

**DRUG UTILIZATION REVIEW (DUR) ANNUAL REPORT
FEDERAL FISCAL YEAR 2001**

I. STATE CODE

IN

II. MEDICAID AGENCY STAFF PERSON RESPONSIBLE FOR DUR ANNUAL REPORT PREPARATION

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III. PROSPECTIVE DUR

**1. During Federal Fiscal Year 2001 prospective DUR was conducted:
(check those applicable)**

- a) By individual pharmacies on-site.
- b) On-line through approved electronic drug claims management system.
- c) Combination of (a) and (b).

2. (a) States conducting prospective DUR on-site have included as ATTACHMENT 1 (check one):

Results of a random sample of pharmacies within the State pertaining to their compliance with OBRA 1990 prospective DUR requirements

Results of State Board of Pharmacy monitoring of pharmacy compliance with OBRA 1990 prospective DUR requirements.

Results of monitoring of prospective DUR conducted by State Medicaid agency or other entities.

(b) States conducting prospective DUR on-line have included as ATTACHMENT 1 a report on State efforts to monitor pharmacy compliance with the oral requirements.

Yes No

3. States conducting prospective DUR on-site plans with regards to Establishment of an ECM system. State:

___ Has no plans to implement an ECM system with prospective DUR capability.

___ Plans to have an operational ECM system with prospective DUR in FFY 2001 or later.

STATES PERFORMING PROSPECTIVE DUR ON-SITE SKIP QUESTIONS 4-8

4. States conducting prospective DUR through an operational on-line POS system provide the following information:

- a) Operational date 9/95 (MM/YY) on which on-line POS system began accepting drug claims for adjudication from providers.
- b) Operational date 3/96 (MM/YY) on which on-line POS System began conducting prospective DUR screening.
- c) Percentage of Medicaid prescriptions processed by ECM System (where applicable) in FFY 2001. 82.8 %
- d) Identify ECM vendor.

EDS (Electronic Data Systems)

1) Was system developed in house? Yes X No ___

2) Is vendor Medicaid Fiscal agent? Yes X No ___

- e) Identify prospective DUR (source of criteria).

EDS (Electronic Data Systems) and First Data Bank

5. With regards to prospective DUR criteria from the vendor identified In 4 (d) above, the DUR Board: (Check one)

(a) ___ Approved in FFY 2001 all criteria submitted by the vendor.

(b) X Chose to approve selected criteria submitted by the vendor.

6. States checking 5 (b) have provided DUR criteria data requested on Enclosed Table 1. Yes X No ___

7. State prospective DUR screening includes screens run before Obtaining DUR Board approval of criteria. Yes X No ___
8. States conducting prospective DUR using an ECM system have Included ATTACHMENT 2. Yes X No ___

IV. RETROSPECTIVE DUR

1. Identify your retrospective DUR vendor during FFY 2001.

EDS (Electronic Data Systems) and Eagle Managed Care

- a) Is the retrospective DUR vendor also the Medicaid fiscal Agent? Yes X No ___
- b) Will your current retrospective DUR vendor contract subject To re-bid in FFY 2001? Yes ___ No X

If your vendor changed during FFY 2001, identify you new vendor.

EDS (Electronic Data Systems) and Eagle Managed Care

- c) Is the retrospective DUR vendor also the Medicaid fiscal Agent? Yes X No ___
- d) Is this retrospective DUR vendor also the developer/supplier of Your retrospective DUR criteria? Yes X No ___

2. If your answer to question 1(c) or 1(d) above is no, identify the Developer/supplier of your retrospective DUR criteria.

(2a) Not Applicable

(2b) Not Applicable

3. Did DUR Board approve all retrospective DUR criteria supplied by The criteria source identified in questions 1(c) and 2 above? Yes X No ___
4. States performing retrospective DUR have provided DUR Board Approved criteria data requested on enclosed hardcopy Table 2. Yes X No ___
5. States conducting retrospective DUR have included ATTACHMENT 3. Yes X No ___

V. DUR BOARD ACTIVITY

1. States have included a brief description of DUR Board activities During FFY 2001 as ATTACHMENT 4. Yes X No ___
2. States have included a brief description of policies used to encourage The use of therapeutically equivalent generic drugs as ATTACHMENT 5. Yes X No ___

VI. PROGRAM EVALUATION/COST SAVINGS

1. Did your State conduct a DUR program evaluation/cost savings Estimate in FFY 2001? Yes X No ___
2. Did you use Guidelines for Estimating the Impact of Medicaid DUR As the basis for developing your program evaluation/cost savings estimate? Yes ___ No X
3. Who conducted your program evaluation/cost savings estimate?
EDS (Electronic Data Systems) and Eagle Managed Care
4. States have provided as ATTACHMENT 6 the program evaluations/ Cost savings estimates. Yes X No ___

ATTACHMENT 1

REPORT ON MONITORING OF COMPLIANCE WITH OBRA '90 PROSPECTIVE DUR REQUIREMENTS

The Indiana Board of Pharmacy, in coordination with Indiana Medicaid, promulgated patient counseling regulations (copy attached) that became effective January 1, 1993. These regulations ensure that prospective drug utilization review activities are offered by pharmacists. Indiana Medicaid does not require the use of the fiscal contractor's electronic claims management POS/pro-DUR system by Indiana Medicaid pharmacy providers, but those that do opt to utilize the system have the benefit of pro-DUR information at the point-of sale.

Since the Indiana Board of Pharmacy is the controlling authority over the patient counseling regulations, they monitor for compliance with same. Each pharmacy is inspected by Board of Pharmacy inspectors on an annual basis, and conformance with patient counseling requirements by the pharmacy is one of twenty-four criteria assessed by the inspector (copy of inspection form attached; reference element number 23). In addition, the Indiana Board of Pharmacy has requested that the Consumer Protection Division of the Indiana Office of the Attorney General forward directly to the Board of Pharmacy any and all consumer complaints regarding patient counseling activities. According to administrative personnel of the Indiana Board of Pharmacy, there were no cases filed by the Attorney General's office and heard before the Board concerning failure to offer to counsel, for the time period covered by this report.

Table 1

**Prospective DUR Criteria
Approved by Indiana DUR Board**

Drug Pregnancy

Severity Level X
Severity Level D
Severity Level 1

High Dose

All Drug Products

Drug-Age/Pediatric

Severity Level 1

Drug/Drug Interactions

Severity Level 1

Overutilization (Early Refill)

All Drug Products

Underutilization (Late Refill)

Xanthines
ACE-Inhibitors
Oral Hypoglycemics
Anti-Convulsants

*Please see Table 1.1 for approved Drug/Disease and Therapeutic Duplication criteria.

Table 1.1

The DUR board chose to go with NDCs that infer a disease instead of using medical claims and ICD-9 diagnosis codes. Below is the criterion that was approved.

Drug-Disease Criteria

<u>INFERRED DISEASE</u>	<u>INFERRING DRUG(S)</u>	<u>DISEASE DURATION</u>	<u>CONTRAIND DRUG(S)</u>
Epilepsy	Mephenytoin	Lifetime	Bupropion Doxapram Maprotiline Metoclopramide Piperazine
Alcoholism	Disulfiram	Lifetime	Benzamphetamine Diethylpropion Fenfluramine MAO-Is Mazindol Phenmetrazine Phendimetrazine Phentermine Methotrexate Bexarotene
Alzheimer's	Tacrine	Lifetime	Aluminum
Arrhythmias	Procainamide	Lifetime	Dopamine Probucof Bepridil. Itraconazole Ibutilide Dofetilide
Calcium Renal Calculi Prophylaxis	Cellulose sodium Phosphate	Lifetime	Calcium phosphate Calcium carbonate
Chronic Angina Pectoris	Bepridil	Lifetime	Serotonin 5-HT1 Agonists Yohimibine Aldesleukin
Congestive Heart Failure	Amrinone Milrinone	Lifetime	Cyclobenzaprine MAO-Is Pargyline Procarbazine Sodium phos laxatives Propranolol Iothalamate Albumin Hetastarch

Drug-Disease Criteria

(continued)

<u>INFERRED DISEASE</u>	<u>INFERRING DRUG(S)</u>	<u>DISEASE DURATION</u>	<u>CONTRAIND DRUG(S)</u>
Congestive Heart Failure (cont)		Lifetime	Corticotropin Gold salt compounds Doxorubicin Metformin Itraconazole Daunorubicin Iodixanol Sibutramine Cilostazol
Constipation	Laxatives	Finite	Aluminum Calcium Alosetron
Cushing's Syndrome	Trilostane	Lifetime	Corticotropin
Diabetes Mellitus	Antidiabetic Drugs Acetohexamide Glipizide Glyburide Tolbutamide Tolazamide, etc. Insulin	Lifetime	Lactulose
Diarrhea	Attapulgate Diphenoxylate/Atropine Kaolin/Pectin/Belladonna/ Opium/Paregoric Loperamide	Finite	Magnesium Magaldrate Irinotecan Poliovirus vaccine
Hyperkalemia	Sodium Polystyrene Sulfonate	Lifetime	Amiloride Potassium/Sodium citrate Spironolactone Methazolamide Triamterene Acetazolamide Mesoridazine Dichlorphenamide
Hypertension	Alseroxylon Benazapril-Amlopdipine B-Blockers Plus: Bendroflumethiazide Chlorthalidone HCTZ Losarten Moexipril	Lifetime	Benzamphetamine Diethylpropion Fenfluramine Mazindol Methylethylergonovine Phentermine Sodium phos laxatives Dozapram Phenmetrazine Phendimetrazine Dextrothyroxine

Drug-Disease Criteria
(continued)

<u>INFERRED DISEASE</u>	<u>INFERRING DRUG(S)</u>	<u>DISEASE DURATION</u>	<u>CONTRAIND DRUG(S)</u>
Hypertension		Lifetime	Anistlepase Corticotropin Gold salt compounds
Hyperthyroidism	Methimazole Propylthiouracil	Lifetime	Benzamphetamine Cyclobenzaprine Diethylpropion Phendimetrazine Phenmetrazine Phenteramine Ritodrine Midodrine Arbutamine
Mental Depression	Amoxapine Bupropion MAO-Is Nortriptyline Venlafaxine	Lifetime	Flurazepam Diazepam Clomiphene Meclopramide Interferon-Alpha 2B
Myasthenia gravis	Ambenonium	Lifetime	Orphenadrine Streptomycin Gentamicin Tobramycin Amikacin Netilmicin Doxacurium
Parkinsonism	Carbidopa/Levodopa Levodopa Pergolide Selegiline	Lifetime	Haloperidol Streptomycin Gentamicin Tobramycin Amikacin Netilmicin Gramcidin
Peripheral Vascular Disease	Pentoxiphylline	Lifetime	Methylergonovine Dihydroergotamine Serotonin 5-HT1 Agonists
Pheochromocytoma	Metyrosine	Lifetime	MAO-Is Metoclopramide Pargyline Droperidol Dopamine Metoclopramide Midodrine

Drug-Disease Criteria
(continued)

<u>INFERRED DISEASE</u>	<u>INFERRING DRUG(S)</u>	<u>DISEASE DURATION</u>	<u>CONTRAIND DRUG(S)</u>
Prostatic Cancer	Buserelin Estramustine Flutamide	Lifetime	Fluoxymesterone Methyltestosterone Nandrolone Oxandrolone Oxymetholone Prasterone Testosterone HCG Hormone
Psychotic disorders	Acetophenazine Molindone Promazine Thiothixene Trifluoperazine	Lifetime	Mazindol Flurazepam
Tuberculosis	Capreomycin Pyrazinamide	Lifetime	Infliximab
Urinary tract infection	Cinoxacin Methenamine Naladixic acid Nitrofurantoin	Finite	BCG live Potassium/Sodium citrate
Ventricular arrhythmias	Encainide Esmolol Flecainide Mexiletine Morcizine Sotalol Tocainide	Lifetime	Bepriidil Dopamine Probucol Intraconazole Ibutilide Dofetilide
Wilson's Disease	Trientine	Lifetime	Copper supplements

Therapeutic Duplication Alert Criteria

Class Code	<u>Description</u>
	Cardiovascular Agents
A1C	Inotropic Drugs
A2A	Antiarrhythmics
A4A	Hypotensives, Vasodilators
A4B	Hypotensives, Sympatholytic
A4C	Hypotensives, Ganglionic Blockers
A4E	Hypotensives, Veratrum Alkaloids
A4Y	Hypotensives, Miscellaneous
A7A	Vasoconstrictors, Arteriolar
A7B	Vasodilators, Coronary
A7C	Vasodilators, Peripheral
A7D	Vasodilators, Peripheral (Continued)
Z4D	Prostacyclines
	ACE Inhibitors and Antagonists
A4D	Hypotensives, ACE Inhibitors
A4F	Hypotensives, Angiotensin Receptor Antagonists
A4K	ACE Inhibitor/Calcium Channel Blocker Combination
	Calcium Channel Blocking Agents
A9A	Calcium Channel Blockers
	H2-Antagonists
D4E	Anti-Ulcer Preparations
D4F	Anti-Ulcer-H.Pylori Agents
Z2D	Histamine H2-Receptor Inhibitors
	Phenothiazines
H2G	Anti-Psychotics, Phenothiazines
H2I	Anti-Psychotics, Phenothiazines (Continued)
	Antidepressants
H2J	Antidepressants
H2K	Antidepressant Combinations
H2N	Antidepressants (Continued)
H2S	Serotonin Specific Reuptake Inhibitors (SSRIs)
H2U	Tricyclic Antidepressants & Rel. Non-Sel. RU-Inhib
H2W	Tricyclic Antidepressants/Phenothiazine Comb
H2X	Tricyclic Antidepressants/Benzodiazepine Comb
H2Y	Tricyclic Antidepressants/Non-Phenothiazine Comb
H7A	Tricyclic ADP/Phenothiazine/Benzodiazepine
H7B	Alpha-2 Receptor Antagonist Antidepressant
H7C	Serotonin-Norepinephrine RU-Inhibitor
H7D	Norepinephrine & Dopamine Reuptake Inhibitor
H7E	Serotonin 2-Antagonist/Reuptake Inhibitor
H7F	Selective Norepinephrine Reuptake Inhibitor
H7G	Serotonin and Dopamine Reuptake Inhibitor
H7H	Serotonin Specific Reuptake Inhibitor/Ergot Comb
H7I	Antidepressant/Barb/Belladonna Alkaloid Comb

H7J MAOIs-Non-Selective and Irreversible
H7K MAOIs-A Selective and Reversible (RIMA)
H7L MAOIs N-S & Irreversible/Phenothiazine Comb
H7M Antidepressant/Carbamate Anxiolytic Combination

Narcotic Analgesics

H3A Analgesics, Narcotics
H3B Analgesics, Narcotics (Continued)
H3H Analgesics Narcotic, Anesthetic Adjunct Agents

Non-Narcotic Analgesics

H3C Analgesics, Non-Narcotics
H3E Analgesics/Antipyretics, Non-Salicylates
H3F Antimigraine Preparations
H3G Analgesics, Miscellaneous

Alpha and Beta Blockers

J7A Alpha/Beta-Adrenergic Blocking Agents
J7B Alpha-Adrenergic Blocking Agents
J7C Beta-Adrenergic Blocking Agents
J7D Beta-Adrenergic blocking Agents (Continued)
J7E Alpha-Adrenergic Blocking Agent/Thiazide Comb.

Anti-Lipidemics

M4E Lipotropics
M4F Lipotropics (Continued)

Diuretics

R1B Osmotic Diuretics
R1C Inorganic Salt Diuretics
R1D Mercurial Diuretics
R1E Carbonic Anhydrase Inhibitors
R1F Thiazide and Related Diuretics
R1G Thiazide and Related Diuretics (Continued)
R1H Potassium Sparing Diuretics
R1J Aminouracil Diuretics
R1K Diuretics, Miscellaneous
R1L Potassium Sparing Diuretics in Combination
R1M Loop Diuretics

NSAIDs and Salicylates

S2B NSAIDs, Cyclooxygenase Inhibitor Type
S2D NSAIDs, Cyclooxygenase Inhibitor Type (Continued)
S2E NSAIDs, Cyclooxygenase Inhibitor Type (Continued)
S2H Anti-Inflammatory/Antiarthritic Agents, Misc.
S2I Anti-Inflammatory, Pyrimidine Synthesis Inhibitors
S2L NSAIDs, Cyclooxygenase 2 Inhibitor Type
S7C Skeletal Muscle Relaxant & Salicylate Combination
H3D Analgesics/Antipyretics, Salicylates

Antimicrobial Products

W1A Penicillins
W1B Cephalosporins
W1C Tetracyclines

W1D	Macrolides
W1E	Chloramphenicol and Derivatives
W1F	Aminoglycosides
W1G	Antitubercular Antibiotics
W1H	Aminocyclitols
W1I	Penicillins (Continued)
W1J	Vancomycin and Derivatives
W1K	Lincosamides
W1L	Antibiotics, Miscellaneous, Other
W1M	Streptogramins
W1N	Polymixin and Derivatives
W1O	Oxazolidinones
W1P	Betalactams
W1Q	Quinolones
W1R	Beta-Lactamase Inhibitors
W1S	Carbapenams (Thienamycins)
W1T	Cephalosporins (Continued)
W1U	Quinolones (Continued)
W1V	Steroidal Antibiotics
W1W	Cephalosporins - 1st Generation
W1X	Cephalosporins - 2nd Generation
W1Y	Cephalosporins - 3rd Generation
W2A	Absorbable Sulfonamides
W2B	Nonabsorbable Sulfonamides
W2C	Absorbable Sulfonamides (Continued)
W2E	Nitrofurans Derivatives
W2Y	Anti-Infectives, Misc. (Antibacterials)

ATTACHMENT 2

The attached reports are year-end reports for prospective DUR. The prospective DUR summaries are categorized under eight separate screening processes:

Drug/Drug Interaction Screening (DD),
Over Utilization Screening (ER),
High Dose Screening (HD),
Under Utilization Screening (LR),
Drug/Disease Interaction Screening (MC),
Drug/Pediatric Screening (PA),
Drug/Pregnancy Screening (PG), and
Therapeutic Duplication Screening (TD).

