was made to know of the 39 patients, how many had received the metoclopramide prescription prior to the dopaminergic agent.
- Heather Kissinger stated that 9 of the 39 patients received metoclopramide prior to receiving a dopaminergic agent.
- Follow-up 4, a request was made during the March 2009 DUR meeting to know how many patients had a diagnosis of a movement disorder and had received a prescription for long term high dose metoclopramide. A search was built using the new metoclopramide criteria

Metoclopramide / Black Box Warning
Alert Message: Chronic and high-dose use of metoclopramide has been linked to tardive dyskinesia even after the drug is discontinued. These adverse effects are rarely reversible and have no known treatment. The patients at greatest risk are the elderly, especially older women, patients who have been on the drug for a long time and patients taking higher doses. The chronic use of metoclopramide should be avoided in all but rare cases where the benefit outweighs the risk and patients should be informed of the risk.

Conflict Code: TA - Therapeutic Appropriateness (Black Box Warning)

Util A | Util B | Util C
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Metoclopramide

References:

- There were 1748 patients who hit on the metoclopramide / black box warning criteria from during the 5/5/09 ICER. There were 51,050 patients who have received a diagnosis for a movement disorder from 1/1/07 through 4/24/09. Movement disorders such as ataxias, dystonias, essential tremor, Huntington’s Disease, myoclonus, Parkinson’s Disease, Restless Leg Syndrome, spasticity, tardive dyskinesia, torticollis, Tourette’s Syndrome, and Wilson’s Disease were considered for this query. Most disorders fell under diagnosis codes 330-370, Hereditary and Degenerative Diseases of the Central Nervous System. A cross reference search was conducted between the patients who received chronic high dose metoclopramide, and patients who were diagnosed with a movement disorder (1/1/07 - 6/1/09). 393 patients were found to have a diagnosis of a movement disorder and also received a chronic high dose metoclopramide prescription.
September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

- An additional Request was made to know of the 393 patients, how many were diagnosed with Parkinson’s disease and Tardive Dyskinesia specifically. If there were a large number of patients the Board suggested an intervention be performed.
- Heather Kissinger stated that of the 1748 patients who received chronic high dose metoclopramide, only 9 patients had a diagnosis of Parkinson’s disease or Tardive Dyskinesia. The breakdown is as follows:
  - 5 patients were diagnosed with Paralysis Agitans (ICD-9 3320)
  - 1 patient was diagnosed with Parkinson’s Disease (ICD-9 332)
  - 1 patient was diagnosed with Secondary Parkinson’s (ICD-9 332.1)
  - 1 patient was diagnosed with both Secondary Parkinson’s and Paralysis Agitans
- Rich Gannon asked if anyone knew the definition of Paralysis Agitans.
- Angela Moemeka stated that it was a manifestation of Parkinson’s Disease.
- Heather Kissinger stated that descriptions of the specific ICD-9 codes could be found on the ICD-9 website and she would send the website link to the members.
- Follow-up 5 and 6, a request was made for Ellen to explain why the alert that states: “A patient has diabetes” is activated when you try to fill a prescription for Metformin. An additional request was made for Ellen to explain what the alert: “This person has been in the hospital” means.
- Ellen Arce stated that based on the NCPDP definition for defining diseases, a wide array of disease states are brought up when the MC (Drug-Disease) alert is activated. In order to solve the issue the MC (Drug-Disease) alert was changed to informational only, meaning pharmacies would no longer have to override this alert for a prescription to pay.
- Follow-up 7, a request was made for Ellen Arce to verify that the alert for Inferred Disease was and is inactive.
- Ellen Arce stated this alert was never active.
- Follow-up 8, a request was made to see the more serious interactions for the Drug-Drug alert set during FFY 2008 within class I and II high severity.
- Ellen Arce produced this report and handed it out to the Board Members.
- Rich Gannon suggested that since Dennis Chapron was not present during the meeting that a copy of the report is sent to him.
- Ellen Arce stated that she would send a copy to Dennis.
Follow-up 9, within the Institute for Safe Medication Practices (ISMP) newsletter quetiapine was ranked in the top 15 medications for most frequent drugs involved in serious, disabling, and fatal events in 2008 3Q. The Board requested to know what the serious, disabling, and fatal events were specifically.

