

June 2012 DUR Board Meeting Minutes

Thursday, June 14, 2012 at 6:30 PM Connecticut Pharmacists Association Office Rocky Hill, CT

ATTENDEES

Board Members Present: Kenneth Fisher, R.Ph. (Chair), Keith Lyke R.Ph., Dennis Chapron, M.S., Bhupesh Mangla, M.D., Charles Caley, Pharm.D., Ram Illindala, M.D., Richard Gannon, Pharm.D.

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

Guests: Terry Lee (Gilead), Ron Menapace (Sunovion), Tom Radice (ViiV Healthcare), Jai Persico (Endo)

INTRODUCTORY BUSINESS

- Ken Fisher called the meeting to order at 6:35 p.m.
- Ken stated that we would begin the meeting by reviewing new criteria selections first, then the previous meeting minutes, followed by the CMS report, and finish up with the remainder of the DUR Board packet.

A. RetroDUR Criteria New Criteria

- Criteria 1, Ranolazine / Potent CYP3A4 Inducers was approved as written by the Board.
- Criteria 2, Aliskiren-All / ACEIs & ARBs / Renal Impairment was approved as written by the Board.
- Criteria 3, Tapentadol ER / Overutilization Hepatic Impairment was approved as written by the Board.
- Criteria 4, Tapentadol IR / Tapentadol ER as written by the Board.
- Criteria 5, Jentadueto / Overutilization as written by the Board.
- Criteria 6, Jentadueto / Nonadherence was approved as written by the Board.
- Criteria 7, Janumet XR/ Nonadherence was approved as written by the Board.
- Criteria 8, Janumet XR/ Overutilization was approved as written by the Board.
- Criteria 9, Metformin All / Hepatic Impairment was approved as written by the Board.
- Criteria 10, Edarbyclor / Overutilization was approved as written by the Board.
- Criteria 11, Tekturna HCT / Overutilization was tabled indefinitely by the Board.
- Criteria 12, Valturna / Overutilization was approved as written by the Board.
- Criteria 13, Amturnide / Overutilization was approved as written by the Board.
- Criteria 14, Tekamlo / Overutilization was approved as written by the Board.
- Criteria 15, Aliskiren-All / Cyclosporine & Itraconazole was approved as written by the Board.
- Criteria 16, Aliskiren-All / NSAIDS & COX-2 Inhibitors was approved as written by the Board.
- Criteria 17, Lovastatin / Ranolazine was approved as written by the Board.
- Criteria 18, Lovastatin / Colchicine was approved as written by the Board.





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- Criteria 19, Lovastatin / Strong CYP3A4 Inhibitors was approved as written by the Board.
- Criteria 20, Rosuvastatin / Kaletra or Atazanavir (Ritonavir-Boost or Alone) was approved as written by the Board.
- Criteria 21, Atorvastatin / Tipranavir / Ritonavir was approved as written by the Board.
- Criteria 22, Atorvastatin-All / Telaprevir was approved as written by the Board.
- Criteria 23, Atorvastatin / Lopinavir + Ritonavir was approved as written by the Board.
- Criteria 24, Atorvastatin / Ritonavir-Boosted Saquinavir, Darunavir & Fosamprenavir was approved as written by the Board.
- Criteria 25, Atorvastatin / Fosamprenavir was approved as written by the Board.
- Criteria 26, Atorvastatin / Clarithromycin & Itraconazole was approved as written by the Board.
- Criteria 27, Atorvastatin / Nelfinavir was approved as written by the Board.
- Criteria 28, Atorvastatin / Strong 3A4 Inhibitors was approved as written by the Board.
- Criteria 29, Caduet / Protease Inhibitors was approved as written by the Board.
- Criteria 30, Caduet / Clarithromycin & Itraconazole was approved as written by the Board.
- Criteria 31, Caduet / Cyclosporine was approved as written by the Board.
- Criteria 32, Pravastatin / Clarithromycin was approved as written by the Board.
- Criteria 33, Vytorin / Renal Impairment was approved as written by the Board.
- Criteria 34, Atorvastatin / Atazanavir was approved as written by the Board.
- Criteria 35, Boceprevir / Atorvastatin 40 & 80mg was approved as written by the Board.
- Criteria 36, Bydureon / Byetta was approved as written by the Board.
- Criteria 37, Bydureon / Insulin was approved as written by the Board.
- Criteria 38, Bydureon / Medullary Thyroid Cancer & MENS was approved as written by the Board.
- Dennis stated that as an aside, information regarding an increased risk of bladder cancer may be associated with pioglitazone use.
- Criteria 39, Exenatide-All / ESRD & Severe Renal Impairment was approved as written by the Board.
- Criteria 40, Exenatide-All / Warfarin was approved as written by the Board.
- Criteria 41, Exenatide-All / Type 1 Diabetes & Ketoacidosis was approved as written by the Board.
- Criteria 42, Exenatide-All / Antibiotics & Oral Contraceptives was approved as written by the Board.
- Criteria 43, Linezolid / Duration > 28 days was approved as written by the Board.