Below is a brief narrative of each of the reports and the information they contain.

Report DUR-0011-A-(High Level Summary by DUR Screen) This report shows each of the pro-DUR screenings that are performed for Indiana Medicaid. It shows the number of alerts that were set for each screen, the number of claims that were overridden by the pharmacist, the number of claims that were canceled due to the pro-DUR alert and the number of non-responses. Please note that a pharmacist has three days to respond to a pro-DUR alert before the system will remove the claim. After the three days, the prescription would need to be resubmitted and the pro-DUR alert overridden if the pharmacist still wanted to dispense the medication.

Report DUR-0012-A-(Summary Data by Drug Involved in DUR Screening) This report can show up to the top twenty-five therapeutic categories and drugs that set for each particular alert. The Indiana DUR board did not approve twenty-five therapeutic categories for each alert, so those alerts that list less than twenty-five show all the therapeutic categories approved by the board. The column titled “# Claims Screened” is the total number of claims that came in through the POS system for that particular therapeutic category and drug, but not all of them set pro-DUR alerts.

Report DUR-0013-A-(Prospective DUR Intervention/Outcome Summary) This report shows the percentage of pro-DUR alerts that were either overridden or canceled based on each of the valid intervention codes for Indiana Medicaid. The only valid intervention codes for Indiana Medicaid are M0 (Prescriber consulted), P0 (Recipient consulted) or R0 (other source consulted).

Report DUR-0014-A-(Summary Report of Intervention and Outcome Overrides by DUR Screen) This report shows how many of each of the valid outcome codes were used with specific pro-DUR alerts and valid intervention codes.

Report DUR-0015-A-(Summary Data by Drug Combination Involved in DUR Screening) This report shows the drug combinations involved in the pro-DUR screening. It is listed by each alert, showing the therapeutic category approved by the DUR board for each alert and the two drugs involved in actually causing the pro-DUR alert to set. It is then broken out to show how many alerts were generated and whether

they were overridden by the pharmacist, canceled or not responded to. The “# Claims Screened” column is the total number of claims that came through the POS system for that therapeutic category and drug, but not all of them set pro-DUR alerts.

Report: DUR-0011-A
Process: DURJA205
Location: DUR0011A

Indiana AIM
High Level Summary by DUR Screen
Period: 10/6/2000 - 10/05/2001

Run Date: 11/09/2001
Run Time: 20:42:26
Page: 1

DUR Screen	# Alerts	# Overrides	# Cancellations	# Non-Responses	% of All DUR Alerts
DD	97,699	82033	15	15,650	11.9%
ER	121,241	95113	129	25,993	14.8%
HD	69,083	59522	10	9,540	8.4%
LR	111,177	98769	13	12,392	13.5%
MC	27,842	21886	6	5,950	3.4%
PA	2,268	2022	0	246	0.3%
PG	672	632	0	40	0.1%
TD	391,427	334955	194	56,240	47.7%

* * END OF REPORT * *

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
 Run Time: 20:43:18
 Page: 1

DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
DD							
	ABSORBABLE SULFONAMIDES	1,406	1,158	248	53,276	2.6%	0.5%
	SULFAMETHOXAZOLE/TRIMETHOPRIM	1,396	1,151	245	51,143	2.7%	0.5%
	ALDOSTERONE ANTAGONISTS (OBSOLETE)	4,113	3,487	626	19,642	20.9%	3.2%
	SPIRONOLACTONE	3,772	3,185	587	17,108	22.0%	3.4%
	ANALGESIC/ANTIPYRETICS, SALICYLATES	1,533	1,070	463	85,309	1.8%	0.5%
	ASPIRIN	1,593	1,092	501	81,111	2.0%	0.6%
	ANTI-PSYCHOTICS,PHENOTHIAZINES	3,279	2,634	645	32,649	10.0%	2.0%
	THIORIDAZINE HCL	2,715	2,208	507	11,259	24.1%	4.5%
	ANTIARRHYTHMICS	1,792	1,619	173	7,680	23.3%	2.3%
	AMIODARONE HCL	1,200	1,128	72	4,209	28.5%	1.7%
	ANTIDEPRESSANTS O.U.	3,079	2,883	195	111,941	2.8%	0.2%
	AMITRIPTYLINE HCL	1,523	1,435	87	11,420	13.3%	0.8%
	BETA-ADRENERGIC AGENTS	9,016	8,349	667	138,683	6.5%	0.5%
	ALBUTEROL	4,521	4,222	299	51,994	8.7%	0.6%
	ALBUTEROL SULFATE	2,551	2,302	249	65,611	3.9%	0.4%
	SALMETEROL XINAFOATE	1,694	1,587	107	17,335	9.8%	0.6%
	BETA-ADRENERGIC BLOCKING AGENTS	3,925	3,284	641	128,091	3.1%	0.5%
	PROPRANOLOL HCL	1,113	919	194	20,657	5.4%	0.9%
	DECARBOXYLASE INHIBITORS	1,477	1,220	257	11,550	12.8%	2.2%
	CARBIDOPA/LEVODOPA	1,477	1,220	570	11,550	12.8%	4.9%
	DIGITALIS GLYCOSIDES	2,150	1,824	326	47,873	4.5%	0.7%
	DIGOXIN	2,150	1,824	326	47,873	4.5%	0.7%
	HYPOTENSIVES,SYMPATHOLYTIC	3,359	2,911	448	24,419	13.8%	1.8%
	CLONIDINE HCL	3,359	2,911	448	23,966	14.0%	1.9%
	ORAL ANTICOAGULANTS,COUMARIN TYPE	9,562	7,167	2,395	40,142	23.8%	6.0%
	WARFARIN SODIUM	9,549	7,154	2,395	40,134	23.8%	6.0%
	POTASSIUM REPLACEMENT	6,564	5,529	1,035	72,419	9.1%	1.4%
	POTASSIUM CHLORIDE	6,380	5,380	1,000	70,650	9.0%	1.4%
	QUINOLONONES	3,398	2,645	753	25,818	13.2%	2.9%
	CIPROFLOXACIN HCL	3,090	2,379	711	22,956	13.5%	3.1%
	SKELETAL MUSCLE RELAXANTS	2,640	2,462	178	69,336	3.8%	0.3%
	CYCLOBENZAPRINE HCL	2,634	2,456	178	31,581	8.3%	0.6%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
 Run Time: 20:43:18
 Page: 2

DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	THIAZIDE AND RELATED DIURETICS	3,912	3,259	653	217,935	1.8%	0.3%
	HCTZ/TRIAMTERENE	2,687	2,279	408	17,420	15.4%	2.3%
	THYROID HORMONES	3,854	2,722	1,132	70,628	5.5%	1.6%
	LEVOTHYROXINE SODIUM	3,632	2,553	1,079	67,885	5.4%	1.6%
	TRICYCLIC ANTIDEPRESSANTS & REL. NON-SEL RU-INHIB	3,662	3,365	297	60,932	6.0%	0.5%
	AMITRIPTYLINE HCL	1,783	1,656	127	32,506	5.5%	0.4%
ER							
	ANALGESICS,NARCOTICS	47,030	36,496	10,528	491,359	9.6%	2.1%
	HYDROCODONE BITARTRATE/APAP	18,488	14,133	4,352	166,431	11.1%	2.6%
	PROPOXYPHENE NAPSYLATE/APAP	8,846	6,570	2,275	106,888	8.3%	2.1%
	OXYCODONE HCL	6,221	5,086	1,134	31,277	19.9%	3.6%
	CODEINE PHOSPHATE/APAP	3,625	2,787	838	62,205	5.8%	1.3%
	FENTANYL	3,506	2,652	853	23,976	14.6%	3.6%
	MORPHINE SULFATE	2,061	1,713	348	10,936	18.8%	3.2%
	OXYCODONE HCL/ACETAMINOPHEN	1,828	1,526	302	17,508	10.4%	1.7%
	ANTICONVULSANTS	50,189	39,522	10,667	235,063	21.4%	4.5%
	DIVALPROEX SODIUM	16,979	13,473	3,506	80,113	21.2%	4.4%
	GABAPENTIN	10,823	8,588	2,235	55,647	19.4%	4.0%
	PHENYTOIN SODIUM EXTENDED	10,482	8,172	2,310	46,033	22.8%	5.0%
	CARBAMAZEPINE	4,122	3,279	843	19,151	21.5%	4.4%
	PHENYTOIN	2,569	1,840	729	11,169	23.0%	6.5%
	PRIMIDONE	1,139	910	229	5,398	21.1%	4.2%
	CALCIUM CHANNEL BLOCKING AGENTS	9,936	7,877	2,059	78,323	12.7%	2.6%
	DILTIAZEM HCL	3,933	3,196	737	29,643	13.3%	2.5%
	AMLODIPINE BESYLATE	2,012	1,554	458	16,411	12.3%	2.8%
	NIFEDIPINE	1,538	1,199	339	12,079	12.7%	2.8%
	VERAPAMIL HCL	1,451	1,147	304	12,010	12.1%	2.5%
	HYPOGLYCEMICS, INSULIN-RELEASE STIMULANT TYPE	10,027	7,996	2,031	61,577	16.3%	3.3%
	GLIPIZIDE	6,763	5,375	1,388	36,981	18.3%	3.8%
	GLYBURIDE	2,333	1,863	470	13,279	17.6%	3.5%
	XANTHINES	3,915	3,119	796	25,277	15.5%	3.1%
	THEOPHYLLINE ANHYDROUS	3,893	3,098	795	25,062	15.5%	3.2%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
HD							
	ANALGESICS,NARCOTICS	52,401	45,906	6,484	491,359	10.7%	1.3%
	HYDROCODONE BITARTRATE/APAP	45,099	39,397	5,692	166,431	27.1%	3.4%
	CODEINE PHOSPHATE/APAP	4,501	3,954	546	65,921	6.8%	0.8%
	OXYCODONE HCL/ACETAMINOPHEN	1,711	1,570	141	17,508	9.8%	0.8%
	CODEINE PHOS/ASA/CAFFEIN/BUTAL	604	540	64	1,764	34.2%	3.6%
	OXYCODONE HCL	379	343	36	31,277	1.2%	0.1%
	ANTI-ANXIETY DRUGS	2,007	1,791	216	252,471	0.8%	0.1%
	DIAZEPAM	1,527	1,354	173	43,060	3.5%	0.4%
	HYDROXYZINE PAMOATE	186	175	11	9,806	1.9%	0.1%
	ANTI-ULCER PREPARATIONS	2,576	2,168	408	146,870	1.8%	0.3%
	SUCRALFATE	1,666	1,356	310	3,981	41.8%	7.8%
	OMEPRAZOLE	776	699	77	70,139	1.1%	0.1%
	CALCIUM CHANNEL BLOCKING AGENTS	1,796	1,165	631	78,323	2.3%	0.8%
	DILTIAZEM HCL	704	560	144	29,643	2.4%	0.5%
	AMLODIPINE BESYLATE	515	223	292	16,411	3.1%	1.8%
	NIFEDIPINE	441	310	131	12,079	3.7%	1.1%
	HISTAMINE H2-RECEPTOR INHIBITORS	1,757	1,297	460	76,856	2.3%	0.6%
	NIZATIDINE	1,262	875	387	21,034	6.0%	1.8%
	RANITIDINE HCL	257	230	27	25,738	1.0%	0.1%
	FAMOTIDINE	191	153	38	22,433	0.9%	0.2%
	HYPOGLYCEMICS, INSULIN-RELEASE STIMULANT TYPE	856	680	176	61,577	1.4%	0.3%
	GLYBURIDE	503	358	145	13,279	3.8%	1.1%
	HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S)	930	467	463	24,587	3.8%	1.9%
	PIOGLITAZONE HCL	930	467	463	24,587	3.8%	1.9%
	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE	6,733	6,022	711	126,415	5.3%	0.6%
	IBUPROFEN	3,699	3,298	401	55,979	6.6%	0.7%
	NAPROXEN SODIUM	1,473	1,347	126	9,616	15.3%	1.3%
	NAPROXEN	631	557	74	21,674	2.9%	0.3%
LR							
	ANTICONVULSANTS	58,110	50,565	7,545	235,063	24.7%	3.2%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
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DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	DIVALPROEX SODIUM	19,450	17,140	2,310	80,113	24.3%	2.9%
	GABAPENTIN	14,445	12,959	1,486	55,647	26.0%	2.7%
	PHENYTOIN SODIUM EXTENDED	10,720	9,432	1,288	46,033	23.3%	2.8%
	CARBAMAZEPINE	4,666	4,079	587	19,151	24.4%	3.1%
	PHENYTOIN	3,098	2,210	888	11,169	27.7%	8.0%
	VALPROATE SODIUM	1,782	1,262	520	3,784	47.1%	13.7%
	PRIMIDONE	1,059	946	113	5,398	19.6%	2.1%
	HYPOGLYCEMICS, INSULIN-RELEASE STIMULANT TYPE	12,740	11,582	1,158	61,577	20.7%	1.9%
	GLIPIZIDE	7,660	6,954	706	36,981	20.7%	1.9%
	GLYBURIDE	2,735	2,491	244	13,279	20.6%	1.8%
	GLYBURIDE/METFORMIN HCL	1,196	1,082	114	5,393	22.2%	2.1%
	HYPOGLYCEMICS, INSULIN-RESPONSE ENHANCER (N-S)	4,835	4,407	428	24,587	19.7%	1.7%
	PIOGLITAZONE HCL	4,835	4,407	428	24,587	19.7%	1.7%
	HYPOTENSIVES, ACE BLOCKING TYPE	28,228	25,546	2,679	146,457	19.3%	1.8%
	LISINOPRIL	11,373	10,138	1,233	60,085	18.9%	2.1%
	QUINAPRIL HCL/MAG CARB	4,247	3,843	404	21,730	19.5%	1.9%
	BENAZEPRIL HCL	2,727	2,485	242	13,843	19.7%	1.7%
	BENAZEPRIL HCL/AMLODIPINE	2,054	1,917	136	10,121	20.3%	1.3%
	LISINOPRIL/HYDROCHLOROTHIAZIDE	1,807	1,675	132	8,993	20.1%	1.5%
	FOSINOPRIL SODIUM	1,693	1,570	123	9,483	17.9%	1.3%
	MOEXIPRIL HCL	1,173	1,078	95	6,084	19.3%	1.6%
	CAPTOPRIL	1,070	969	101	5,228	20.5%	1.9%
	XANTHINES	6,445	5,906	539	25,277	25.5%	2.1%
	THEOPHYLLINE ANHYDROUS	6,388	5,854	534	25,062	25.5%	2.1%
MC	ALDOSTERONE ANTAGONISTS (OBSOLETE)	1,602	1,308	294	19,642	8.2%	1.5%
	HCTZ/SPIRONOLACTONE	200	163	37	2,534	7.9%	1.5%
	AMMONIA INHIBITORS	2,240	1,502	738	18,255	12.3%	4.0%
	LACTULOSE	2,240	1,502	738	18,242	12.3%	4.0%
	ANTACIDS	5,653	4,085	1,568	16,919	33.4%	9.3%
	MAG HYDROX/AL HYDROX/SIMETH	4,084	2,983	1,101	9,463	43.2%	11.6%
	MAGNESIUM HYDROXIDE/AL HYDROX	1,007	727	280	2,734	36.8%	10.2%
	MAG CARB/AL HYDROX/ALGINIC AC	490	313	177	1,003	48.9%	17.6%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	ANTI-ANXIETY DRUGS	1,672	1,413	259	231,521	0.7%	0.1%
	DIAZEPAM	1,672	1,413	259	39,358	4.2%	0.7%
	ANTI-NARCOLEPSY/ANTI-HYPERKINESIS AGEN	683	594	89	41,516	1.6%	0.2%
	METHYLPHENIDATE HCL	683	594	89	41,516	1.6%	0.2%
	ANTI-PSYCHOTICS, NON-PHENOTHIAZINES	323	253	70	63,091	0.5%	0.1%
	HALOPERIDOL	228	186	42	15,982	1.4%	0.3%
	ANTIMIGRAINE PREPARATIONS	688	632	56	11,311	6.1%	0.5%
	SUMATRIPTAN SUCCINATE	626	573	53	7,391	8.5%	0.7%
	BETA-ADRENERGIC BLOCKING AGENTS	1,460	1,226	234	118,189	1.2%	0.2%
	PROPRANOLOL HCL	1,451	1,220	231	19,007	7.6%	1.2%
	HEMATINICS, OTHER	259	194	65	1,995	13.0%	3.3%
	EPOETIN ALFA	259	194	65	1,995	13.0%	3.3%
	HEPARIN AND RELATED PREPARATIONS	556	400	156	5,702	9.8%	2.7%
	HEPARIN SODIUM, PORCINE	369	264	105	3,646	10.1%	2.9%
	HYPOGLYCEMICS, BIGUANIDE TYPE (NON-SULFONYLUREA)	418	321	97	32,980	1.3%	0.3%
	METFORMIN HCL	418	321	97	32,600	1.3%	0.3%
	INTESTINAL MOTILITY STIMULANTS	3,549	2,765	784	23,264	15.3%	3.4%
	METOCLOPRAMIDE HCL	3,545	2,763	782	23,075	15.4%	3.4%
	LAXATIVES AND CATHARTICS	349	323	26	28,477	1.2%	0.1%
	LACTULOSE	349	323	26	4,193	8.3%	0.6%
	NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIB (NDRIS	1,384	1,191	193	33,487	4.1%	0.6%
	BUPROPION HCL	1,384	1,191	193	33,487	4.1%	0.6%
	ORAL ANTICOAGULANTS, COUMARIN TYPE	3,519	2,749	770	40,142	8.8%	1.9%
	WARFARIN SODIUM	3,519	2,749	770	40,134	8.8%	1.9%
	PLATELET AGGREGATION INHIBITORS	1,109	995	114	11,345	9.8%	1.0%
	CLOPIDOGREL BISULFATE	1,109	995	114	6,659	16.7%	1.7%
	THIAZIDE AND RELATED DIURETICS	876	705	171	217,935	0.4%	0.1%
	HCTZ/TRIAMTERENE	817	654	163	17,420	4.7%	0.9%
PA	ACNE AGENTS, SYSTEMIC	246	215	31	598	41.1%	5.2%
	ISOTRETINOIN	246	215	31	598	41.1%	5.2%
	ANDROGENIC AGENTS	49	44	5	1,566	3.1%	0.3%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
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DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	TESTOSTERONE CYPIONATE	35	30	5	396	8.8%	1.3%
	FLUOXYMESTERONE	7	7	0	89	7.9%	0.0%
	TESTOSTERONE ENANTHATE	4	4	0	37	10.8%	0.0%
	ANTICONSULTANTS	195	173	22	235,063	0.1%	0.0%
	VALPROATE SODIUM	134	120	14	3,784	3.5%	0.4%
	DIVALPROEX SODIUM	59	52	7	80,113	0.1%	0.0%
	ANTI-HISTAMINES	69	63	6	71,384	0.1%	0.0%
	P-EPHED HCL/CARBINOX MAL	35	30	5	4,612	0.8%	0.1%
	DIPHENHYDRAMINE HCL	23	22	1	26,573	0.1%	0.0%
	CARBINOXAMINE MALEATE	7	7	0	381	1.8%	0.0%
	ANTIMALARIAL DRUGS	3	2	1	2,024	0.1%	0.0%
	CHLOROQUINE PHOSPHATE	3	2	1	20	15.0%	5.0%
	ANTIVIRALS, HIV-SPECIFIC	20	20	0	2,304	0.9%	0.0%
	ZIDOVUDINE/LAMIVUDINE	20	20	0	1,961	1.0%	0.0%
	COUGH AND/OR COLD PREPARATIONS	1,523	1,362	161	102,818	1.5%	0.2%
	PHENYLEPHRINE/PYRIL TAN	1,429	1,280	149	1,321	108.2%	11.3%
	DM HB/P-EPHED HCL/CARBINOX	76	67	9	27,649	0.3%	0.0%
	P-EPHED HCL/COD PHOS/TRIPROL	18	15	3	321	5.6%	0.9%
	FOLLICLE STIM./LUTEINIZING HORMONES	9	9	0	11	81.8%	0.0%
	GONADOTROPIN, CHORIONIC, HUMAN	9	9	0	10	90.0%	0.0%
	PERIODONTAL COLLAGENASE INHIBITORS	3	1	2	297	1.0%	0.7%
	DOXYCYCLINE HYCLATE	3	1	2	297	1.0%	0.7%
	QUINOLONES	148	130	18	25,818	0.6%	0.1%
	OFLOXACIN	116	101	15	1,209	9.6%	1.2%
	MOXIFLOXACIN HCL	13	11	2	310	4.2%	0.6%
	CIPROFLOXACIN LACTATE/D5W	9	9	0	76	11.8%	0.0%
	NORFLOXACIN	8	7	1	553	1.4%	0.2%
PG	ABSORBABLE SULFONAMIDES	54	53	1	53,276	0.1%	0.0%
	SULFAMETHOXAZOLE/TRIMETHOPRIM	54	53	1	51,143	0.1%	0.0%
	ALDOSTERONE ANTAGONISTS (OBSOLETE)	9	9	0	18,066	0.0%	0.0%
	SPIRONOLACTONE	9	9	0	15,736	0.1%	0.0%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
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DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	ANAEROBIC ANTIPROTOZOAL-ANTIBACTERIAL AGENTS	127	119	8	15,398	0.8%	0.1%
	METRONIDAZOLE	127	119	8	15,371	0.8%	0.1%
	ANALGESIC/ANTIPYRETICS, SALICYLATES	54	52	2	91,769	0.1%	0.0%
	ASPIRIN	52	50	2	81,111	0.1%	0.0%
	ANTI-ANXIETY DRUGS	38	34	4	252,471	0.0%	0.0%
	ALPRAZOLAM	27	24	3	76,827	0.0%	0.0%
	DIAZEPAM	11	10	1	43,060	0.0%	0.0%
	ANTI-MANIA DRUGS	26	23	3	25,557	0.1%	0.0%
	LITHIUM CARBONATE	26	23	3	25,074	0.1%	0.0%
	ANTI-ULCER PREPARATIONS	12	12	0	132,013	0.0%	0.0%
	MISOPROSTOL	12	12	0	1,527	0.8%	0.0%
	ANTICONSULTANTS	126	116	10	235,063	0.1%	0.0%
	DIVALPROEX SODIUM	77	73	4	80,113	0.1%	0.0%
	PHENYTOIN SODIUM EXTENDED	35	31	4	46,033	0.1%	0.0%
	CARBAMAZEPINE	11	10	1	17,373	0.1%	0.0%
	CONTRACEPTIVES,INJECTABLE	18	16	2	5,575	0.3%	0.0%
	MEDROXYPROGESTERONE ACET	18	16	2	5,575	0.3%	0.0%
	CONTRACEPTIVES,ORAL	13	13	0	47,582	0.0%	0.0%
	LEVONORGESTREL-ETH ESTRA	8	8	0	5,538	0.1%	0.0%
	ESTROGENIC AGENTS	11	10	1	70,636	0.0%	0.0%
	ESTROGENS,CONJUGATED	7	6	1	58,206	0.0%	0.0%
	HYPOTENSIVES, ACE BLOCKING TYPE	62	61	1	146,457	0.0%	0.0%
	LISINAPRIL	35	34	1	60,085	0.1%	0.0%
	QUINAPRIL HCL/MAG CARB	9	9	0	19,942	0.0%	0.0%
	LAXATIVES AND CATHARTICS	19	18	1	28,477	0.1%	0.0%
	PSYLLIUM SEED/SUCROSE	18	17	1	6,037	0.3%	0.0%
	RECTAL PREPARATIONS	14	14	0	2,134	0.7%	0.0%
	HYDROCORTISONE	11	11	0	1,193	0.9%	0.0%
	TOPICAL ANTI-INFLAMMATORY STEROIDAL	18	16	2	23,136	0.1%	0.0%
	HYDROCORTISONE VALERATE	9	7	2	6,916	0.1%	0.0%
	HYDROCORTISONE	9	9	0	15,327	0.1%	0.0%