Heather Kissinger stated that she contacted the ISMP newsletter and requested to know what serious, disabling, and fatal events specifically made quetiapine rank in the top 15 medications in QuarterWatch Report (2008 Q3). Michelle Bell, RN, ISMP’s Safe Medication Management Fellow responded to the request by saying that the QuarterWatch report is based on the FDA MedWatch reports. Because ISMP receives the MedWatch reports from the FDA, they cannot release them to a third party.

Angela Moemeka stated that the information could be found through the public MedWatch reports sent out by the FDA.

Ram Illindala stated that the Board wanted to know what serious, disabling, and fatal events occurred from the use of quetiapine during 2008 and the reports didn’t necessarily have to come directly from ISMP.

Heather Kissinger stated she would research the topic again and follow-up during the December 2009 DUR Board meeting.

Follow-up 10, the Board requested that an intervention regarding use of PPIs post hospitalization be performed.

Heather Kissinger stated that HID did not have criteria for PPI use post hospitalization. April, HID’s systems analyst wrote specific programming for this criteria based on type-of-bill codes that indicates whether a patient was recently discharged from the hospital. The new criteria can be found in section 8, number 41, and will be reviewed later in the meeting.

Follow-up 11, a request was made to know how each criterion is categorized into major, moderate or minor.

Heather Kissinger stated that the drug interaction criteria ratings come from the reference material (F & C, Drugdex, Clinical Pharmacology) and are as follows:

- Black Box Warnings and Contraindications are major.
- Excessive use is major.
- Nonadherence is major.
- Precautions/Warnings are moderate.
- Therapeutic Appropriateness is moderate.
The cost control criteria are rated minor - because it is not really a problem that the reviewer should consider before another drug-related issue.

- Follow-up 12, a request was made to know the cutoff age was for the following criteria prior to activation.

**Milnacipran / Risk of Suicide (Black Box Warning)**

Alert Message: Savella (milnacipran) is a selective serotonin and norepinephrine reuptake inhibitor (SNRI), similar to some drugs used for the treatment of depression and other psychiatric disorders. SNRIs may increase the risk compared to placebo of suicidal thinking and behavior in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders. Monitor patients closely for unusual changes in behavior.

Conflict Code: TA – Therapeutic Appropriateness

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References:
Savella Prescribing Information, Jan 2009, Cypress Bioscience, Inc.
Facts & Comparisons, 2009 Updates.

- Heather Kissinger stated HID uses the age range 0-24 for this black box warning for antidepressants. It can be modified to the age of eighteen. The Board requested that this criteria be tabled until the December 2009 meeting when Charlie Caley will be present to review.

**C. Criteria Trend Summary**

- Heather Kissinger stated that section 4 is the criteria trend summary, the purpose of this report is to review criteria previously reviewed 6 months after intervention letters are mailed to evaluate if the intervention had an impact on the population.

- Criteria 2283, (Alert message: Epidemiological studies suggest atypical antipsychotics may exacerbate pre-existing diabetes. A dose adjustment in the patient's current diabetic medication(s) may be necessary for optimal blood glucose levels. Blood glucose and HgA1c monitoring should be conducted in conjunction with monitoring for weight gain and signs of hyperglycemia. All patients should be advised to report signs of ketoacidosis or glycosuria) had 2507 hits in January 2009 and increased to 3069 hits in July 2009.
Connecticut Medical Assistance Pharmacy Program
Drug Utilization Review (DUR) Program
DUR Board Meeting

September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

- Criteria 3906, (Alert message: Lidoderm (transdermal lidocaine) is FDA approved only for the relief of pain associated with postherpetic neuralgia. Our records do not indicate a supporting diagnosis for the use of this medication. The long-term safety and efficacy of this agent in treating other disease states is unknown) had 1110 hits in February 2009 and decreased to 1094 hits in August 2009.