B. Previous Meeting Minutes

- It was requested change "resent" to "present" in the last bullet on page one.
- It was requested change "who" to "for whom" in the second bullet on page 2.





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- Ken stated that going forward Heather refer to patients as recipients when writing in Medicaid context, but continue to use the term patient when writing in physician/patient context.
- Jim Zakszewski stated that client can also be used in place of patient when writing in Medicaid context.
- It was requested change "increased" to "decreased" in the first bullet on page six.
- It was requested add "that" to the first bullet on page ten so the sentence would read, "Jim stated that CMS is mandating **that** all prescribers..."
- The March 2012 DUR Board meeting minutes were approved with changes by all members.

C. CMS Report

- The Board began reviewing the FFY 2011 CMS report found in section 5.
- Heather stated that the CMS report is comprised of 3 tables and 9 attachments and its purpose is to provide prospective and retrospective DUR data to CMS on an annual basis.
- Heather stated the Executive Summary could be found on pages 3-7 and the CMS Survey could be found on page 8-16.
- The executive summary summarizes the key points made throughout the report, lists the number of DUR meetings during the year, lists prospective and retrospective reviews, and highlights the cost savings. The CMS survey is a high level survey regarding each attachment/table with the CMS report.
- Heather stated that one change needed to be made on page 7 of the executive summary, the lock-in table should read FFY 2011 (October 1, 2010 September 30 2011).
- The Board members reviewed ProDUR Table 1 and 1a on pages 17-22.
- Heather stated there are 12 ProDUR criteria, 8 requiring an override, and 4 that are informational in nature. The 8 requiring an override are; Early Refill, Therapeutic Duplication, Drug-Drug Interaction, High Dose, Pregnancy, Drug-Age Pediatric & Geriatric combined, Ingredient Duplication, and Drug Disease. The 4 alerts that are informational in nature are; Low Dose, Late Refill, Minimum Duration and Maximum Duration.
- Rich suggested that having a ProDUR alerts at point of sale for therapeutic duplication of long acting opiates would be a good idea.
- Heather stated that according to Table 1, therapeutic duplication of opiates does require an override by the pharmacist.
- Mark stated he would look into the alert to make sure it did require an override and if it included all opiates, not just the long acting products.
- Ken suggested Heather run a query regarding the therapeutic duplication of long acting injectable antipsychotics.
- Jim requested the results be stratified by age.
- Heather stated she would follow up with results from the query request.
- Heather reported that table 2 of the CMS report could be found on pages 23-24 and included Retrospective DUR criteria approved by the DUR Board during FFY 2011.