Report: DUR-0012-A
 Process: DURJA235
 Location: DUR0012A

Indiana Aim
 Summary Data by Drug Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
 Run Time: 20:43:18
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DUR Screen	Therapeutic Category/ Drug(s) (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-Responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	ANALGESICS,NARCOTICS	199,179	173,220	25,923	491,359	40.5%	5.3%
	HYDROCODONE BITARTRATE/APAP	56,753	47,730	9,011	166,431	34.1%	5.4%
	OXYCODONE HCL	35,176	31,772	3,404	31,277	112.5%	10.9%
	FENTANYL	21,551	18,522	3,024	20,260	106.4%	14.9%
	PROPOXYPHENE NAPSYLATE/APAP	18,751	16,281	2,470	106,888	17.5%	2.3%
	TRAMADOL HCL	16,066	14,055	2,011	54,556	29.4%	3.7%
	MORPHINE SULFATE	16,101	14,160	1,933	10,936	147.2%	17.7%
	OXYCODONE HCL/ACETAMINOPHEN	11,146	9,957	1,189	17,508	63.7%	6.8%
	CODEINE PHOSPHATE/APAP	10,830	9,091	1,731	65,921	16.4%	2.6%
	ANTI-ANXIETY DRUGS	44,207	37,203	7,004	252,471	17.5%	2.8%
	ALPRAZOLAM	11,681	9,821	1,860	76,827	15.2%	2.4%
	LORAZEPAM	11,468	9,081	2,387	68,685	16.7%	3.5%
	DIAZEPAM	7,642	6,520	1,122	43,060	17.7%	2.6%
	HYDROXYZINE HCL	5,473	4,922	551	27,806	19.7%	2.0%
	ANTI-PSYCHOTICS,PHENOTHIAZINES	12,654	10,138	2,516	32,649	38.8%	7.7%
	THIORIDAZINE HCL	6,031	4,959	1,072	11,259	53.6%	9.5%
	ANTIDEPRESSANTS O.U.	41,276	36,493	4,783	111,941	36.9%	4.3%
	TRAZODONE HCL	7,301	6,384	917	11,728	62.3%	7.8%
	HYPOTENSIVES, ACE BLOCKING TYPE	11,727	9,576	2,151	146,457	8.0%	1.5%
	LISINOPRIL	5,312	4,155	1,157	60,085	8.8%	1.9%
	SEROTONIN SPECIFIC REUPTAKE INHIBITOR (SSRIS)	35,046	28,669	6,377	223,204	15.7%	2.9%
	SERTRALINE HCL	11,853	9,235	2,618	71,881	16.5%	3.6%
	FLUOXETINE HCL	9,526	8,280	1,246	53,989	17.6%	2.3%
	PAROXETINE HCL	8,069	6,740	1,329	57,639	14.0%	2.3%
	SEROTONIN-NOREPINEPHRINE REUPTAKE-INHIB (SNRIS)	8,940	7,608	1,332	28,919	30.9%	4.6%
	VENLAFAXINE HCL	8,940	7,608	1,332	28,919	30.9%	4.6%
	TRICYCLIC ANTIDEPRESSANTS & REL. NON-SEL RU-INHIB	9,675	8,508	1,167	60,932	15.9%	1.9%
	AMITRIPTYLINE HCL	4,568	4,049	519	32,506	14.1%	1.6%

** END OF REPORT **

Report: DUR-0013-A
Proces: DURJA210
Location: DUR0013A

Indiana AIM
Prospective DUR Intervention/Outcome Summary
Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
Run Time: 20:43:03
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DUR Screen	Prescriber % Overrides	Consulted (M0) % Cancellations	Patient % Overrides	Consulted (P0) % Cancellations	Other Source % Overrides	Consulted (R0) % Cancellations
DD	34.1	0.0	5.0	0.0	44.9	0.0
ER	30.7	0.0	5.9	0.1	41.9	0.0
HD	32.8	0.0	6.4	0.0	47.0	0.0
LR	32.8	0.0	9.4	0.0	46.6	0.0
MC	33.7	0.0	4.1	0.0	41.0	0.0
PA	38.2	0.0	5.9	0.0	44.4	0.0
PG	40.2	0.0	10.6	0.0	42.9	0.0
TD	35.4	0.0	5.6	0.0	44.5	0.0

** END OF REPORT **

Report: DUR-0014-A
 Process: DURJA215
 Location: DUR0014A

Indiana AIM
 Summary Report of Intervention and Outcome Overrides by DUR Screen
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
 Run Time: 20:43:16
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DUR Screen	1A False Positive	1B Filled As Is	1C Diff Dose	1D Diff Direct	1E Diff Drug	1F Diff Qty	1G Prescriber Approval
DD	2,869	61,091	38	5,120	53	23	12,839
Prescriber Consulted	1,181	21,094	19	119	9	16	10,660
Patient Consulted	358	4,172	1	6	0	0	343
Other Source Consulted	1,330	35,825	18	4,995	44	7	1,836
ER	3,290	73,201	250	4,825	169	20	13,358
Prescriber Consulted	1,350	23,397	161	1,029	11	13	11,163
Patient Consulted	821	6,019	8	35	0	3	292
Other Source Consulted	1,119	43,785	81	3,761	158	4	1,903
HD	1,972	46,930	168	1,059	45	27	9,321
Prescriber Consulted	826	14,007	32	327	7	22	7,449
Patient Consulted	262	3,767	10	11	0	0	348
Other Source Consulted	884	29,156	126	721	38	5	1,524
LR	3,143	79,191	74	2,903	59	25	13,374
Prescriber Consulted Patient	1,165	23,374	22	906	1	24	10,928

Report: DUR-0014-A
 Process: DURJA215
 Location: DUR0014A

Indiana AIM
 Summary Report of Intervention and Outcome Overrides by DUR Screen
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
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DUR Screen	1A False Positive	1B Filled As Is	1C Diff Dose	1D Diff Direct	1E Diff Drug	1F Diff Qty	1G Prescriber Approval
Consulted Other Source	674	9,254	2	13	0	0	477
Consulted	1,304	46,563	50	1,984	58	1	1,969
MC	906	16,374	12	1,211	15	3	3,365
Prescriber Consulted	468	5,779	5	312	0	3	2,715
Patient Consulted	75	986	0	0	0	0	80
Other Source Consulted	363	9,609	7	899	15	0	570
PA	51	1,607	7	4	3	0	350
Prescriber Consulted	23	520	7	1	2	0	315
Patient Consulted	6	122	0	0	0	0	2
Other Source Consulted	22	965	0	3	1	0	33
PG	26	504	0	0	0	0	102
Prescriber Consulted	7	185	0	0	0	0	77
Patient Consulted	14	49	0	0	0	0	7
Other Source Consulted	5	270	0	0	0	0	18

Report: DUR-0014-A
Process: DURJA215
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Indiana AIM
Summary Report of Intervention and Outcome Overrides by DUR Screen
Period: 10/6/2000 - 10/5/2001

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DUR Screen	1A False Positive	1B Filled As Is	1C Diff Dose	1D Diff Direct	1E Diff Drug	1F Diff Qty	1G Prescriber Approval
TD	11,479	258,402	873	13,649	1,021	105	49,426
Prescriber Consulted	4,876	88,457	393	2,590	216	87	42,108
Patient Consulted	2,351	18,056	70	31	38	8	1,246
Other Source Consulted	4,252	151,889	410	11,028	767	10	6,072

** END OR REPORT **

Report: DUR-0015-A
 Process: DURJA240
 Location: DUR0015A

Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
DD	ABSORBABLE SULFONAMIDES	1,406	1,158	248	53,276	2.6%	0.5%
	SULFAMETHOXAZOLE/TRIMETHOPRIM	1,396	1,151	245	51,143	2.7%	0.5%
	CYCLOSPORINE, MODIFIED	658	608	50	0	0.0%	0.0%
	WARFARIN SODIUM	505	337	168	0	0.0%	0.0%
	CYCLOSPORINE	198	181	17	0	0.0%	0.0%
	METHENAMINE MANDELATE	22	16	6	0	0.0%	0.0%
	METHEN MAND/NAPHOS M-B M-H	5	4	1	0	0.0%	0.0%
	METHENAMINE HIPPURATE	5	2	3	0	0.0%	0.0%
	MTH/ME BLUE/SALICY/NA PHOS/HYO	3	3	0	0	0.0%	0.0%
	ALDOSTERONE ANTAGONISTS (OBSOLETE)	4,113	3,487	626	19,642	20.9%	3.2%
	SPIRONOLACTONE	3,772	3,185	587	17,108	22.0%	3.4%
	POTASSIUM CHLORIDE	3,664	3,090	574	0	0.0%	0.0%
	POTASSIUM BICARBONATE/CIT AC	69	57	12	0	0.0%	0.0%
	POT BICARB/POTASSIUM CIT/CA	22	22	0	0	0.0%	0.0%
	POT CHLORIDE/POT BICARB/CIT AC	15	14	1	0	0.0%	0.0%
	POTASSIUM CHLORIDE/D5-0.45NACL	2	2	0	0	0.0%	0.0%
	ANALGESIC/ANTIPYRETICS, SALICYLATES	1,767	1,230	537	91,769	1.9%	0.6%
	ASPIRIN	1,593	1,092	501	81,111	2.0%	0.6%
	WARFARIN SODIUM	1,289	848	441	0	0.0%	0.0%
	HEPARIN SODIUM,PORCINE	139	121	18	0	0.0%	0.0%
	METHOTREXATE SODIUM	129	99	30	0	0.0%	0.0%
	ENOXAPARIN SODIUM	24	17	7	0	0.0%	0.0%
	KETOROLAC TROMETHAMINE	9	6	3	0	0.0%	0.0%
	ANISINDIONE	2	0	2	0	0.0%	0.0%
	DALTEPARIN SODIUM,PORCINE	1	1	0	0	0.0%	0.0%
	ANTI-PSYCHOTICS,PHENOTHIAZINES	3,279	2,634	645	32,649	10.0%	2.0%
	THIORIDAZINE HCL	2,715	2,208	507	11,259	24.1%	4.5%
	PROPRANOLOL HCL	711	601	110	0	0.0%	0.0%
	RISPERIDONE	561	455	106	0	0.0%	0.0%
	FLUOXETINE HCL	377	276	101	0	0.0%	0.0%
	QUETIAPINE FUMARATE	235	191	44	0	0.0%	0.0%
	SERTRALINE HCL	214	189	25	0	0.0%	0.0%