- Criteria 2382, (Alert message: Tussionex (hydrocodone/chlorpheniramine) may be over-utilized. If used for several weeks, Tussionex can cause dependence and tolerance. In treating allergic rhinitis or common cold, it is vital to assess the patient regularly and systematically to ensure continued effectiveness of selected agent and the relative occurrence of side effects) had 165 hits in March 2009 and decreased to 45 hits in September 2009.

- Criteria 2551, (Alert message: Venlafaxine may be over-utilized. Doses exceeding 225 mg/day of the extended-release product have been associated with increased risk of adverse events including elevations in blood pressure) had 282 hits in March 2009 and decrease to 213 hits in September 2009.

- Criteria 2684, (Alert message: Fentanyl transdermal patches may be over-utilized. The majority of patients are adequately maintained with administration every 72 hours. Some patients may not achieve adequate analgesia using this dosing interval and may require systems to be applied every 48 hours rather than every 72 hours. An increase in the transdermal dose should be evaluated before changing dosing intervals in order to maintain patients on a 72-hour regimen) had 175 hits in March 2009 and decreased to 109 hits in September 2009.

- Criteria 3907, (Alert message: Our records do not indicate the use of an oral NSAID prior to the prescribing of the Flector Patch (diclofenac epolamine transdermal). If no contraindications are present consider prescribing a less expensive oral NSAID as first-line therapy for the treatment of acute pain due to minor strains, sprains, and contusions) had 46 hits in March 2009 and decreased to 38 hits in September 2009.

- Criteria 3908, (Alert message: The manufacturer recommends that Flector Patches (diclofenac epolamine transdermal) be used for shortest duration consistent with individual treatment goals for the relief of acute pain due to minor strains, sprains, and contusions. The recommended days supply is 10 days. If the patient's pain is chronic and requires extended therapy consider re-evaluation of the condition and treatment regimen) had 169 hits in March 2009 and increased to 173 hits in September 2009.

Retrospective Drug Utilization Review

The preparation of this document was financed under an agreement with the Connecticut Department of Social Services.
September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

A. Program Summary Review
- The Board reviewed the program summary review for 2nd quarter 2009.
- The average prescription cost increased by $1.09 compared to 1st quarter 2009.

B. Intervention Activity Report
- The Board reviewed the Intervention Activity report for 2nd quarter 2009.
- It was stated that the Intervention Activity Report is a monthly summary of the distribution of letters mailed to prescribers and also summarizes the main criteria that were reviewed each month.
- In April 2009, 1165 letters were sent. The main interventions reviewed were: Therapeutic duplication of long-acting stimulants may be occurring (190 letters), and Stimulants are contraindicated in patients with marked anxiety and/or panic disorder since these drugs may aggravate symptoms of anxiety, tension or agitation (201 letters), and the lock-in criteria (474 letters).
- In May 2009, 1639 letters were sent. The main intervention reviewed was: Lipid lowering agents may be underutilized resulting in subtherapeutic effects (834 letters), and the lock-in criteria (559 letters).
- In June 2009, 1546 letters were sent. The main intervention reviewed was: Clinical trials have not shown Lunesta (eszopiclone) to be superior to other sedative/hypnotics for the treatment of insomnia. If no contraindications are present consider prescribing a less expensive generic sedative/hypnotic agent before prescribing a brand name product. Generic sedative/hypnotic options include zolpidem, estazolam, flurazepam, temazepam, and triazolam (648 letters) and the lock-in criteria (495 letters).

C. Therapeutic Criteria Exception Report: ICER Date 8-5-09
- The Board reviewed the Therapeutic Criteria Exception Report that was created using the ICER ran on 8-5-09.
- Heather Kissinger stated this report is meant to help guide which interventions the Board decides to use.
- Jim Zakszewski stated that the second to last criteria on page 5 did not have a criteria number next to it. He also stated he found that particular criteria interesting and it may be worthwhile to
Connecticut Medical Assistance Pharmacy Program  
Drug Utilization Review (DUR) Program  
DUR Board Meeting  

September 2009 DUR Board Meeting Minutes  
Thursday, September 10, 2009 at 6:30 PM  
Connecticut Pharmacists Association Office  
Rocky Hill, CT  

run an intervention for it in the future. (Alert message: This patient has a history of diabetes and hypertension and may benefit from the addition of an anti-hypertensive agent to reduce cardiovascular morbidity and mortality. The coexistence of these conditions imposes a need for a significantly lower goal blood pressure (130/80mmHG) than the goal recommended for a non-diabetic patient with hypertension (140/80mmHG). If lifestyle modifications alone are no longer effective consider JNC-7 treatment recommendations for the selection of the optimal anti-hypertensive therapy).