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- The Board reviewed Table 2 and had no questions, changes, or comments.
- Heather reported that Attachment 1 of the CMS report could be found on pages 25-60. Attachment 1 is the year end summary report on prospective DUR screening using the on-line POS system.
- Each of the 8 ProDUR alerts that require an override has a 3 page section that includes a table and a bar graph to illustrate the top 20 therapeutic categories by HIC3 class that made each alert hit. The alerts that require an override also have an additional page displaying a bar graph of the % overrides versus the % cancelled and no response. The 4 ProDUR alerts that do not require an override have a 2 page section that includes a table and a bar graph to illustrate the top 20 therapeutic categories by HIC3 class that made each alert hit.
- Ken requested that for the next CMS report (FFY 2012) the pharmacy responses alerts graphs in Attachment 1 be changed to show 90-100% instead of 0-100% on the X-axis.
- The Board had no further questions, changes, or comments regarding Attachment 1.
- Heather reported that Attachment 2 of the CMS report could be found on pages 61-62 and is a report on the monitoring of pharmacy compliance with all prospective DUR requirements performed by the State Medicaid agency and the State Board of Pharmacy.
- Heather stated Attachment 3 could be found on pages 63-77 and is a yearend summary report on retrospective screening and interventions.
- Heather stated that attachment 3a is the summary of the Therapeutic Class Exceptions (TCEs) submitted by HID and summarizes the total number of patients who hit on a TCE within each AHFS drug class during FFY 2011. Attachment 3b is the summary of the interventions performed during FFY 2011 by HID summarized by AHFS class
- Heather stated that the totals for each of the graphs were not computed and she would add those in prior to submitting the reports. The total number of TCEs during FFY 2011 was 3,767,407 and the total number of interventions performed during FFY 2011 was 19,186.
- Charlie requested to know why AHFS class 280804 (NSAIDs) was the only class that made PG (pregnancy category) TCEs hit during FFY 2011.
- Heather stated she would look into the request and follow-up.
- Heather stated the Attachment 3c is the summary of the patient profiling performed for DUR and Lock-In during FFY 2011.
- Heather stated two changes needed to be made to Attachment 3c:
 - o Change "FFY 2009" to "FFY 2011" in the last paragraph on page 73.
 - o Change the lock-in table on page 77 to read "FFY 2011 (October 1, 2010 September 30 2011)"
- Heather reported that Attachment 4 of the CMS report could be found on pages 81-113.
- It was stated that attachment 4 includes the FFY 2011 DUR Board meeting minutes, criteria selections, and quarterly provider newsletters.





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- Heather stated that the first 2 pages of Attachment 4 were in justified format and she would change the formatting prior to submission of the final report.
- The Board reviewed Attachment 4 and had no additional questions, changes, or comments.
- Heather reported that Attachment 5 of the CMS report could be found on page 114 and describes and policies in place to encourage the use of therapeutically equivalent generic drugs.
- Heather stated Table 3 of the CMS report and can be found on page 115. The Generic Dispensing Rate (GDR) for FFY 2011 was 66.05%.
- Heather reported that attachment 6 of the CMS report could be found on pages 116-132 and is the program evaluations/cost savings estimates prepared by HID, and HP.
- RetroDUR and Lock-In cost savings during FFY 2011 reported by HID was \$2,405,071.
- ProDUR cost savings during FFY 2011 was estimated to be a total of \$16,442,637 on 1,872,273 prescriptions.
- Rich requested to know why the return on investment decreased for the RetroDUR Program during the past 3 years.
- Heather stated she would look into the request.
- Heather stated Attachment 7 of the CMS report can be found on pages 133-134. Attachment 7 describes the Prescription Drug Monitoring Program (PDMP) in CT. The cost savings generated from the PMP during calendar year 2011 is estimated at \$805,000.
- Heather stated Attachment 8 of the CMS report can be found on page 135. Attachment 8 describes innovative practices developed during FFY 2011. The narrative focuses on the newly introduced monthly pediatric reviews and the doubling of the lock-in reviews as well as the polypharmacy specialty mailing performed on the adult population during June and July 2011.
- Heather stated Attachment 9 of the CMS report can be found on pages 136-157. Attachment 9 describes E-Prescribing in CT.
- Mark stated that the information regarding formulary downloads, eligibility requests, and medication history requests would be updated to reflect FFY 2011 data prior to the submission of the CMS report.
- The Board approved the CMS report contingent upon Heather Kissinger making the changes that were requested.

D. Follow-Up from Previous Meeting

- The Board reviewed section 3 titled "Follow-up from the March 2012 DUR Board Meeting."
- Follow-up 1, a request was made to resend the members the top 50 drugs by cost list for the past 3 quarters to try and determine if the increase in the average cost per prescription was due to an increase in utilization of any of the top 50 drugs. It was also requested to include this information in the June 2012 DUR Board meeting packets.
- Heather Kissinger stated that she e-mailed the top 50 drugs list to the members on March 9, 2012 and did include this information as Attachment A.