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Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	PAROXETINE HCL	192	162	30	0	0.0%	0.0%
	FLUVOXAMINE MALEATE	117	87	30	0	0.0%	0.0%
	METOPROLOL TARTRATE	63	60	3	0	0.0%	0.0%
	IMIPRAMINE HCL	40	37	3	0	0.0%	0.0%
	PINDOLOL	37	14	23	0	0.0%	0.0%
	CHLORPROMAZINE HCL	50	39	11	583	8.6%	1.9%
	VENLAFAXINE HCL	27	18	9	0	0.0%	0.0%
	DOXEPIN HCL	23	19	4	0	0.0%	0.0%
	ERYTHROMYCIN BASE	15	12	3	0	0.0%	0.0%
	SALMETEROL XINAFOATE	15	15	0	0	0.0%	0.0%
	DESIPRAMINE HCL	14	14	0	0	0.0%	0.0%
	HALOPERIDOL	13	8	5	0	0.0%	0.0%
	TAMOXIFEN CITRATE	13	13	0	0	0.0%	0.0%
	HALOPERIDOL DECANOATE	6	4	2	0	0.0%	0.0%
	INDAPAMIDE	5	4	1	0	0.0%	0.0%
	ANTIARRHYTHMICS	1,792	1,619	173	7,680	23.3%	2.3%
	AMIODARONE HCL	1,200	1,128	72	4,209	28.5%	1.7%
	DIGOXIN	690	653	37	0	0.0%	0.0%
	WARFARIN SODIUM	504	470	34	0	0.0%	0.0%
	QUINIDINE GLUCONATE	17	15	2	47	36.2%	4.3%
	QUINIDINE SULFATE	20	14	6	49	40.8%	12.2%
	ANTIDEPRESSANTS O.U.	3,079	2,883	195	111,941	2.8%	0.2%
	AMITRIPTYLINE HCL	1,523	1,435	87	11,420	13.3%	0.8%
	ALBUTEROL	443	419	24	0	0.0%	0.0%
	ALBUTEROL SULFATE	283	253	30	0	0.0%	0.0%
	SALMETEROL XINAFOATE	213	204	9	0	0.0%	0.0%
	P-EPHED SUL/LORATADINE	119	110	9	0	0.0%	0.0%
	AMPHET ASP/AMPHET/D-AMPHET	78	77	1	0	0.0%	0.0%
	GUAIFENESIN/P-EPHED HCL	70	67	2	0	0.0%	0.0%
	GUAIFENESIN/PPA HCL	90	81	9	0	0.0%	0.0%
	METHYLPHENIDATE HCL	70	69	1	0	0.0%	0.0%
	PSEUDOEPHEDRINE SULFATE/AZATA	14	13	1	0	0.0%	0.0%
	PHENYLEPHRINE/HYDROCOD BIT/CP	11	11	0	0	0.0%	0.0%

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Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	PSEUDOEPHEDRINE HCL/CHLOR-MAL	14	14	0	0	0.0%	0.0%
	P-EPHED HCL/CHLOR-MAL/SCOP	10	10	0	0	0.0%	0.0%
	METAPROTERENOL SULFATE	8	8	0	0	0.0%	0.0%
	PSEUDOEPHEDRINE HCL	11	10	1	0	0.0%	0.0%
	PHENYLEPHRINE/CHLOR-MAL/SCOP	12	12	0	0	0.0%	0.0%
	CAR-B-PEN TA/PHENYLEPHRINE/CP	6	6	0	0	0.0%	0.0%
	GUAIFENESIN/P-EPHED HCL/HCOD	6	6	0	0	0.0%	0.0%
	PHENYLEPHRINE HCL/PROMETH HCL	6	6	0	0	0.0%	0.0%
	PIRBUTEROL ACETATE	5	5	0	0	0.0%	0.0%
	GUAIFENESIN/PHENYLEPHRINE/HCOD	7	7	0	0	0.0%	0.0%
	BETA-ADRENERGIC AGENTS	9,016	8,349	667	138,683	6.5%	0.5%
	ALBUTEROL	4,521	4,222	299	51,994	8.7%	0.6%
	AMITRIPTYLINE HCL	1,938	1,823	115	0	0.0%	0.0%
	CYCLOBENZAPRINE HCL	1,167	1,087	80	0	0.0%	0.0%
	DOXEPIN HCL	561	507	54	0	0.0%	0.0%
	IMIPRAMINE HCL	280	254	26	0	0.0%	0.0%
	NORTRIPTYLINE HCL	271	256	15	0	0.0%	0.0%
	AMITRIPTYLINE HCL/PERPHENAZINE	131	128	3	0	0.0%	0.0%
	DESIPRAMINE HCL	57	54	3	0	0.0%	0.0%
	AMITRIP HCL/CHLORDIAZEPOXIDE	51	51	0	0	0.0%	0.0%
	CLOMIPRAMINE HCL	27	27	0	0	0.0%	0.0%
	AMOXAPINE	14	13	1	0	0.0%	0.0%
	MAPROTILINE HCL	11	9	2	0	0.0%	0.0%
	IMIPRAMINE PAMOATE	9	9	0	0	0.0%	0.0%
	PROTRIPTYLINE HCL	2	2	0	0	0.0%	0.0%
	TRIMIPRAMINE MALEATE	2	2	0	0	0.0%	0.0%
	ALBUTEROL SULFATE	2,551	2,302	249	65,611	3.9%	0.4%
	AMITRIPTYLINE HCL	1,121	1,030	91	0	0.0%	0.0%
	CYCLOBENZAPRINE HCL	574	515	59	0	0.0%	0.0%
	DOXEPIN HCL	279	239	40	0	0.0%	0.0%
	NORTRIPTYLINE HCL	198	165	33	0	0.0%	0.0%
	IMIPRAMINE HCL	181	167	14	0	0.0%	0.0%
	AMITRIPTYLINE HCL/PERPHENAZINE	105	97	8	0	0.0%	0.0%

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Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	AMITRIP HCL/CHLORDIAZEPOXIDE	33	31	2	0	0.0%	0.0%
	DESIPRAMINE HCL	24	24	0	0	0.0%	0.0%
	CLOMIPRAMINE HCL	18	18	0	0	0.0%	0.0%
	MAPROTILINE HCL	10	10	0	0	0.0%	0.0%
	PROTRIPTYLINE HCL	4	2	2	0	0.0%	0.0%
	TRIMIPRAMINE MALEATE	2	2	0	0	0.0%	0.0%
	AMOXAPINE	1	1	0	0	0.0%	0.0%
	SALMETEROL XINAFOATE	1,694	1,587	107	17,335	9.8%	0.6%
	AMITRIPTYLINE HCL	757	719	38	0	0.0%	0.0%
	CYCLOBENZAPRINE HCL	399	370	29	0	0.0%	0.0%
	DOXEPIN HCL	180	169	11	0	0.0%	0.0%
	NORTRIPTYLINE HCL	177	165	11	0	0.0%	0.0%
	IMIPRAMINE HCL	78	67	11	0	0.0%	0.0%
	AMITRIPTYLINE HCL/PERPHENAZINE	35	32	3	0	0.0%	0.0%
	THIORIDAZINE HCL	23	23	0	0	0.0%	0.0%
	AMITRIP HCL/CHLORDIAZEPOXIDE	16	13	3	0	0.0%	0.0%
	CLOMIPRAMINE HCL	11	11	0	0	0.0%	0.0%
	DESIPRAMINE HCL	8	8	0	0	0.0%	0.0%
	MAPROTILINE HCL	6	6	0	0	0.0%	0.0%
	TRIMIPRAMINE MALEATE	3	3	0	0	0.0%	0.0%
	MESORIDAZINE BESYLATE	1	1	0	0	0.0%	0.0%
	BETA-ADRENERGIC BLOCKING AGENTS	3,925	3,284	641	128,091	3.1%	0.5%
	PROPRANOLOL HCL	1,113	919	194	20,657	5.4%	0.9%
	THIORIDAZINE HCL	711	599	112	0	0.0%	0.0%
	CLONIDINE HCL	239	218	21	0	0.0%	0.0%
	CHLORPROMAZINE HCL	162	101	61	0	0.0%	0.0%
	EPINEPHRINE	1	1	0	0	0.0%	0.0%
	DECARBOXYLASE INHIBITORS	1,477	1,220	257	11,550	12.8%	2.2%
	CARBIDOPA/LEVODOPA	1,477	1,220	257	11,550	12.8%	2.2%
	SELEGILINE HCL	274	230	44	0	0.0%	0.0%
	FERROUS SULFATE	281	204	77	0	0.0%	0.0%
	MULTIVITS W-IRON,HEMATINIC	242	201	41	0	0.0%	0.0%
	MULTIVITS W-FE,OTHER MIN	118	101	17	0	0.0%	0.0%

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Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	MULTIVITS,THERAP W-FE,HEMATIN	89	86	3	0	0.0%	0.0%
	FE P-SAC CMLPX/VIT B12/FA	90	81	9	0	0.0%	0.0%
	MULTIVITAMINS W-IRON	85	66	19	0	0.0%	0.0%
	IRON POLYSACCHARIDES COMPLEX	74	65	9	0	0.0%	0.0%
	MULTIVITS,TH W-CA,FE,OTH MIN	63	51	12	0	0.0%	0.0%
	MULTIVITS,TH W-FE,OTHER MIN	42	34	8	0	0.0%	0.0%
	FE FUMARATE/VIT C/B12-IF/FA	22	22	0	0	0.0%	0.0%
	FE FUMARATE/VIT C/VIT B12/FA	17	2	15	0	0.0%	0.0%
	PRENATAL VIT/FE FUMARATE/FA	13	13	0	0	0.0%	0.0%
	FE FUMARATE/VIT C/B12/STOMC	12	9	3	0	0.0%	0.0%
	FERROUS FUMARATE/VIT C/B12-IF	10	10	0	0	0.0%	0.0%
	FERROUS SULFATE/VIT C/FA	9	9	0	0	0.0%	0.0%
	FERROUS SULFATE/FA/VIT BCOMP&C	8	8	0	0	0.0%	0.0%
	PRENATAL VIT/FE P-SAC CMLPX/FA	6	6	0	0	0.0%	0.0%
	PRENATAL VITS W-CA,FE,FA(1MG)	7	7	0	0	0.0%	0.0%
	MULTIVITS W-CA,FE,OTHER MIN	5	5	0	0	0.0%	0.0%
	DIGITALIS GLYCOSIDES	2,150	1,824	326	47,873	4.5%	0.7%
	DIGOXIN	2,150	1,824	326	47,873	4.5%	0.7%
	VERAPAMIL HCL	925	731	194	0	0.0%	0.0%
	AMIODARONE HCL	672	623	49	0	0.0%	0.0%
	PROPAFENONE HCL	283	234	49	0	0.0%	0.0%
	QUINIDINE GLUCONATE	97	87	10	0	0.0%	0.0%
	FLECAINIDE ACETATE	88	70	18	0	0.0%	0.0%
	QUINIDINE SULFATE	56	48	8	0	0.0%	0.0%
	CYCLOSPORINE, MODIFIED	22	22	0	0	0.0%	0.0%
	CYCLOSPORINE	11	11	0	0	0.0%	0.0%
	HYPOTENSIVES,SYMPATHOLYTIC	3,359	2,911	448	24,419	13.8%	1.8%
	CLONIDINE HCL	3,359	2,911	448	23,966	14.0%	1.9%
	ATENOLOL	1,248	1,067	181	0	0.0%	0.0%
	METOPROLOL TARTRATE	841	726	115	0	0.0%	0.0%
	METOPROLOL SUCCINATE	664	618	46	0	0.0%	0.0%
	PROPRANOLOL HCL	223	201	22	0	0.0%	0.0%
	LABETALOL HCL	53	15	38	0	0.0%	0.0%

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Indiana AIM
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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	BETAXOLOL HCL	49	43	6	0	0.0%	0.0%
	TIMOLOL MALEATE	45	36	9	0	0.0%	0.0%
	ATENOLOL/CHLORTHALIDONE	45	43	2	0	0.0%	0.0%
	BISOPROLOL FUMARATE/HCTZ	58	41	17	0	0.0%	0.0%
	NADOLOL	33	31	2	0	0.0%	0.0%
	LEVOBUNOLOL HCL	24	20	4	0	0.0%	0.0%
	ACEBUTOLOL HCL	19	19	0	0	0.0%	0.0%
	TIMOLOL MALEATE/DORZOLAM HCL	19	17	2	0	0.0%	0.0%
	PINDOLOL	11	11	0	0	0.0%	0.0%
	METIPRANOLOL	7	4	3	0	0.0%	0.0%
	METOPROLOL TARTRATE/HCTZ	8	8	0	0	0.0%	0.0%
	BISOPROLOL FUMARATE	5	4	1	0	0.0%	0.0%
	SOTALOL HCL	2	2	0	0	0.0%	0.0%
	ORAL ANTICOAGULANTS,COUMARIN TYPE	9,562	7,167	2,395	40,142	23.8%	6.0%
	WARFARIN SODIUM	9,549	7,154	2,395	40,134	23.8%	6.0%
	LEVOTHYROXINE SODIUM	5,026	3,783	1,243	0	0.0%	0.0%
	ASPIRIN	1,596	1,148	448	0	0.0%	0.0%
	VITAMIN E	952	602	350	0	0.0%	0.0%
	AMIODARONE HCL	557	508	49	0	0.0%	0.0%
	SULFAMETHOXAZOLE/TRIMETHOPRIM	271	205	66	0	0.0%	0.0%
	PHENOBARBITAL	252	206	46	0	0.0%	0.0%
	THYROID	207	186	21	0	0.0%	0.0%
	PRIMIDONE	176	162	14	0	0.0%	0.0%
	CIMETIDINE	93	82	11	0	0.0%	0.0%
	FENOFIBRATE,MICRONIZED	68	45	23	0	0.0%	0.0%
	METRONIDAZOLE	69	42	27	0	0.0%	0.0%
	ME-TESTOSTERONE/ESTROGEN,ESTER	56	44	12	0	0.0%	0.0%
	LIOTHYRONINE SODIUM	35	0	35	0	0.0%	0.0%
	CLARITHROMYCIN	37	26	11	0	0.0%	0.0%
	ASPIRIN/CALCIUM CARB/MAGNESIUM	25	6	19	0	0.0%	0.0%
	ACETAMINOPHEN/CAFFEINE/BUTALB	22	18	4	0	0.0%	0.0%
	ERYTHROMYCIN BASE	19	18	1	0	0.0%	0.0%
	SULFASALAZINE	13	11	2	0	0.0%	0.0%

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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	ASA/CALCIUM CARB/MAGNESIUM/ALH	14	11	3	0	0.0%	0.0%
	ACETAMINOPHEN/BUTALBITAL	8	8	0	0	0.0%	0.0%
	POTASSIUM REPLACEMENT	6,564	5,529	1,035	72,419	9.1%	1.4%
	POTASSIUM CHLORIDE	6,380	5,380	1,000	70,650	9.0%	1.4%
	SPIRONOLACTONE	3,490	2,914	576	0	0.0%	0.0%
	HCTZ/TRIAMTERENE	2,238	1,887	351	0	0.0%	0.0%
	HCTZ/SPIRONOLACTONE	327	293	34	0	0.0%	0.0%
	HYDROCHLOROTHIAZIDE/AMILOR HCL	145	127	18	0	0.0%	0.0%
	TRIAMTERENE	103	92	11	0	0.0%	0.0%
	AMILORIDE HCL	77	67	10	0	0.0%	0.0%
	QUINOLONES	3,398	2,645	753	25,818	13.2%	2.9%
	CIPROFLOXACIN HCL	3,090	2,379	711	22,956	13.5%	3.1%
	CALCIUM CARBONATE/VITAMIN D2	758	558	200	0	0.0%	0.0%
	FERROUS SULFATE	475	345	130	0	0.0%	0.0%
	MULTIVITS W-IRON,HEMATINIC	291	252	39	0	0.0%	0.0%
	MAGNESIUM HYDROXIDE	241	178	63	0	0.0%	0.0%
	MULTIVITS W-FE,OTHER MIN	187	143	44	0	0.0%	0.0%
	MULTIVITAMINS W-IRON	147	73	74	0	0.0%	0.0%
	CALCIUM CARBONATE	118	79	39	0	0.0%	0.0%
	FE P-SAC CMLPX/VIT B12/FA	121	109	12	0	0.0%	0.0%
	MULTIVITS,TH W-CA,FE,OTH MIN	94	82	12	0	0.0%	0.0%
	MULTIVITS,THERAP W-FE,HEMATIN	88	76	12	0	0.0%	0.0%
	MAG HYDROX/AL HYDROX/SIMETH	92	76	16	0	0.0%	0.0%
	IRON POLYSACCHARIDES COMPLEX	78	73	5	0	0.0%	0.0%
	MULTIVITS,TH W-FE,OTHER MIN	62	52	10	0	0.0%	0.0%
	FE FUMARATE/VIT C/B12/STOMC	50	37	13	0	0.0%	0.0%
	ASPIRIN/CALCIUM CARB/MAGNESIUM	46	32	14	0	0.0%	0.0%
	PRENATAL VIT/FE FUMARATE/FA	37	31	6	0	0.0%	0.0%
	CALCIUM CARBONATE	32	24	8	0	0.0%	0.0%
	MAGNESIUM HYDROXIDE/AL HYDROX	20	16	4	0	0.0%	0.0%
	FERROUS SULFATE/FA/VIT BCOMP&C	17	17	0	0	0.0%	0.0%
	NORETH A-ET ESTRA/FE FUMARATE	15	13	2	0	0.0%	0.0%
	SKELETAL MUSCLE RELAXANTS	2,640	2,462	178	69,336	3.8%	0.3%