- Heather Kissinger stated that criteria 2949, (Alert message: Low dose Seroquel (quetiapine), less than 200 mg, is sometimes used off-label as a sedative agent. Quetiapine is not FDA approved for the treatment of sleep-related problems. The long-term safety and efficacy of this treatment strategy have not been evaluated) is currently being reviewed for the September 2009 cycle.
- Angela Moemeka commented on criteria 3235 (Alert message: The patient is under the age of 18 with a diagnosis of ADHD and is receiving an atypical antipsychotic with no evidence, in their diagnostic history, of a FDA approved indication for use. Atypical antipsychotics have not been shown to be safe and effective for the treatment of ADHD. These agents have significant adverse effects which can be more prevalent and severe in pediatric patients) and stated that many patients under the age of 18 with a diagnosis of ADHD are receiving atypical antipsychotics due to a diagnosis of Oppositional Defiance Disorder, not for the diagnosis of ADHD.

C. RetroDUR New Criteria Selections  
- Criteria 1, Fluvoxamine/ CYP 3A4 Metabolized Statins was approved as written by the Board.
- Criteria 2, NSAIDS/ Diabetes was approved as written by the Board.
- Criteria 3, NSAIDS/ Pain in Older Patients was tabled indefinitely by the Board.
- Criteria 4, Pimozide/ Citalopram & Escitalopram was approved as written by the Board.
- Criteria 5, Tamoxifen/ Mod. to Potent 2D6 Inhibitor Antidepressants was approved as written by the Board.
- Criteria 6, Tamoxifen/ Mod. to Potent 2D6 Inhibitors was approved as written by the Board.
- Criteria 7, Leukotriene Inhibitors/ Neuropsychiatric Events was tabled until the next meeting by the Board. The Board members requested that Heather Kissinger find more information regarding this issue.
September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

- Angela Moemeka suggested possibly adding ADHD and antipsychotic drug therapy to the negating category for this criteria.
- Criteria 8, Tolvaptan/ Potent CYP3A4 Inhibitors was approved as written by the Board.
- Criteria 9, Tolvaptan/ Moderate CYP3A4 Inhibitors was approved as written by the Board.
- Criteria 10, Tolvaptan/ CYP3A4 Inducers was approved as written by the Board.
- Criteria 11, Tolvaptan/ P-glycoprotein Inhibitors was approved as written by the Board.
- Criteria 12, Tramadol Extended Release/ High Dose was approved as written by the Board.
- Criteria 13, Tramadol/ Therapeutic Duplication was approved as written by the Board.
- Criteria 14, Tramadol ER/ Suicidality and Addiction was approved as written by the Board.
- Criteria 15, ACE Inhibitors/ ARBs was tabled until the next meeting by the Board. The Board members requested that Heather Kissinger send them information regarding this interaction.
- Ram Illindala stated that he recalled a study in the past evaluating the use of both an ACEI and an ARB together that could be beneficial in patients with diabetic nephropathy.
- Rich Gannon suggested creating a criteria that would target patients on both an ACEI and an ARB who are also prescribed NSAIDS.
- Criteria 16, Tapentadol/ Overutilization was approved as written by the Board.
- Criteria 17, Tapentadol/ Impaired Pulmonary Function was rejected by the Board.
- Criteria 18, Tapentadol/ Paralytic Ileus was rejected by the Board.
- Criteria 19, Tapentadol / MAO Inhibitors was approved as written by the Board.
- Criteria 20, Tapentadol / Seizures was approved as written by the Board.
- Criteria 21, Tapentadol / Opiates & Alcohol Dependence/Abuse was approved as written by the Board.
- Criteria 22, Tapentadol / Serotonergic Drugs was approved as amended by the Board with the deletion of Fentanyl from Util. B.
- Criteria 23, Tapentadol / Severe Renal Impairment was approved as written by the Board.
- Criteria 24, Tapentadol / Hepatic Impairment was approved as written by the Board.
- Criteria 25, Tapentadol / Pancreatic & Biliary Tract Disease was rejected by the Board.
- Criteria 26, Lacosamide/ Overutilization was approved as written by the Board.
- Criteria 27, Lacosamide/ PR Prolongation Drugs was approved as written by the Board.
- Bhupesh Mangla commented that PR prolongation can cause first degree heart block, whereas QTC prolongation can cause torsades.
- Criteria 28, Lacosamide/ Cardiac Conduction Problems was approved as written by the Board.
Connecticut Medical Assistance Pharmacy Program
Drug Utilization Review (DUR) Program
DUR Board Meeting