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- Rich stated that Lidoderm utilization is high and costing the State a lot of money.
- Heather stated she would run a monthly intervention of Lidoderm utilization.
- Follow-up 2, a request was made to know the overlap timeframe for criteria 535 to hit (Alert message: Therapeutic duplication of NSAID agents and/or COX2 inhibitors may be occurring.)
- Heather stated that the total days supply for all GCNs found must meet or exceed 30 days and the two drugs must occur within 25 days of each other.
- Follow-up 3, a request was made to know how many patients have signed consent for the e-prescribing program.
- Mark stated that based on the number of medication history transactions, about 17-20% of the Medicaid population have consented to the e-prescribing program. Mark added that some physician's offices are incorporating the consent for access to the e-prescribing program into the HIPPA consent.
- Ken stated he did not agree with the idea of combining HIPPA consent with e-prescribing consent because the patients may not fully understand what they are consenting to when signing the two forms concurrently.
- Follow-up 4, a request was made to know the drugs that make criteria 5959 hit (Alert message: Antipsychotics or major tranquilizers may lower the seizure threshold. Exercise caution when prescribing antipsychotics in patients with a history seizure disorders.)
- Heather stated the following drugs make criteria 5959 hit:

Util A antipsychotics - All H2GA] [CHLORPROMAZINE H2GD] [FLUPHENAZINE H2GE] [PERPHENAZINE H2GF | [PROCHLORPERAZINE H2GG] [TRIFLUOPERAZINE H2GH | [THIORIDAZINE H2LA] [CHLORPROTHIXENE H2LT] [THIOTHIXENE H7OE] [HALOPERIDOL H7RB] [PIMOZIDE H7TA] [RISPERIDONE H7TB | [CLOZAPINE H7TD] [OLANZAPINE [H7TF] [QUETIAPINE H7TG] [ZIPRASIDONE H7TH | [PALIPERIDONE H7TI] [ASENAPINE H7TK] [ILOPERIDONE H7TL] [LURASIDONE H7UA] [LOXAPINE H7XA] [ARIPIPRAZOLE Util B Seizure Disorders (with Drugs) [H2FZ] [CLOBAZAM H4BA] [PHENYTOIN H4BB] [ETHOTOIN

H4BD] [VALPROIC ACID





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H4BE] [DIVALPROEX SODIUM H4BF] [VIGABATRIN H4BG] [LAMOTRIGINE H4BH] [FELBAMATE H4BI] [GABAPENTIN H4BJ] [PRIMIDONE H4BR] [ETHOSUXIMIDE H4BV] [CARBAMAZEPINE H4BZ] [OXCARBAZEPINE H4BZ] [OXCARBAZEPINE H4CA] [TIAGABINE H4CB] [LEVETIRACETAM H4CC] [ZONISAMIDE H4CE] [RUFINAMIDE

H4CG] [LACOSAMIDE

E. Criteria Trend Summary

• Heather 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.

For the Adult reviews:

- Criteria 1408 (Alert Message: Coadministration of bupropion and drugs metabolized by P450 isoenzyme 2D6 should be approached with caution. Bupropion may inhibit the metabolism of 2D6 substrate drugs such as nortriptyline, imipramine, desipramine, paroxetine, fluoxetine, sertraline, haloperidol, risperidone, thioridazine, metoprolol, propafenone, and flecainide. Consider using lower doses of these interacting medications if giving bupropion concomitantly.) had 1142 hits in September 2011. 654 patients had letters mailed to their prescribers. Criteria 1408 increased to 1228 hits in April 2012, and of those patients, 269 of them were from the original list of patients who were intervened on.
- Criteria 3089 (Alert Message: It appears that the patient may be receiving long-term therapy of short-acting opioid pain relievers in the absence of any long-acting analgesics. When treating chronic severe pain, it is typically recommended that a continuous baseline of pain coverage be established by using a long-acting opioid. This is supplemented with the addition of an immediate-release product for breakthrough pain control. If the long-acting opioid is properly adjusted and dosed on a scheduled basis, breakthrough medication should only be necessary 1 or 2 times daily, based on the patient's activity.) had 863 hits in October 2011. 479 patients had letters mailed to their prescribers. Criteria 3089 increased to 801 hits in May 2012, and of those patients, 77 of them were from the original list of patients who were intervened on.
- Criteria 463 (Alert Message: Therapeutic duplication of antiulcer agents may be occurring.) had 889 hits in November 2011. 492 patients had letters mailed to their prescribers. Criteria 463 increased to 1100 hits in June 2012, and of those patients, 68 of them were from the original list of patients who were intervened on.