Report: DUR-0015-A
 Process: DURJA240
 Location: DUR0015A

Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	CYCLOBENZAPRINE HCL	2,634	2,456	178	31,581	8.3%	0.6%
	ALBUTEROL	933	869	64	0	0.0%	0.0%
	ALBUTEROL SULFATE	508	466	42	0	0.0%	0.0%
	SALMETEROL XINAFOATE	333	317	16	0	0.0%	0.0%
	P-EPHED SUL/LORATADINE	181	174	7	0	0.0%	0.0%
	GUAIFENESIN/P-EPHED HCL	116	104	12	0	0.0%	0.0%
	METHYLPHENIDATE HCL	74	70	4	0	0.0%	0.0%
	GUAIFENESIN/PPA HCL	74	69	5	0	0.0%	0.0%
	AMPHET ASP/AMPHET/D-AMPHET	47	44	3	0	0.0%	0.0%
	PHENYLEPHRINE/CHLOR-MAL/SCOP	33	31	2	0	0.0%	0.0%
	SELEGILINE HCL	32	30	2	0	0.0%	0.0%
	PSEUDOEPHEDRINE SULFATE/AZATA	24	23	1	0	0.0%	0.0%
	DM HB/P-EPHED HCL/CARBINOX	26	22	4	0	0.0%	0.0%
	PHENYLEPHRINE HCL/COD/PROMETH	20	17	3	0	0.0%	0.0%
	PSEUDOEPHEDRINE HCL/CHLOR-MAL	20	20	0	0	0.0%	0.0%
	PIRBUTEROL ACETATE	18	18	0	0	0.0%	0.0%
	TERBUTALINE SULFATE	17	15	2	0	0.0%	0.0%
	PHENYLEPHRINE/HYDROCOD BIT/CP	14	13	1	0	0.0%	0.0%
	PHENYLEPHRINE/HYDROCOD BIT/PYR	14	14	0	0	0.0%	0.0%
	PHENYLEPHRINE/PYRIL TAN/CP	17	17	0	0	0.0%	0.0%
	P-EPHED HCL/BROMPHENIRAMIN	13	12	1	0	0.0%	0.0%
	THIAZIDE AND RELATED DIURETICS	3,912	3,259	653	217,935	1.8%	0.3%
	HCTZ/TRIAMTERENE	2,713	2,289	415	17,420	15.6%	2.4%
	POTASSIUM CHLORIDE	2,104	1,765	339	0	0.0%	0.0%
	IBUPROFEN	287	244	43	0	0.0%	0.0%
	DICLOFENAC SODIUM/MISOPROSTOL	96	89	7	0	0.0%	0.0%
	LITHIUM CARBONATE	53	49	4	0	0.0%	0.0%
	DICLOFENAC SODIUM	56	54	2	0	0.0%	0.0%
	INDOMETHACIN	42	41	1	0	0.0%	0.0%
	POTASSIUM BICARBONATE/CIT AC	12	12	0	0	0.0%	0.0%
	POT BICARB/POTASSIUM CIT/CA	8	0	8	0	0.0%	0.0%
	FLURBIPROFEN	10	7	3	0	0.0%	0.0%
	POT CHLORIDE/POT BICARB/CIT AC	4	4	0	0	0.0%	0.0%

Report: DUR-0015-A
 Process: DURJA240
 Location: DUR0015A

Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
 Run Time: 19:09:26
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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	POTASSIUM CITRATE	3	2	1	0	0.0%	0.0%
	LITHIUM CITRATE	38	31	7	0	0.0%	0.0%
	THYROID HORMONES	3,854	2,722	1,132	70,628	5.5%	1.6%
	LEVOTHYROXINE SODIUM	3,632	2,553	1,079	67,885	5.4%	1.6%
	WARFARIN SODIUM	3,629	2,550	1,079	0	0.0%	0.0%
	DICUMAROL	3	3	0	0	0.0%	0.0%
	TRICYCLIC ANTIDEPRESSANTS & REL. NON-SEL.RU-INHIB	3,662	3,365	297	60,932	6.0%	0.5%
	AMITRIPTYLINE HCL	1,783	1,656	127	32,506	5.5%	0.4%
	ALBUTEROL	555	525	30	0	0.0%	0.0%
	ALBUTEROL SULFATE	356	320	36	0	0.0%	0.0%
	SALMETEROL XINAFOATE	281	268	13	0	0.0%	0.0%
	P-EPHED SUL/LORATADINE	123	113	10	0	0.0%	0.0%
	GUAIFENESIN/P-EPHED HCL	89	78	11	0	0.0%	0.0%
	METHYLPHENIDATE HCL	76	75	1	0	0.0%	0.0%
	AMPHET ASP/AMPHET/D-AMPHET	53	52	1	0	0.0%	0.0%
	PSEUDOEPHEDRINE SULFATE/AZATA	38	32	6	0	0.0%	0.0%
	PIRBUTEROL ACETATE	35	27	8	0	0.0%	0.0%
	METAPROTERENOL SULFATE	31	30	1	0	0.0%	0.0%
	PSEUDOEPHEDRINE HCL/CHLOR-MAL	21	21	0	0	0.0%	0.0%
	GUAIFENESIN/PPA HCL	16	15	1	0	0.0%	0.0%
	PSEUDOEPHEDRINE HCL	13	11	2	0	0.0%	0.0%
	PHENYLEPHRINE/CHLOR-MAL/SCOP	11	11	0	0	0.0%	0.0%
	PHENYLEPHRINE/HYDROCOD BIT/CP	10	9	1	0	0.0%	0.0%
	P-EPHED HCL/BROMPHENIRAMIN	8	7	1	0	0.0%	0.0%
	P-EPHED HCL/CHLOR-MAL/SCOP	8	7	1	0	0.0%	0.0%
	D-METHORPHAN HB/P-EPD HCL/BPM	6	6	0	0	0.0%	0.0%
	PIMOZIDE	6	5	1	0	0.0%	0.0%
	DM HB/P-EPHED HCL/CARBINOX	5	4	1	0	0.0%	0.0%
MC	ALDOSTERONE ANTAGONISTS (OBSOLETE)	1,602	1,308	294	19,642	8.2%	1.5%
	SPIRONOLACTONE	1,402	1,145	257	17,108	8.2%	1.5%
	AMMONIA INHIBITORS	2,240	1,502	738	18,255	12.3%	4.0%

Report: DUR-0015-A
 Process: DURJA240
 Location: DUR0015A

Indiana AIM
 Summary Data by Drug Combination Involved in DUR Screening
 Period: 10/6/2000 - 10/5/2001

Run Date: 11/09/2001
 Run Time: 19:09:26
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DUR Screen	Therapeutic Category/ Drug Combo (Hierarchical Ingredient)	# Alerts	# Overrides	# Cancellations & Non-responses	# Claims Screened	% Alerts /Total Rx	% Cancels /Total Rx
	ANTACIDS	5,653	4,085	1,568	16,919	33.4%	9.3%
	ANTI-ANXIETY DRUGS	1,672	1,413	259	231,521	0.7%	0.1%
	ANTI-NARCOLEPSY/ANTI-HYPERKINESIS AGENTS	683	594	89	41,516	1.6%	0.2%
	ANTI-PSYCHOTICS, NON-PHENOTHIAZINES	323	253	70	63,091	0.5%	0.1%
	ANTIMIGRAINE PREPARATIONS	688	622	56	11,311	6.1%	0.5%
	BETA-ADRENERGIC BLOCKING AGENTS	1,460	1,226	234	118,189	1.2%	0.2%
	HEMATINICS, OTHER	259	194	65	1,995	13.0%	3.3%
	HEPARIN AND RELATED PREPARATIONS	556	400	156	5,702	9.8%	2.7%
	HYPOGLYCEMICS, BIGUANIDE TYPE (NON-SULFONYLUREAS)	418	321	97	32,980	1.3%	0.3%
	INTESTINAL MOTILITY STIMULANTS	3,549	2,765	784	23,264	15.3%	3.4%
	LAXATIVES AND CATHARTICS	349	323	26	25,311	1.4%	0.1%
	NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIB (NDRIS)	1,384	1,191	193	33,487	4.1%	0.6%
	ORAL ANTICOAGULANTS, COUMARIN TYPE	3,519	2,749	770	40,142	8.8%	1.9%
	PLATELET AGGREGATION INHIBITORS	1,109	995	114	11,345	9.8%	1.0%
	THIAZIDE AND RELATED DIURETICS	876	705	171	217,935	0.4%	0.1%
TD	ANALGESICS, NARCOTICS	199,179	173,220	25,923	491,359	40.5%	5.3%
	ANTI-ANXIETY DRUGS	44,207	37,203	7,004	252,471	17.5%	2.8%
	ANTI-PSYCHOTICS, PHENOTHIAZINES	12,654	10,138	2,516	32,649	38.8%	7.7%
	ANTIDEPRESSANTS O.U.	41,276	36,493	4,783	111,941	36.9%	4.3%
	HYPOTENSIVES, ACE BLOCKING TYPE	11,727	9,576	2,151	146,457	8.0%	1.5%
	SEROTONIN SPECIFIC REUPTAKE INHIBITOR (SSRIS)	35,046	28,669	6,377	223,204	15.7%	2.9%
	SEROTONIN-NOREPINEPHRINE REUPTAKE-INHIB (SNRIS)	8,940	7,608	1,332	28,919	30.9%	4.6%
	TRICYCLIC ANTIDEPRESSANTS & REL. NON-SEL. RU-INHIB	9,675	8,508	1,167	60,932	15.9%	1.9%

** END OF REPORT **

ATTACHMENT 3

Electronic Data Systems (EDS) is the agent responsible for analyzing pharmacy claims, producing intervention packets, and conducting retro-DUR program activities and assessments for the Indiana Medicaid Program. EDS contracted Eagle Managed Care to assist the EDS Pharmacist in performing the requirements of the program. The following information is a year-end analysis of retro-DUR activities and outcomes that were approved by the DUR Board and performed by the EDS pharmacist.

FFY 1Q2001 (10/1/00-12/31/00)

Purpose of Study:

The purpose of the study was to identify prescribers that exhibit a prescribing pattern of selecting Azithromycin, Zyxon, or a fluoroquinolone as first line agents for antimicrobial therapy.

Methodology:

Patient profiles were reviewed during a one-month period to identify those patients who were prescribed azithromycin, a fluoroquinolone, or Zyxon as first-line antimicrobial therapy. The profiles of the patients identified were further analyzed to select only those patients who were younger than 55 years old and did not receive antimicrobial treatment, a bronchodilator, or inhaled steroid during a 60-day period prior to the claim. Prescribers of these patients were identified from the profile review and the number of incidents per prescriber totaled to determine the top 250-350 prescribers who exhibited the highest number of patient-related occurrences for that month.

Intervention Goals:

Reserve second-line antibiotics, such as azithromycin, fluoroquinolones and linezolid (Zyxon), for patients who fail to respond to first-line agents (and in the case of linezolid, second-line agents), those who experience recurrent infections, or those who are immunocompromised.

Intervention Results:

Patient profiles were reviewed and identified. The profiles were then grouped by prescribers, and the prescribers were ranked in order of highest to lowest occurrence. The top 248 prescribers who exhibited the highest number of patient-related occurrences for the month were selected for intervention. Out of a total of 9,353 prescriptions identified, 2,573 were addressed in interventions to the prescribers. There were 1846 instances where azithromycin was being utilized as a first-line therapy, 724 for fluoroquinolones and 3 for linezolid.

Responses

94 physicians responded to the intervention packets (38%):

- 57 agreed with the recommendation and would consider first-line antibiotic agents for common bacterial infections. However, 29 would continue therapy for these patients.
- 37 physicians, including the 29, who agreed with the recommendation, chose to continue use with the second or third-line agents.
- 10 physicians responded that these are no longer or never have been their patients.

FFY 2Q2001 (1/1/2001-3/31/2001)

Purpose of Study:

The purpose of the study was to identify patient profiles that contain BID dosing of Proton Pump Inhibitors (PPIs) for greater than 90 days and/or identify dosages higher than recommended by the manufacturer for maintenance therapy.

Methodology:

Patient profiles were reviewed during a one month period to identify those patients who were prescribed Aciphex[®] (rabeprazole), Prevacid[®] (lansoprazole), Prilosec[®] (omeprazole), or Protonix[®] (pantoprazole) for BID dosing for greater than 90 days of therapy and/or for daily dosages higher than recommended by the manufacturer. The profiles of the patients identified were further analyzed to select only those patients who were not diagnosed with hypersecretory conditions. Prescribers of these patients were identified from the profile review and the number of incidents per prescriber was totaled to determine the top 250-350 prescribers exhibiting the highest number of patient-related occurrences for that month.

Intervention Goals:

To encourage the initiation of lifestyle modifications, antacids, and/or the utilization of Histamine 2 receptor blockers or Proton pump inhibitors as first-line therapy in acute treatment and employ strategies for maintenance therapy that continues to encourage lifestyle modifications, and/or drug therapy with Histamine 2 receptor blockers or Proton Pump inhibitors at the lowest effective dose.

Promote the recommended dosing for PPIs in acute GERD therapy, and in chronic, long-term GERD therapy maintenance.

Intervention Results:

Letters were sent to 204 physicians whose 571 patients were receiving prescriptions for twice daily PPI therapy. (583 interventions)

The letter encouraged the initiation of lifestyle modifications, antacids, and/or the utilization of Histamine 2 receptor blockers or proton pump inhibitors at the lowest effective dose. It promoted the recommended dosing for PPIs in acute GERD therapy, and in chronic, long-term GERD therapy maintenance.

Patients unresponsive to low doses of PPIs may be given higher dose therapy for 8 weeks. However, low doses should be attempted after 8 weeks of high dose treatment.

Responses

257 responses (44%) were received from 100 physicians (49%):

- For 74 patients, physicians agreed with the recommendations
- for 22 patients, physicians would attempt lifestyle modifications along with once daily PPI therapy
- for an additional 59 patients, physicians would consider once daily PPI therapy
- For 125 patients, physicians chose to continue current twice daily therapy:
- 16 patients were receiving PPIs once daily
- 39 patients were no longer receiving care from these physicians
- 9 physicians report that these recipients were not their patients

FFY 3Q2001 (4/1/2001-6/30/2001)

Purpose of Study:

The purpose of the study was to examine pharmacy claims where the indicator “Brand Medically Necessary” was provided on the claim, allowing the higher brand-name price to pay in situations affecting Federal Upper Limits (FUL).

Methodology:

Pharmacy claims were reviewed over a one-month period to identify those claims that were submitted with “Brand Medically Necessary” overrides. From those claims, only those drug products that were branded and included in the FUL list would be selected for analysis in the process of developing intervention packets. Claims for the following branded drug products were excluded:

- Coumadin®
- Dilantin®
- Lanoxin®
- Premarin®
- Provera®
- Synthroid®
- Tegretol®

Intervention letters were generated for each prescriber identified in the analysis who was responsible for four, or more, BMN prescriptions, or greater than \$400 per month in BMN prescription costs.

Intervention Goals:

To identify prescribers who requested “Brand Medically Necessary” on their prescriptions for drug products that were on the FUL list. The intervention packet focused on educating those prescribers on appropriate substitution of A-rated generic products that would assure quality drug therapy while being economical.

The intervention would also identify those prescribers who reported that they did not request “Brand Medically Necessary” on their prescriptions, and those claims

were reviewed to determine if SURs involvement was necessary with respective pharmacy providers.

Intervention Results:

Out of the 6,678 prescription episodes identified with “Brand Medically Necessary” overrides, 117 Physicians were identified who were responsible for four, or more, BMN prescriptions, or greater than \$400 per month in BMN prescription costs. (407 patients pertaining to 698 prescriptions). The total cost for these prescriptions was \$58,259.

Letters were not mailed due to the fact that brand products now require prior approval. However, cost analyses were done to compare the effect of prior authorization for brand products.

FFY 4Q2001 (7/1/200-9/30/200)

Purpose of Study:

The purpose of the study was to identify medication profiles of patients 65 years of age and older who were receiving a benzodiazepine drug product for over 60 days.

Methodology:

Medication profiles of patients were reviewed during a two month period to identify those members who were 65 years of age and older, and who;

- were prescribed a benzodiazepine product, and;
- were taking their benzodiazepines prescription for over 60 days in concurrent duration.

Intervention Goals:

- To alert prescribing physicians of patients who may have been at risk of CNS toxicity due to benzodiazepines.
- To alert prescribing physicians of patients who may have been at risk of falls and injuries due to prolonged therapies with benzodiazepines.
- To avoid benzodiazepine when an anxiolytic medication was required in a patient 65 years of age and older.

Intervention Results:

349 patients, age 65 or older, were identified as receiving a benzodiazepine drug for a period of at least 60 days. 295 physicians received intervention packets for a total of 356 interventions.

Responses

187 responses (53%) were received from 162 physicians (55%)

- For 83 patients, physicians agreed with the recommendation and would re-evaluate benzodiazepine therapy.
- Physicians would discontinue benzodiazepine therapy for 10 patients.

- For 10 patients, physicians agreed with the recommendation to change to a non-benzodiazepine hypnotic.
- For 79 patients, physicians chose to continue the current therapy for the following reasons:
 1. Effective medication
 2. Patients are stable
 3. Patients tolerate well

ATTACHMENT 4

Six Indiana DUR Board meetings were conducted during FFY2001. The Board had conducted quarterly meetings until June 2001, at which time a legislative mandate required them to meet monthly.

On December 8, 2000, the DUR Board re-elected Chairperson G. Thomas Wilson, B.S. Pharm., J.D. and Vice Chairperson Patricia Treadwell, M.D. to serve in their capacities for the calendar year 2001. The Board roster, as it existed on September 2001, consisted of four physicians, four pharmacists, a pharmacologist, and a representative of the Office of Medicaid Policy and Planning who serves as an ex-officio non-voting member of the Board. Two positions were not filled and require individuals with the following requirements:

- a member employed by a health maintenance organization that has a pharmacy benefit and has expertise in formulary development and pharmacy benefit administration
- a member who is a health economist

Changes to the Board membership during FFY2001 include the admission in July 2001 of a pharmacist to the Board. This pharmacist fills the vacant position left from a resignation of a pharmacist Board member in December 2000. Another resignation received during FFY2001 came from the Board member employed by a health maintenance organization that had a pharmacy benefit and had expertise in formulary development and pharmacy benefit administration.

During FFY2001, the DUR Board reviewed the prospective DUR program that was supported by the Indiana AIM system. On a quarterly basis, the Board reviewed updates made to the system that were presented by the DUR Coordinator. These changes were the results of new criteria added to the proDUR modules maintained by First DataBank. The updates were applied to the system monthly to assure that the most current criteria was applied to proDUR screening by the system. The Board reviewed and approved all changes that were made during the year. A copy of the changes is included in Table 1 of this attachment.

During FFY2001, the DUR Coordinator submitted a report to the DUR Board that summarized the proDUR alert activity for FFY2000. The Board requested that information concerning a potential drug-drug interaction that appeared in the report (interaction between clonidine and beta-adrenergic blockers) be included in the next DUR Board Newsletter. Two articles were written from the information in the report and published in the March 2001 and September 2001 DUR Board Newsletters.