September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

- Criteria 29, Lacosamide/ Renal Impairment was approved as written by the Board.
- Criteria 30, Lacosamide/ Hepatic Impairment was approved as written by the Board.
- Criteria 31, Propoxyphene/ Black Box Warning (Suicidality & Addiction) was approved as written by the Board.
- Criteria 32, Propoxyphene/ Black Box Warning (Max Dose) was approved as written by the Board.
- Criteria 33, Iloperidone/ High Dose was approved as written by the Board.
- Criteria 34, Iloperidone/ Nonadherence was tabled by the Board until the next meeting when Charlie Caley will be present.
- Criteria 35, Iloperidone/ Potent 2D6 and/or 3A4 Inhibitors was approved as written by the Board.
- Criteria 36, Iloperidone/ QT Prolongation or Problems Associated w/ Prolongation was approved as written by the Board.
- Criteria 37, Iloperidone/ QT Prolongation Drugs was approved as written by the Board.
- Criteria 38, Iloperidone/ Hepatic Impairment was approved as written by the Board.
- Criteria 39, Iloperidone/ Alpha1-Adrenergic Receptor Blockers was approved as written by the Board.
- Criteria 40, Milnacipran/ Risk of Suicide (Black Box Warning) was tabled by the Board until the next meeting when Charlie Caley will be present.
- Criteria 41, Proton Pump Inhibitors/ PPI Negating was approved as amended by the Board for patients on a PPI without a supporting diagnosis who have a hospital discharge in the last 60 days.

D. Newsletter
- The Board approved the September 2009 DUR Newsletter with the following modifications:
  - Update the H1N1 Virus section with the new information published on the CDC website within the last week regarding the production of a new vaccine, the vaccine release date and the hospitalized/death cases.
  - Mention the H1N1 vaccine is free for children and their parents and is covered under “Vaccines for Children.”
  - H1N1 section, second paragraph, add that the CDC recommends in addition to the H1N1 vaccine to also get the seasonal flu vaccine.
September 2009 DUR Board Meeting Minutes
Thursday, September 10, 2009 at 6:30 PM
Connecticut Pharmacists Association Office
Rocky Hill, CT

- H1N1 section, fifth paragraph, change the last sentence to read: “CDC laboratory results have shown that approximately one-third of adults over the age of 60 may have antibodies against the virus. Adults younger than 60 and children tend not to have antibodies against the virus.”
- Palivizumab section, first sentence, change “is used to prophylaxis” to “is used for prophylaxis.”

- The Board agreed that the newsletter would be approved once those changes were made.
- Heather Kissinger stated that she would e-mail the newsletter to the members by the close of business on Friday September 11 and if there were any additional changes to have the feedback no later than the close of business on Monday September 14. If there were no additional comments or changes Heather would send the newsletter to the printer to begin the mailings.

NEW BUSINESS
- The date for the December 2009 DUR Board meeting was confirmed as Thursday December 10, 2009.
- Heather Kissinger stated the DUR Board By-Laws would be revised and reviewed for the next meeting.
- The meeting was adjourned at 8:01 pm.