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For the Pediatric Reviews:

- Criteria 5957 (Alert Message: The Connecticut DCF Psychotropic Medication Monitoring Guidelines recommend that all children and adolescents on an atypical antipsychotic should have a fasting lipid profile, fasting glucose, and LFTs at 3 months and then every 6 months.) had 2078 hits in September 2011. 530 patients had letters mailed to their prescribers. Criteria 5957 increased to 2534 hits in April 2012, and of those patients, 153 of them were from the original list of patients who were intervened on.
- Problem Code 186, Inappropriate Pediatric Therapy had 2206 hits in October 2011. 480 patients had letters
 mailed to their prescribers. Problem code 186 decreased to 1873 hits in May 2012, and of those, 38 of them were
 from the original list of patients who were intervened on.
- Problem Code 186, Inappropriate Pediatric Therapy had 1593 hits in November 2011. 374 patients had letters mailed to their prescribers. Problem code 186 increased to 2074 hits in June 2012, and of those, 47 of them were from the original list of patients who were intervened on.

F. Program Summary Review

- The Board reviewed the program summary for 1st quarter 2012 in section 6.
- Heather stated that recently there was a request to show 4 quarters worth of data, rather than the standard 2 quarter comparison. Also added was a full 12 month assessment at the bottom of the 1st page.
- Heather stated that during 1st quarter 2012 prescription claims cost was approximately \$187 million, the number of prescriptions in the 1st QTR was approximately 2 million, the number of unique recipients receiving a prescription was approximately 339,000 and the average paid per prescription was \$85.31

G. Intervention Activity Report

- The Board reviewed the Intervention Activity report for 1st quarter 2012 in section 7.
- 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 January 2012, 2,842 profiles were reviewed and 2,036 letters were sent. The main interventions reviewed for the adult population were:

- The recommended dose of citalopram in elderly patients is 20 mg once daily, with titration to 40 mg per day in nonresponsive patients only. Citalopram should not be dosed above 40 mg per day due to the risk of QT prolongation which can lead to torsades de pointes, a potentially life-threatening arrhythmia. Citalopram is contraindicated in patients with congenital long QT syndrome. (3 Letters)
- Citalopram causes dose-dependent QT prolongation and should not be dosed above 40 mg per day. QT prolongation can lead to torsades de pointes, a potentially life-threatening arrhythmia. Citalopram is contraindicated in patients with congenital long QT syndrome. (167 Letters)