On July 2001, EDS upgraded the proDUR system in Indiana AIM. Prior to July 2001, the criteria used by the system to screen for drug-drug interactions utilized the DDIM version 3.0, provided by First DataBank. Because of the limitations inherent in the 3.0 DDIM, First DataBank announced that they would no longer support this version. During the

conversion, EDS inactivated and removed the criteria related to the 3.0 version of the DDIM and replaced it with First DataBank's new DDIM version 3.2. This version gives Indiana Medicaid greater flexibility and specificity in screening for drug-drug interactions. The Board has approved the activation of severity level 1 alerts under the new DDIM version 3.2. The drug-drug criteria that was activated in the proDUR system is found in Table 1 of this attachment.

The Board continued the retrospective DUR function by conducting profile analyses for each of the four quarters in FFY2001. The criteria for review included the following:

- First Quarter FFY2001: Pharmacy claims were examined to identify occurrences where azithromycin, linezolid or a fluoroquinolone was being used as a first-line antimicrobial agent. Each prescriber identified in the review was mailed an intervention packet that listed their patient(s) and antimicrobial prescribing occurrence(s) that fell outside the Board approved criteria. The prescriber was asked to respond to their prescribing pattern and practice.
- Second Quarter FFY 2001: Patient profiles were reviewed to identify those patients who were prescribed twice-daily doses of proton pump inhibitors (PPIs) for greater than ninety days. Patients diagnosed with hypersecretory conditions were not included in the review. Each prescriber identified in the review was mailed an intervention packet that contained a profile for each patient whose therapy duration exceeded the Board approved criteria. The prescriber was asked to respond to each separate patient profile occurrence.
- Third Quarter FFY2001: Pharmacy claims were reviewed over a one-month period to identify those claims that were submitted with "Brand Medically Necessary" overrides. Because of processes implemented requiring prior authorization for "Brand Medically Necessary" overrides, intervention packets were not mailed. Instead, the analysis was used to create a baseline that was later compared to claims processed in December 2001.
- Fourth Quarter FFY2001: Patient profiles were reviewed to identify patients sixty-five years of age or older who were receiving prescriptions for benzodiazepine products for a period of at least 60 days or greater. Each prescriber identified in the review was mailed an intervention packet that contained a profile for each patient whose therapy fell outside the Board approved criteria. The prescriber was asked to respond to each separate patient profile occurrence.

The response rate from intervention packets that were mailed to the prescribing physicians and returned with comments to the Board was 44%. Intervention packets for each retro-DUR activity performed in FFY2001 were mailed to the prescribing physicians according to the methodology that was approved by the Board. Each packet contained response forms specific to the issues addressed in the analysis. The response rate pertains to the number of prescribers who returned response forms to the Board, after having received intervention packets.

Educational inserts were also included in two of the three retro-DUR intervention packets that were approved and mailed by the DUR Board. The educational inserts contained information relevant to the purpose of the intervention packet and addressed issues

related to first-line antimicrobial product selection, and drug therapy durations with proton pump inhibitors. Prescribers expressed appreciation for the educational material they received in the intervention packets, and the educational approach presented in the cover letters.

During FFY2001, the Board approved a prior authorization program for brand name drug products that are subjected to Indiana's generic substitution law (see Attachment 5). The program requires prior authorization for branded multi-sourced drugs that have lower cost generic alternatives available for substitution whenever a prescriber indicates "Brand Medically Necessary" either orally or in writing on the prescription or drug order. The basis for this program is to require prescribers to substantiate what constitutes the medical necessity of a given brand name drug, when a less expensive, equally effective, generic equivalent is available for use.

Prior authorization is required only for those drugs that have an established federal upper limit (FUL), maximum allowable cost (MAC), and an "AA" or "AB" rated generic equivalent. Certain drugs are excluded from the program and include Coumadin[®], Dilantin[®], Lanoxin[®], Premarin[®], Provera[®], Synthroid[®], and Tegretol[®].

A copy of the bulletin that was mailed to the provider community highlighting the program is included as Attachment 5.

The DUR Board website continues to be used by Indiana Medicaid and the provider community in communicating information about the activities of the Board, and educational articles. Providers who access the DUR Board website are able to retrieve copies of DUR Board Newsletters that were produced in FFY2001 and earlier, meeting minutes from the six DUR Board meetings in FFY2001, future meeting agendas and public announcements, duties of the Board, the Board's charter, and a listing of times and locations of future DUR Board meetings. The website also allows providers to contact the Board through an e-mail link, enabling them to submit inquiries or request Board consideration for adding products to the Indiana Medicaid OTC Drug Formulary, which is an advisory function of the Board. Providers who desire an opportunity to speak during public comment at the Board meetings are able to utilize the speaker request form option on the DUR Board website. The speaker request form enables the public to submit an electronic request for public comment before the Board. The chairperson is provided copies of all requests prior to the start of each meeting.

Educational efforts continued throughout the year with the publication of three newsletters. The topics of articles in the newsletters included the following:

- An article addressing the use of generic drug products versus branded drug products. Readers were informed on the potential cost savings the Indiana Medicaid program would experience if generic drug products were prescribed at a higher rate, whether a therapeutic difference exists between branded and generic drug products, concerns with narrow therapeutic index drugs, the FDA's position on therapeutic equivalency, and who to contact if a difference is observed between brand and generic products.

- An article discussing the organizational structures and processes that are in place for reporting drug and medical product problems. Readers were informed about the FDA's MedWatch program and its goals, what constitutes a product problem, how the FDA handles a product problem, and how to report complete a MedWatch form.
- An article describing what an adverse drug event is and what constitutes a serious adverse event.
- An article discussing the considerations involved in the management of pain with scheduled II prescription drugs. Readers were informed on the concerns related to abuse, especially with Oxycontin, the laws involving schedule II drugs, factors related to addiction, and helpful materials for managing the chronic pain patient.
- An article warning providers of the potential drug-drug interaction in patient profiles containing clonidine together with a beta-adrenergic blocking agent. The article was written in response to the number of drug-drug proDUR alerts related to these two drugs.
- Two different articles reported the trends in pro-DUR alerts that were generated from POS claims submitted by pharmacy providers:
 1. A summary of pro-DUR alerts related to September 2000 claim submissions on POS. The report identified the occurrence of high dose alerts for NSAIDs and late refill alerts for anticonvulsants, oral hypoglycemics, ACEI/hypotensive agents, and xanthines.
 2. A summary of pro-DUR alerts occurring in FFY2000. The article provided high-level analysis of the types of proDUR alerts that occurred and the percentage override in the pharmacy provider community.
- Listings of top 25 drugs paid per quarter by Indiana Medicaid.

Copies of DUR Board Newsletters are included at the end of this Attachment.

Attachment 4

Table 1

**ProDUR Criteria Updates
Federal Fiscal Year 2001**

DRUG PREGNANCY ALERT (PG)

<u>Transaction</u>	<u>Description</u>	<u>Severity</u>
Add	Hyaluronate Sodium Intraoculr 10mg/ml Dispe Syrin	1
Add	Chondro Su A/Hyalur Sod Intraoculr 40-30mg/ml Disp Syrin	1
Add	Fluorescein Sodium/Hyalur Sod Intraoculr 0.5-10mg Disp Syrin	1
Add	Hyaluronate Sodium Intraoculr 14mg/ml Disp Syrin	1
Add	Chondro Su A/Hyalur Sod Intraoculr Kit	1
Add	Hyaluronate Sodium Intraoculr 12mg/ml Disp Syrin	1
Add	Hyaluronate Sodium Intraoculr 16mg/ml Disp Syrin	1
Add	Meloxicam Oral 15mg Tablet	2
Add	Hyaluronate Sodium Intraartic 10mg/ml Disp Syrin	1
Add	Hyaluronate Sodium Intraartic 10mg/ml Vial	1
Add	Hyaluronate Sodium Intraartic 8mg/ml Disp Syrin	1
Add	Chondro Su A/Hyalur Sod Intraoculr 0.35-0.4 Kit	1
Add	Chondro Su A/Hyalur Sod Intraoculr 0.5-0.55 Kit	1
Add	Vit A/Vit C/Bioflav/Zn/Herb25 Oral Capsule	1
Add	Fluvastatin Sodium Oral 80mg Tab.SR 24h	1
Add	Arsenic Trioxide Intraven. 10mg/10ml Ampul	1
Add	Tazarotene Topical 0.05% Cream (Gm)	1
Add	Tazarotene Topical 0.1% Cream (Gm)	1

Add	Tamoxifen Citrate Miscell. Powder	1
Add	Levocarnitine Intraven. 1G/5ml Vial	1
Add	Paclitaxel, Semi-Synthetic Intraven. 6mg/ml Vial	1
Add	Aspirin/Acetaminophen/Caffeine Oral 240-125-32 Tablet	1
Add	PPA Bit/Aspirin/Chlorphenir Oral 20-325-2mg Tablet Eff	1
Add	PPA Bit/Aspirin/Chlorphenir Oral 15-325-2mg Tablet Eff	1
Add	Ibuprofen/Pseudoephedrine HCl Oral 100-15mg/5 Oral Susp	1
Add	Telmisartan Oral 20mg Tablet	1
Add	Amitrip HCl/Chlordiazepoxide Oral 12.5-5mg Tablet	1
Add	Amitrip HCl/Chlordiazepoxide Oral 25-10mg Tablet	1
Add	Mifepristone Oral 200mg Tablet	1
Add	Enalaprilat Dihyrate Intraven. 1.25mg/ml Disp Syrin	1
Add	St. John's Wort Oral 150mg Capsule	1
Add	St. John's Wort Oral 225mg Capsule	1
Add	St. John's Wort Oral 300mg Capsule	1
Add	St. John's Wort Oral 375mg Capsule	1
Add	St. John's Wort Oral 450mg Capsule	1
Add	St. John's Wort Oral 600mg Capsule	1
Add	St. John's Wort Oral 300mg Tablet	1
Add	St. John's Wort Oral 450mg Tablet SA	1
Add	St. John's Wort Oral 500mg/ml Solution	1
Add	St. John's Wort Oral 25mg/ml Drops	1
Add	Benactyzine HCl/Meproamate Oral Tablet	1
Add	PPA Bit/Aspirin/Chlorphenir Oral 24-325-2mg Tablet Eff	1
Add	Telmisartan/HCTZ Oral 80-12.5mg Tablet	1
Add	Telmisartan/HCTZ Oral 40-12.5mg Tablet	1
Add	Guaifen/DM HB/P-Ephedrine Oral 200-10-15 Liquid	1
Add	Fluorouracil Topical 0.5% Cream (GM)	1
Add	Chlorambucil Miscell. Powder	1
Add	Levonorgestrel Vaginal 62mg IUD	1

Add	Trimetrexate Glucuronate Intraven. 25mg Vials	1
Add	HCG Alpha, Recombinant Subcutane. 250mcg Vial	1
Add	Cetrorelix Acetate Subcutane. 0.25mg Kit	1
Add	Cetrorelix Acetate Subcutane. 3mg Kit	1
Add	Glucosamine HCl/Chondro SU A Oral 1.5-1.2G Capsule	1
Add	Trimetrexate Glucuronate Intraven. 200mg Vial	1
Add	Hydroxyurea Oral 1000mg Tablet	1
Add	Follitropin Alpha, Recomb Subcutane. 600U/ML Kit	1
Add	Ibuprofen Oral 200mg Capsule	3
Add	Leuprolide/Lidocaine HCL Implant 120mcg/24h Kit	1
Add	Desogestrel-Ethinyl Estradiol Oral 7-7-7 Tablet	1
Add	Methotrexate Sodium Oral 10mg Tablet	1
Add	Methotrexate Sodium Oral 7.5mg Tablet	1
Add	Feverfew Oral 200mg Capsule	1
Add	Leuprolide Acetate Intramusc. 11.25mg Kit	1
Add	Leuprolide Acetate Intramusc. 7.5mg Kit	1
Add	Ethinyl Estradiol/Drospirenone Oral 0.03-3mg Tablet	1
Add	Methotrexate Sodium Oral 5mg Tablet	1
Add	Methotrexate Sodium Oral 15mg Tablet	1
Add	Borage Oral 1000mg Capsule	1
Add	Passion Flower/Valerian Root Oral 500-500mg Capsule	1
Add	Rutin/Quercetin/Bioflav/Bilber Oral 40mg Capsule	1
Add	St. John's Wort Oral 1000mg Capsule	1
Add	Leuprolide Acetate Intramusc. 15mg Kit	1
Add	Guara/Sginrt/ Amer Gins/K.Ginsg Oral 125-85mg Capsule	1
Add	Psyll Seed/Pot Gluc/B6/Herb29 Oral Tablet	1
Add	Sginr/Saw Pal/A.Gins/Kgn/Bgins Oral 500-500mg Capsule	1
Add	Lecith/Gnkbillf/S.Ginseng/Gotk Oral 50-150-250 Tablet	1
Add	Gluc Su/Chondro Su A/Vit C/Mn Oral 750-600mg Tablet	1
Add	C/Ech/St.Jhnwt/Eld/Sgin/Herb30 Oral Capsule	1

Add	Imatinib Mesylate Oral 100mg Capsule	1
Add	Guara/I2/Medsws/S.Ginsg/Herb31Oral 125-12.5mg Capsule	1
Add	HC Acetate/Lidocaine HCl Topical 0.5%-3% Cream(GM)	1
Add	Sod/Ca Carbonate/A/Vit D3/K/B2 Oral 600mg-200U Tab Chew	1
Add	Cal/VitA/C/Horse C-Nut/Grp Oral Tablet	1
Add	Cat's Claw Oral 1000mg Capsule	1
Add	Gluc Su/Fe/Sod/Vit C/Vitamin E Oral 500-60mg Tablet	1
Add	Licorice Root Oral 450mg Capsule	1
Add	Melatonin Sublingual 5mg Tab Subl	1
Add	Lecith/Pyridox HCl/I/Cider Vgr Oral 200-5-75 Tablet	1
Add	Lysin HC/Vit E Ac/FA/B&C/MN Oral 0.5mg Capsule	1
Add	Vit E Ac/Min/HRB37/Bov Cplx Oral Tablet	1
Add	Vit E Ac/Min/HRB38/Bov Cplx Oral Tablet	1
Add	Doxycycline Hyclate Oral 20mg Tablet	1
Add	Passion Flower Oral 250mg Capsule	1
Add	Thiotepa Injection 30mg Vial	1
Add	Doxycycline Monohydrate Oral 100mg Tablet	1
Add	Doxycycline Monohydrate Oral 50mg Tablet	1
Add	Am Ac/E Ac Succ/Zn/Herb9/Prost Oral Tablet	1
Add	Enzym,Plt/Herbal Complex No.12 Oral Capsule	1
Add	Mg Cit/E Ac Succ/Hesper/Herb13 Oral Capsule	1
Add	Enzym,Plt/Herbal Complex No.14 Oral Capsule	1
Add	Guar/Chrm/Gr Tea/Yrb Mat/Hrb39 Oral Tablet	1
Add	Guar Sd Xt/Ch/Vanad/Sgin/Hrb40 Oral Tablet	1
Add	Vitamin A Palmitate Miscell. Liquid	1
Add	DHA/Epa/MV/Dng Qui/HRB42 Oral Tablet	1
Add	L-Carnitine Fumarate Oral 200mg Capsule	1
Add	L-Carn Fum/Vit E Ac/Ubidecar Oral 50-30-25 Capsule	1
Add	Lecith/Pyridox HCl/I/Cider Vgr Oral 200-5-75 Capsule	1
Add	Berb SU/Herbal Complex No.18 Oral Capsule	1

Add	Ca Ph Tri/E Ac Succ/Herb23 Oral Tablet	1
Add	Bioflav/MV-Mn/Soyb/Evepr/Hrb32 Oral Combo. Pkg	1
Add	Quinine Sulfate Oral 324mg Capsule	1
Add	Quinapril HCl/HCTZ/Mag Carb Oral 20-12.5mg Tablet	1
Add	Quinapril HCl/HCTZ/Mag Carb Oral 10-12.5mg Tablet	1
Add	Quinapril HCl/HCTZ/Mag Carb Oral 20-25mg Tablet	1
Add	Glucosam HCl/Chondro Su A/C Oral 500-400-20 Tablet	1
Add	Cal/Vit Bcomp\$C/Val/St.Jhnwt Oral 50-300mg Tablet	1
Add	Valsartan Oral 320mg Tablet	1
Add	Vanadyl Sulfate Oral 10mg Tablet	1
Add	Horse Chestnut Seed Oral 150mg Capsule	1
Add	Horse Chestnut Seed Oral 300mg Tablet	1
Add	Horse Chestnut Seed Oral 300mg Cap12H Pel	1
Add	Horse Chestnut Seed Oral 300mg Capsule	1
Add	Vanadyl Sulfate Oral 50mg Tablet	1
Add	Theophylline/Potassium Iodide Oral 80-130/15 Elixir	1
Add	Theophylline/Ephed HCl/Phenobarb Oral 130-24-8mg Tablet	1
Add	Ephedrine/Potassium Iodide Oral 8-150mg/5 Syrup	1
Add	Amyl Nitrate Inhalation 0.3ml Ampul	1
Add	Phenylephrine/Cod/Cp/Pot Iod Oral 2.5-5-75/5 Syrup	1
Add	Codeine Phos/Carisoprodol/ASA Oral 16-200-325 Tablet	1
Add	Chlorcyclizine HCl/HC Acetate Topical 2-0.5% Cream (GM)	1
Add	HC/Resor/Bismuth Subgal/Znox Rectal 2.5% Cream (GM)	1
Add	HC/Resor/Bismuth Subgal/Znox Rectal 25mg Supp.Rect	1
Add	Hydrocortisone/Benz Per Topical 0.5-5% Lotion	1
Add	Neomycin/Bacitra/Polymixin/HC Topical 1% Oint.(GM)	1
Add	Neomy Sulf/Polymyx B Sulf/HC Topical 0.5% Cream(GM)	1
Add	Colchicine/Probenecid Oral 0.5-500mg Tablet	1
Add	Phenazopy HCl/Hyoscy/Butabarb Oral 150-0.3-15 Tablet	1
Add	Samarium SM 153 Lexidronam Intraven. 50mci/ml Vial	1

Add	Ribavirin Oral 200mg Capsule	1
Add	Methoxsalen Injection 20mcg/ml Vial	1
Add	Yohimbe Bark Oral 760mg Tablet	1
Update	Cal/Magnesium/Bioflav/MV/HRB33 Oral 1500-600 Combo. Pkg	2
To	Cal/Magnesium/Bioflav/MV/HRB33 Oral 1500-600 Combo. Pkg	1
Update	Amino Ac/Vit B12/B6/CH/HRB35 Oral 300-165mg Tablet	2
To	Amino Ac/Vit B12/B6/CH/HRB35 Oral 300-165mg Tablet	1
Update	Taur/Po Chl/Mag Salt/B6/HRB34 Oral 42mg Capsule	2
To	Taur/Po Chl/Mag Salt/B6/HRB34 Oral 42mg Capsule	1
Update	Lecith/FA/Vit Bcomp&C/Herb10 Oral Tablet	3
To	Lecith/FA/Vit Bcomp&C/Herb10 Oral Tablet	1
Update	Ca Citrate/Mg Ox/Nia/B6/Herb16 Oral Capsule	3
To	Ca Citrate/Mg Ox/Nia/B6/Herb16 Oral Capsule	1
Update	Potass/Vit C/Min/Herb17 Oral Capsule	2
To	Potass/Vit C/Min/Herb17 Oral Capsule	1
Update	Glucos-MSM/Vit C/Mang/Hrb21 Oral Tablet	2
To	Glucos-MSM/Vit C/Mang/Hrb21 Oral Tablet	1
Update	Thio Ac/Biofl/MV/Gr Tea/Hrb41 Oral Tablet SA	2
To	Thio Ac/Biofl/MV/Gr Tea/Hrb41 Oral Tablet SA	1
Update	Glucos-MSM/Colg II/C/Mn/Hrb21 Oral 500-333-5 Capsule	2
To	Glucos-MSM/Colg II/C/Mn/Hrb21 Oral 500-333-5 Capsule	1
Delete	Guar SD XT/Sginrt/A.Gins/K.Gin Oral 125-85mg Capsule	1

DRUG/AGE - PEDIATRIC (PA)

<u>Transaction</u>	<u>Description</u>	<u>Severity</u>	<u>Min.Age/yrs</u>	<u>MaxAge/yrs</u>
Add	Fluvastatin Sodium Oral 80mg Tab.SR 24h	1	1 (day)	16 years
Add	Phenyleph HCl/APAP/Chlorphenir Oral 5-162-2mg Tablet	1	1 (day)	16 years

Add	D-Methorphan HB/PE HCl/CP Oral 10-5-2mg/5 Syrup	1	1 (day)	16 years
Add	D-Methorphan HB/PE HCl/CP Oral 15-10-4mg/5 Solution	1	1 (day)	16 years
Add	Phenyleph HCl/APAP/Chlorphenir Oral 5-325-2mg Tablet	1	1 (day)	16 years
Add	PPA Bit/Aspirin/Chlorphenir Oral 20-325-2mg Tablet Eff	1	1 (day)	16 years
Add	PPA HCl/Aspirin/Chlorphenir Oral 15-325-2mg Tablet Eff	1	1 (day)	16 years
Add	PPA HCl/Chlor-Mal Oral 12.5-2mg/5 Syrup	1	1 (day)	6 years
Add	P-Ephed HCl/APAP/Chlorphenir Oral 30-325-2mg Capsule	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/CP Oral 20-60-500 Packet	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/CP Oral 20-60-650 Packet	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/CP Oral 30-60-650 Packet	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/CP Oral 30-60-1000 Packet	1	1 (day)	30 days
Add	Zidovudine/Lamivudine/Abacavir Oral 300-150mg Tablet	1	1 (day)	16 years
Add	DM HB/P-Ephed HCl/CP Oral 7.5-15-160 Liquid	1	1 (day)	16 years
Add	DM HB/P-Ephed HCl/CP Oral 5-15-160 Liquid	1	1 (day)	16 years
Add	DM HB/P-Ephed HCl/CP Oral 2.5-7.5-80 Tab Chew	1	1 (day)	30 days
Add	Phenyleph HCl/Pyrid Mal/CP Oral 10-10-2/5 Liquid	1	1 (day)	16 years
Add	Trovafloxacin Mesylate Oral 100mg Tablet	1	1 (day)	18 years
Add	Trovafloxacin Mesylate Oral 200mg Tablet	1	1 (day)	18 years
Add	Alatrofloxacin Mesylate Intraven. 5mg/ml Vial	1	1 (day)	18 years
Add	Moxifloxacin HCL Oral 400mg Tablet	1	1 (day)	18 years
Add	Gatifloxacin Oral 200mg Tablet	1	1 (day)	18 years
Add	Gatifloxacin Oral 400mg Tablet	1	1 (day)	18 years
Add	Gatifloxacin Intraven. 10mg/ml Vial	1	1 (day)	18 years
Add	Gatifloxacin/Dextrose 5%-Water Intraven. 200mg/100	1	1 (day)	19 years
Add	Gatifloxacin/Dextrose 5%-Water Intraven. 400mg/2	1	1 (day)	18 years
Add	DM HB/P-Ephed HCl/Carbinox Oral 4-25-2/ml Drops	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/Carbinox Oral 15-60-4/5 Syrup	1	1 (day)	30 days
Add	P-Ephed HCl/Br-Phenir Mal Oral 120-10mg Cap. SR 12H	1	1 (day)	30 days
Add	P-Ephed HCl/Chlor-Mal/Scop Oral 90-8-2.5mg Tab. SR 12H	1	1 (day)	30 days
Add	D-Methorphan HB/P-Epd HC/BPM Oral 5-15-1mg/5 Elixir	1	1 (day)	30 days

Add	P-Ephed HCl/Br-Phenir Mal Oral 15-1mg/5ml Elixir	1	1 (day)	30 days
Add	Carbinoxamine Maleate Oral 8mg Tablet	1	1 (day)	30 days
Add	D-Methorphan HB/APAP/CP Oral 15-325-4mg Capsule	1	1 (day)	30 days
Add	Car-B-Pen TA/Chlor-Tan Oral 60-5mg Tablet	1	1 (day)	30 days
Add	Propofol Intraven. 10mg/ml Ampul	1	1 (day)	18 years
Add	Propofol Intraven 10mg/ml Vial	1	1 (day)	18 years
Add	Propofol Intraven 10mg/ml Disp Syrin	1	1 (day)	18 years
Add	Chlorpheniramine Maleate Oral 4mg Capsule	1	1 (day)	30 days
Add	Acetaminophen/Phenyltolx Cit Oral 500-60mg Tablet	1	1 (day)	30 days
Add	Pseudoephedrine HCl/Chlor-Mal Oral 15-1mg/5ml Syrup	1	1 (day)	30 days
Add	Doxycycline Hyclate Oral 20mg Tablet	1	1 (day)	8 years
Add	Doxycycline Hyclate Oral 100mg Tablet	1	1 (day)	8 years
Add	Doxycycline Hyclate Oral 50mg Tablet	1	1 (day)	8 years
Add	P-Ephed HCl/Pyr Ma/P-Tlox/Pnm Oral 40-8-8-8mg Caps SA	1	1 (day)	30 days
Add	P-Ephed HCl/Pyr Ma/P-Tlox/Pnm Oral 80-16-16mg Caps SA	1	1 (day)	30 days
Add	Acetaminophen/Phenyltolx Cit Oral 325-60mg Tablet	1	1 (day)	30 days
Add	Brompheniramine Maleate Oral 6mg Tab.SR 12H	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/Carbinox Oral 4-15-1/MI Drops	1	1 (day)	30 days
Add	D-Methorphan HB/P-Epd HCl/BPM Oral 15-45-4/5 Syrup	1	1 (day)	30 days
Add	P-Ephed HCl/Carbinox Mal Oral 15-1mg/ml Drops	1	1 (day)	30 days
Add	P-Ephed HCl/Brompheniramin Oral 45-4mg/5ml Syrup	1	1 (day)	30 days
Add	DM HB/P-Ephed HCl/Carbinox Oral 15-15-2/5 Syrup	1	1 (day)	30 days
Add	D-Methorphan HB/PE/Chlorphenir Oral 15-10-2/5 Syrup	2	1 (day)	16 years
Add	Tramadol HCl/Acetaminophen Oral 37.5-325mg Tablet	1	1 (day)	16 years
Add	Guaifen/P-Ephed HCl/D-Cp Oral 100-20-2/5 Expect.	1	1 (day)	30 days
Add	E-phed HCl/Carbinox Mal Oral 25-2mg/ml Drops	1	1 (day)	30 days
Add	E-phed HCl/Carbinox Mal Oral 60-4mg Tablet	1	1 (day)	30 days
Add	E-phed HCl/Carbinox Mal Oral 120-8mg Tab.SR 12H	1	1 (day)	30 days
Add	HC/Resor/Bismuth Subgal/Znox Ractal 2.5% Cream(GM)	1	1 (day)	16 years
Add	HC/Resor/Bismuth Subgal/Znox Ractal 25mg Supp.Rect	1	1 (day)	16 years

Add	Pyril Mal/Phenyltolox/Phenir Oral 4-4-4mg/5 Elixir	1	1 (day)	30 days
Add	Guaifen/Kg/DM/Pyril/Sodium Cit Oral 10-10-200 Liquid	1	1 (day)	30 days
Add	Guaifen/D-Methorphan HB/BPM Oral 200-15-2/5 Liquid	1	1 (day)	30 days
Add	Guaifen/DM HB/P-Ephedrine/D-BP Oral 30-30-1/10 Liquid	1	1 (day)	30 days
Add	Ribavirin Oral 200mg Capsule	1	1 (day)	16 years
Add	Guaifen/DM HB/P-Ephedrine/BPM Oral 50-5-30-2 Syrup	1	1 (day)	30 days
Add	D-Methorphan HB/P-Epd HCl/BPM Oral 4-15-1mg/1 Drops	1	1 (day)	30 days
Add	P-Ephed HCl/Brompheniramin Oral 15-1mg/ml Drops	1	1 (day)	30 days
Add	D-Methorphan HB/P-Ephed HCl/CP Oral 15-15-2/5 Syrup	1	1 (day)	30 days
Add	D-Methorphan HB/P-Ephed HCl/CP Oral 5-15-1mg/5 Syrup	1	1 (day)	30 days
Update	Amiodarone HCl Intraven. 50mg/ml Ampul	2	1 (day)	16 years
To	Amiodarone HCl Intraven. 50mg/ml Ampul	1	1 (day)	16 years
Delete	Isotretinoin Oral 10mg Capsule	1	1 (day)	16 years
Delete	Isotretinoin Oral 20mg Capsule	1	1 (day)	16 years
Delete	Isotretinoin Oral 40mg Capsule	1	1 (day)	16 years

UNDERUTILIZATION ALERT (LR)

<u>Transaction</u>	<u>Description</u>
Add	Candesartan Cilexetil/HCTZ Oral 16-12.5mg Tablet
Add	Candesartan Cilexetil/HCTZ Oral 32-12.5mg Tablet
Add	Telmisartan Oral 20mg Tablet
Add	Telmisartan/HCTZ Oral 80-12.5mg Tablet
Add	Telmisartan/HCTZ Oral 40-12.5mg Tablet
Add	Nateglinde Oral 120mg Tablet
Add	Nateglinde Oral 60mg Tablet
Add	Gabapentin Oral 250mg/5ml Solution
Add	Quinapril HCl/HCTZ/Mag Carb Oral 20-12.5mg Tablet

Add	Quinapril HCl/HCTZ/Mag Carb Oral 10-12.5mg Tablet
Add	Quinapril HCl/HCTZ/Mag Carb Oral 20-25mg Tablet
Add	Valsartan Oral 320mg Tablet
Add	Guaifenesin/Dyphylline Oral 100-100/15 Elixir

OVERUTILIZATION ALERT (ER)

<u>Transaction</u>	<u>Description</u>
Add	Telmisartan Oral 20mg Tablet
Add	Hydrocodone Bitartrate/APAP Oral 5-325mg Tablet
Add	Hydrocodone Bitartrate/APAP Oral 7.5-325mg Tablet
Add	Oxtriphylline Miscell. Powder
Add	Gabapentin Oral 250mg/5ml Solution
Add	Oxacarbazepine Oral 300mg/5ml Oral Susp
Add	Hydrocodone Bitartrate/APAP Oral 10-250mg Tablet
Add	Hydromorph HCl/Na Chlor 0.9% Injection 0.2mg/ml Disp Syrin
Add	Hydromorph HCl/Na Chlor 0.9% Injection 1mg/ml Disp Syrin
Add	Morphine Sulfate/D5W Injection 2mg/ml Disp Syrin
Add	Hydromorph HCl/Na Chlor 0.9% Injection 0.2mg/ml Plast. Bag
Add	Meperidine HCl/Na Chlor 0.9% Injection 10mg/ml Plast. Bag
Add	Morphine Suldate/Na Chlor 0.9% Injection 1mg/ml Plast. Bag
Add	Fentanyl/Bupivac HCl/Na 0.9% Injection 5-625mcg/1 Plast. Bag
Add	Fentanyl/Bupivac HCl/Na 0.9% Injection 4-625mcg/1 Plast. Bag
Add	Fentanyl/Bupivac HCl/Na 0.9% Injection 2-1250mcg Plast. Bag
Add	Fentanyl/Bupivac HCl/Na 0.9% Injection 2-1000mcg Plast. Bag
Add	Fentanyl/Bupivac HCl/Na 0.9% Injection 5-1000mcg Plast. Bag
Add	Fentanyl/Bupivac HCl/Na 0.9% Injection 5-1250mcg Plast. Bag
Add	Fentanyl Citrate/Na Chlor 0.9% Injection 10mcg/ml Plast. Bag
Add	Fentanyl Citrate/Na Chlor 0.9% Injection 5mcg/ml Disp Syrin
Add	Hy-Morph HCl/Bupiv HCl/Na 0.9% Injection 20-1250mcg Plast. Bag

Add Hy-Morph HCl/Bupiv HCl/Na 0.9% Injection 20-600mcg Plast. Bag

Add Fentanyl Citrate/Na Chlor 0.9% Injection 2mcg/ml Plast. Bag

Add Fentanyl Citrate/Na Chlor 0.9% Injection 5mcg/ml Plast. Bag

Add Fentanyl Citrate/Na Chlor 0.9% Injection 20mcg/ml Plast. Bag

Add Fentanyl/Bupivac HCl/Na 0.9% Injection 4-1000mcg Plast. Bag

Add Fentanyl/Bupivac HCl/Na 0.9% Injection 5-375mcg/1 Plast. Bag

Add Fentanyl/Bupivac HCl/Na 0.9% Injection 10-1000mcg Plast. Bag

Add Fentanyl/Bupivac HCl/Na 0.9% Injection 20-2500mcg Plast. Bag

Add Hydromorph HCl/Na Chlor 0.9% Injection 1mg/ml Plast. Bag

Add Morphine Sulfate/Na Chlor 0.9% Injection 0.1mg/ml Plast. Bag

Add Morphine Sulfate/D5W Injection 1mg/ml Plast. Bag

Add Gabapenting Miscell. Powder

Add Theophylline/Potassium Iodide Oral 80-130-15 Elixir

Add Theophylline/Ephed HCl/Phenobarb Oral 130-24-8mg Tablet

Add Guaifenesin/Dyphylline Oral 100-100/15 Elixir

Add Guaifenesin/Oxtriphylline Oral 150-300/15 Elixir

Add Guaifenesin/Hydromorphone HCl Oral 100-1mg/5 Syrup

Add Phenylephrine/Cod/CP/Pot Iod Oral 2.5-5-75/5 Syrup

Add Codeine/Promethazine HCl Oral 10-6.25/5 Syrup

Add Codeine Phosphate/Br-DPHA HCl Oral 10-12.5/5 Syrup

Add Hydrocod Bit/Homatropine Oral 5-1-.5mg/5 Syrup

Add Hydrocod PSX/Chlor-Poli Oral 10-8mg/5ml Sus.12H SR

Add Phenylephrine HCl/Cod/Prometh Oral 5-10-6.25 Syrup

Add Phenylephrine/Hydrocod Bit/Pyr Oral 5-1.66mg/5 Syrup

Add P-Ephed HCl/Cod/Chlorphenir Oral 30-10-2/5 Liquid

Add P-Ephed HCl/Hydrocod Bit Oral 60-5mg Tablet

Add Codeine Phos/Carisoprodol/ASA Oral 16-200-325 Tablet

Add P-Ephed HCl/Hydrocod Bit/CP Oral 30-2.5-2/5 Syrup

Add Guaifen/P-Ephed HCl/Hcod/CP Oral 15-2.5-2/5 Liquid

Add Phenylephrine/Hydrocod Bit/CP Oral 7.5-2-2/5 Syrup

Add	Phenylephrine/Hydrocod Bit/CP Oral 7.5-3.5-2 Syrup
Add	Guaifenesin/Phenylephrine/Cod Oral 125-4-12.5 Syrup

THERAPEUTIC DUPLICATION (TD)

<u>Transaction</u>	<u>Description</u>
Add	Drug Tx-Chronic Inflamm. Colon Dx, 5-Aminosalicylat

DRUG/DRUG INTERACTION (DD)