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- The recommended dose of citalopram in patients with reduced hepatic function is 20 mg per day, with titration to 40 mg per day in nonresponsive patients only. Citalopram should not be dosed above 40 mg per day in any patient due to the risk QT prolongation which can lead to torsades de pointes, a potentially life-threatening arrhythmia. Reduced hepatic function decreases the clearance of citalopram resulting in increased plasma levels and half-life. (106 Letters)
- The brand name product Celexa (citalopram) has generic equivalents available. (2 Letters)
- The simvastatin-containing agent may be over-utilized. The recommended dosing range for simvastatin is 5 to 40 mg per day. Exceeding the recommended range may increase the risk of adverse effects, including the occurrence of myopathy and/or rhabdomyolysis. The use of an 80 mg dose of simvastatin should be restricted to patients who have been taking simvastatin chronically (e.g., 12 months or more) without evidence of muscle toxicity. (210 Letters)
- The dose of the simvastatin-containing agent (Zocor, Vytorin or Juvisync) should not exceed 20 mg per day when co-administered with amiodarone due to the risk of simvastatin-related myopathy and/or rhabdomyolysis. Consider using an alternative statin (i.e., pravastatin or rosuvastatin) with less potential for interaction. (10 Letters)
- The dose of the simvastatin-containing agent (Zocor, Vytorin or Juvisync) should not exceed 10 mg per day when co-administered with verapamil due to the risk of myopathy and/or rhabdomyolysis. Consider using an alternative statin (i.e., pravastatin or rosuvastatin) with less potential for interaction. (44 Letters)
- The dose of a simvastatin-containing product should not exceed 20 mg per day in patients receiving Ranexa (ranolazine) due to the increased risk of simvastatin-induced myopathy and rhabdomyolysis. Concurrent use of ranolazine and simvastatin may result in increased exposure to simvastatin due to the ranolazine-mediated inhibition of simvastatin P-gp transport and CYP3A4 metabolism. (8 Letters)
- The concurrent use of Simcor (simvastatin/niacin ER) and gemfibrozil, cyclosporine, danazol, amiodarone, verapamil, diltiazem or a potent CYP3A4 inhibitor is contraindicated due to the risk of simvastatin-related myopathy and/or rhabdomyolysis. (2 Letters)
- The concurrent use of the simvastatin-containing agent, Zocor, Vytorin or Juvisync, with gemfibrozil, cyclosporine, danazol or a potent CYP3A4 inhibitor is contraindicated due to the risk of simvastatin-related myopathy and rhabdomyolysis. (44 Letters)
- Concurrent use of the simvastatin-containing agent and diltiazem may increase the risk of myopathy/rhabdomyolysis due to the inhibition, by diltiazem, of CYP3A4-mediated simvastatin metabolism. Consider using an alternative statin (i.e., pravastatin or rosuvastatin) which is not metabolized by CYP3A4. If coadministration with these agents is unavoidable the dose of the simvastatin-containing agent should not exceed 10 mg per day. (69 Letters)
- Lock-in criteria (358 letters)

The main intervention reviewed for the pediatric population was:





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• Pediatric Psychotropic Med Max Dosing (193 Letters)

In February 2012, 2,868 profiles were reviewed and 2,167 letters were sent.

The main interventions reviewed for the adult population were:

- Underutilization of Lipid Lowering Agents (1010 Letters)
- Lock-in criteria (420 letters)

The main intervention reviewed for the pediatric population was:

• Therapeutic Duplication of Antidepressants (67 Letters)

In March 2012, 2,806 profiles were reviewed and 2,515 letters were sent.

The main interventions reviewed for the adult population were:

- Additive Anticholinergic Effects (544 Letters)
- Lock-in criteria (470 letters)
- Dennis requested to know if the anticholinergic burden is calculated for each patient when looking at the individual criteria for additive anticholinergic effects.
- Heather stated the criteria are built using GCNs for the anticholinergic drugs and the anticholinergic burden of each drug is not taken into consideration for individual criteria.
- Heather stated she would follow-up with a list of the individual criteria that make up the problem code Additive Anticholinergic Effects.
- Dennis stated that there is a web site available to input the names of drugs a patient is taking and have their anticholinergic burden calculated.
- Bhupesh found the website and sent the link to Heather.
- Heather stated she would list the website in the September follow-up section for the next DUR meeting.

The main intervention reviewed for the pediatric population was:

• The use of antibiotics during the first year of life has been associated with an increased risk of developing childhood asthma. The risk increases with the use of multiple courses of antibiotics and the use of broad-spectrum antibiotics. The risk may be reduced by the judicious and appropriate prescribing of antibiotics, particularly avoiding the use of broad-spectrum cephalosporins. (749 Letters)

H. Newsletter

- The Board approved the June 2012 DUR Newsletter with the following modifications:
 - Page1, third column, third paragraph, remove "More than 111 million prescriptions are written for NSAIDs in the USA annually, and they account for approximately 60% of the USA over-the-counter (OTC) analgesic market."
 - o Page 1, third column, remove fourth paragraph.





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o With the removal of some of the wording and paragraphs, there is now room to make the reference section a larger font, increase font size to 6 or 7.

NEW BUSINESS

- Heather stated that the September 2012 DUR Board meeting is scheduled for September 13th at 6:30 pm.
- Joe Paradis from HID will be facilitating the September meeting due to Heather being on maternity leave.
- The meeting was adjourned at 8:35 pm.