<u>Transaction</u>	<u>Description</u>	<u>Severity</u>
Add	Guanethidine, Guanadrel/Tricyclic Compounds	1
Add	Selected Phenothiazines/Selected Beta-Blockers	1
Add	Methamphetamine/Sulfonamides	1
Add	Sympathomimetics/MAOIs; Furazolidone	1
Add	Tri;Tetracyclic Compounds/MAOIs; Furazolidone	1
Add	Selected Narcotics/MAOIs; Furazolidone	1
Add	Meperidine:Dextromethorphan/MAOIs; Furazolidone	1
Add	Levodopa/MAOIs; Furazolidone	1
Add	Buspirone/Monamine Oxidase Inhibitors; Furazolidone	1
Add	Neuromuscular Blocking Agents/Quinine	1
Add	Succinylcholine/Trimethaphan	1
Add	SSRI's/MAOIs; Furazolidone	1
Add	Theophylline/Halothane	1
Add	Misc Antifungal Agents/Nonsedating Antihistamines	1
Add	Nonsedating Antihistamines/ Macrolide Antibiotics	1
Add	Contraceptives, Oral/Troleandomycin	1
Add	Metrizamide/Phenothiazines	1
Add	Metyrapone/Cyproheptadine	1
Add	Cisapride/Azole Antifungal Agents	1

Add	Cisapride/Selected Macrolide Antibiotics	1
Add	Nonsedating Antihistamines/SSRI's;Nefazodone	1
Add	Ketorolac/Probenecid	1
Add	Nefazodone; Fluvoxamine/Cisapride	1
Add	Nelfinavir; Ritonavir/Amiodarone	1
Add	Amprenavir; Ritonavir/Bepridil	1
Add	Ritonavir/Bupropion	1
Add	Protease Inhibitors/Cisapride	1
Add	Ritonavir/Clozapine	1
Add	Selected Protease Inhibitors/Flecainide	1
Add	Ritonavir/Meperidine	1
Add	Protease Inhibitors/Medazolam; Triazolam	1
Add	Selected Protease Inhibitors/Propafenone	1
Add	Ritonavir/Propoxyphene	1
Add	Ritonavir/Zolpidem	1
Add	Dexfenfluramine; Fenfluramine/Serotonergic Agents	1
Add	Selected Azoles/Select HMG-CoA Reductase Inhibitors	1
Add	5HT-1D Agonists/Ergotamines; Methysergide	1
Add	Selected Azole Antifungals/Selected Benzodiazepines	1
Add	Selected Quinolones/Class 1A & III Antiarrhythmics	1
Add	Grepafloxacin; Sparfloxacin/Erythromycin	1
Add	Grepafloxacin; Sparfloxacin/Nonsedating Antihistamines	1
Add	Grepafloxacin; Sparfloxacin/Cisapride	1
Add	Grepafloxacin; Sparfloxacin/Pentamidine	1
Add	Grepafloxacin; Sparfloxacin/Tricyclic Compounds	1
Add	Grepafloxacin; Sparfloxacin/Phenothiazines	1
Add	Metformin/Iodinated Contrast Materials	1
Add	Live Vaccines/Antibiotics	1
Add	Astemizole; Terfenidine/Mibefradil	1
Add	Cisapride/Selected Calcium Channel Blockers	1

Add	Naltrexone/Opioid Analgesics	1
Add	Acitretin/Methotrexate	1
Add	Ketorolac/NSAID; Aspirin	1
Add	Apraclonidine; Brinonidine/MAOI's	1
Add	Bupropion/MAOI's	1
Add	Cabergoline; Perfolide/Antipsychotics	1
Add	Cabergoline/Metoclopramide	1
Add	Hormonal Contraceptive Agents/Nevirapine	1
Add	Aspirin, Papaveretum/MAOI's	1
Add	Grepafloxacin; Sparfloxacin/Bepriidil	1
Add	Mibefradil/Selected Agents	1
Add	Sibutramine/MAOI's	1
Add	Sibutramine/Serotonergic Agents	1
Add	Sibutramine/Select Opioids	1
Add	Sibutramine/Lithium	1
Add	Sibutramine/Tryptophan	1
Add	Protease Inhibitors/Pimozide	1
Add	Protease Inhibitors/Ergot Derivatives	1
Add	Tobramycin Inh/Selected Diuretics	1
Add	Halofantrine/Antimalarials	1
Add	Halofantrine/Tricyclic Compounds	1
Add	Halofantrine/Antipsychotics	1
Add	Halofantrine/Class I and III Antiarrhythmics	1
Add	Halofantrine/Astemizole; Terfenadine	1
Add	Saquinavir Base/Ergot Derivatives	1
Add	Pimozide/Phenothiazines	1
Add	Pimozide/Class I and III Antiarrhythmics	1
Add	Pimozide/Tricyclic Compounds	1
Add	Mefloquine/Chloroquine; Quinidine; Quinine	1
Add	Sildenafil/Nitrates	1

Add	Mizolastine/Selected Class I and III Antiarrhythmics	1
Add	Arbutamine/Selected Antiarrhythmics	1
Add	Arbutamine/Atropine	1
Add	Arbutamine/Tricyclic Compounds	1
Add	Arbutamine/Beta-Blockers	1
Add	Cisapride/Selected Class IA & III Antiarrhythmics	1
Add	Cisapride/Tricyclic & Tetracyclic Compounds	1
Add	Cisapride/Certain Antipsychotics	1
Add	Cisapride/Potassium Wasting Diuretics	1
Add	Methotrexate/Asparaginase	1
Add	Altretamine; Cisplatin/Pyridoxine	1
Add	Dipyridamole Injectable/Xanthine Derivatives	1
Add	Carbamazepine/MAOI's	1
Add	Astemizole; Terfenadine/Efavirenz	1
Add	Midazolam; Triazolam/Efavirenz	1
Add	Cisapride/Efavirenz	1
Add	Ergotamine Derivatives/Efavirenz	1
Add	Sertindole/Quinidine	1
Add	Sertindole/Thioridazine	1
Add	Sertindole/Itraconazole; Ketoconazole	1
Add	Sertindole/Astemizole; Terfenadine	1
Add	Fosphenytoin; Phenytoin/Azapropazone	1
Add	Alitretinoin; Bexarotene/Diethyltoluamide (DEET)	1
Add	Miglitol/Amylase: Pancreatin	1
Add	Entacapone; Tolcapone/MAOI's	1
Add	Pimozide/Selected Macrolide Antibiotics	1
Add	Indoramin/MAOI's; Furazolidone	1
Add	Bethanidein/MAOI's; Furazolidone	1
Add	Dexfenfluramine; Fenfluramine/MAOI's; Furazolidone	1
Add	Selected Protease Inhibitors/Rifampin	1

Add	Astemizole/Quinine	1
Add	Selected 5HT-1D Agonists/MAOI's	1
Add	Ritonavir/Piroxicam	1
Add	Saquinavir/Rifabutin	1
Add	Nelfinavir; Ritonavir/Quinidine	1
Add	Protease Inhibitors/Nonsedating Antihistamines	1
Add	Halothane/Rifampin	1
Add	Methoxyflurane/Barbituates	1
Add	Pimozide/Selected Azole Antifungals	1
Add	Pimozide/Nefazodone	1
Add	Pimozide/Zileuton	1
Add	Quinidine/Itraconazole	1
Add	Selected Antiarrhythmics/Quinupristin	1
Add	Astemizole; Terfenadine/Quinupristin	1
Add	Cisapride/Quinupristin-Dalfopristin	1
Add	Clarithromycin; Erythromycin/Quinupristin-Dalfopristin	1
Add	Haloperidol; Pimozide/Quinupristin-Dalfopristin	1
Add	Sirolimus/Ketoconazole	1
Add	Dofetilide/Verapamil	1
Add	Dofetilide/Cimetidine	1
Add	Dofetilide/Trimethoprim	1
Add	Dofetilide/Ketoconazole	1
Add	Dofetilide/Prochlorperazine	1
Add	Dofetilide/Megestrol	1
Add	Dofetilide/Class I and III antiarrhythmics	1
Add	Selected Protease Inhibitors/St. John's Wort	1
Add	Cisapride/Cimetidine	1
Add	Propylene Glycol/Disulfiram	1
Add	Propylene Glycol/Metronidazole	1
Add	Mycophenolate/Cholestyramine	1

Add	Zidovudine/Ribavirin	1
Add	Thioridazine/Selected SSRI's	1
Add	Delavirdine/Rifampin; Rifabutin	1
Add	Ketoconazole/Nevirapine	1
Add	Lovastatin; Simvastatin/ Selected Protease Inhibitors	1
Add	Mifepristone/Corticosteroids	1
Add	Mifepristone/Anticoagulants	1
Add	Cerivastatin/Fibrates	1
Add	Live Viral Vaccines/Alemtuzumab	1
Add	Ziprasidone/Selected Antiarrhythmics	1
Add	Ziprasidone/Pimozide; Thioridazine	1
Add	Ziprasidone/Moxifloxacin; Sparfloxacin	1
Add	Thioridazine/QT Prolongating Agents	1
Add	Bepidil/QT Prolongating Agents	1
Add	Ziprasidone/QT Prolongating Agents	1
Add	Mesoridazine/QT Prolongating Agents	1
Add	Pimozide/QT Prolongating Agents	1
Add	Halofantrine/ QT Prolongating Agents	1
Add	Sparfloxacin/ QT Prolongating Agents	1
Add	Levomethadyl/ QT Prolongating Agents	1
Add	Nefazodone/Carbamazepine	1
Add	Stavudine/Zidovudine	1
Add	Zidovudine/Doxorubicin	1
Add	Warfarin/Imatinib	1
Update	Dofetilide/Ketoconazole	1
To	Dofetilide/Itraconazole; Ketoconazole	1
Update	Pimozide/Nefazodine	1
To	Pimozide/Fluvoxamine; Nefazodine	1

Delete	Ritonavir/Bupropion	1
Delete	Ritonavir/Meperidine	1
Delete	Ritonavir/Propoxyphene	1
Delete	Ritonavir/Zolpidem	1
Delete	Selected Narcotics/MAOI's; Furazolidone	1

HIGH DOSE INTERACTION (HD)

<u>Transaction</u>	<u>Description</u>	<u>Unit Quantity</u>
Add	Glyburide/Metformin HCl Oral 2.5-500mg Tablet	4
Add	Meloxicam Oral 15mg Tablet	1
Add	Gluburide/Metformin HCl Oral 1.25-250mg Tablet	8
Add	Glyburide/Metformin HCl Oral 5-500mg Tablet	4
Add	Metformin HCl Oral 500mg Tab. SR 24H	4
Add	Nateglinide Oral 120mg Tablet	3
Add	Nateglinide Oral 60mg Tablet	6
Add	Diltiazem HCL Oral 360mg Cap. SR 24H	1
Add	Ibuprofen Oral 200mg Capsule	12
Add	Glipizide Oral 2.5mg Tab SA OSM	16
Delete	Omeprazole Oral 20mg Capsule DR	8
Delete	Omeprazole Oral 40mg Capsule DR	8
Delete	Lansoprazole Oral 30mg Capsule DR	8
Delete	Omeprazole Oral 10mg Capsule DR	8
Delete	Lansoprazole Oral 15mg Capsule DR	8



October 2000
Volume 3, Issue 3

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Indiana Medicaid DUR Board
402 West Washington Street
Room W382
Indianapolis, Indiana 46204

Indiana Medicaid Drug Utilization Review Board Newsletter

Generic vs. Branded Drug Products

The rise in the cost of prescription drugs is a major concern to the health care industry. In Indiana, the cost of providing prescription drug services for traditional Medicaid members has risen dramatically. The increase in prescription drug costs for traditional Medicaid members between State Fiscal Year 1999 and State Fiscal Year 2000 was 23% for the one-year period. The "State Fiscal Year" (SFY) is the time period from July 1 of the previous year, to June 30 of the fiscal year. SFY 2000 figures includes expenditures from July 1, 1999 to June 30, 2000.

In the last three years, expenditures for prescription drugs to traditional Medicaid members have risen over 62%. The goal of providing prescription drug services that are effective as well as economical is a major focus for the Office of Medicaid Policy and Planning, as well as the Indiana Medicaid DUR Board, when overseeing the prescription benefit costs of its members. Legislation is in effect that requires a pharmacist to substitute generically equivalent drug products in place of the brand name drug products to a traditional Medicaid member, where the substitution would result in a lower price (IC 16-42-22). According to IC 16-42-22-7, if a prescription is filled under the Medicaid program (42 U.S.C. 1396 et seq.), the pharmacist is required to substitute a generically equivalent drug product unless the words "Brand Medically Necessary" are written in the prescriber's own handwriting on the form. This mandatory substitution provides significant savings to the program, as it requires the pharmacist to dispense and bill a generic drug product, which can be one-fifth of the cost of a

brand name drug. However, when "Brand Medically Necessary" (BMN) is written on the prescription by the prescribing physician, the program pays the cost of the higher brand name drug product.

A report from The Medstat Group, to members of the Indiana Medicaid DUR Board on September 8, 2000, reported the incidence of "Brand Medically Necessary" (BMN) overrides, during SFY 1999. BMN overrides were submitted on 246,322 pharmacy claims, which consists of 3% of the total number of prescription claims submitted for the year. The average paid amount for claims with BMN overrides was \$66.10, which is 55% higher than the average per claim amount for the entire traditional Medicaid drug program. It is estimated that because of BMN overrides, an additional \$5.7 million was paid by the program to provide brand name drugs over cheaper generic alternatives.

The Cost of Brand vs. MAC Drugs

The State of Indiana is able to take advantage of another program that was developed to assure cost effective prescription drug programs for Medicaid members through the utilization of a multiple source drug products listing, provided by the Health Care Financing Administration (HCFA). HCFA creates the listing, which identifies and sets upper price limits for multiple source drug products that meet certain requirements. All the formulations of the multiple source drug products must be evaluated by the FDA as being therapeutically equivalent and classified as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*. The multiple source drug products must also have at least three

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suppliers that list the drug for sale nationally. The upper price limits are established by HCFA for each multiple source product and is equal to 150% of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in common quantities. These upper price limits are called "Federal Upper Limits" (FUL), and are sometimes referred to as MAC (Maximum Allowable Cost) rates. Traditional Medicaid claims submitted for services that include these multiple source drugs are automatically paid at the lower of the pharmacy's usual and customary charge, or the FUL rate for the drug quantity, plus a professional fee. The Average Wholesale Price of a multiple source drug is not considered in calculating a Medicaid allowable, unless the prescribing physician indicates in writing, that the prescription is for Brand Medically Necessary, in which case, the BMN override, discussed earlier, is in effect.

In the report from The Medstat Group to members of the Indiana Medicaid DUR Board on September 8, 2000, the number of pharmacy drug claims for multiple source drugs with FUL was reported at 2,754,672 claims, or 34% of all prescription drug claims paid for SFY 1999. The average cost per claim for multiple source drugs with FUL was \$13.83, or one-third of the cost of the average legend drug claim in the traditional Medicaid drug program. BMN overrides for multiple source drugs with FUL accounted for nearly 75,000 prescriptions, with an average cost per claim at \$42.26. It is likely that an additional \$2.1 million was paid by the program to provide brand name drugs in place of the therapeutically equivalent, multiple source drug product with FUL.

The lost opportunities for reducing the incidence of BMN overrides and allowing the Indiana Medicaid prescription drug program pay pharmacy providers the lower generic or FUL rate may stem from concerns about generic drug products. The remainder of this article will address this concern and respond with information from the Food and Drug Administration that is

supportive of generic drug product substitution.

Is There a Therapeutic Difference?

The Food and Drug Administration (FDA) is aware of the public and professional concerns about whether or not generic drugs are therapeutically equivalent to brand name, or innovator, drugs. It is their responsibility to assess the quality of products in the marketplace and thoroughly research and evaluate reports of alleged drug product inequivalence. For both brand-name and generic drugs, the FDA works with pharmaceutical companies to assure that all the drugs marketed in the United States meet specifications for identity, strength, quality, purity and potency. In the process of approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and conditions of use. The brand-name drug products and therapeutically equivalent generic drug products are identified in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," more commonly called the "Orange Book." To date, the FDA is not aware of any documented occurrence where a generic product listed in the Orange Book could not be used interchangeably with the corresponding brand name drug. Although there have been concerns in the past that were brought to the FDA's attention regarding brand name and generic products, post-market testing performed by the FDA on many of these drugs revealed compliance to established standards of purity and quality. Reports of increased incidence of adverse symptoms, decreased efficacy, and increased toxicity, which were related to substitution of one drug product for another have been investigated by the FDA. The FDA's results in these investigations were that the problems reported were not attributed to the substitution of one approved drug product for another.

When a generic drug is presented for market to the FDA, the generic drug manufacturer is not required to conduct the same clinical trails that were performed in the development of the brand name, or innovator, drug. Instead the generic drug company is required to show that their product is bioequivalent to the innovator drug. Scientific studies are performed to assure that the generic version of the drug delivers the same amount of active ingredient into the patient's bloodstream, and in the same time as the innovator drug. Generic drugs that fall into acceptable parameters for bioavailability when compared to the innovator drug are considered therapeutically equivalent. Such testing is not any different than what is required by the FDA from any innovator drug company when that company changes their innovator drug formulation, changes their manufacturing site, or changes their manufacturing processes after their drug is in the marketplace.

What About Narrow Therapeutic Index (NTI) Drugs?

There are drugs in the marketplace that may be described in FDA approved labeling as narrow therapeutic range drugs. These drugs are products in which small changes in the dose and/or blood concentration could change their clinical efficacy or safety. Such products are characterized as requiring frequent adjustments in dosing and careful monitoring of the drugs' concentrations in the bloodstream, or the clinical effect in the patient, that is irrespective of whether the drug is a brand or generic drug product.

In the course of reviewing a product's therapeutic equivalence, the FDA may recommend to the manufacturer additional tests for approval. The tests are recommended regardless of whether the drug is a brand or generic drug product, and depends on the complexity of the drug product or substance, and if the drug is considered a NTI product. The FDA's recommendation to the manufacturer for these additional tests is

Continued on Page 3

designed to give the practitioner and patient additional assurance of product quality and interchangeability and reduce the clinical scrutiny that might exist when therapeutic interchange occurs.

FDA Concludes Therapeutic Equivalence between Generic and Brand Drugs

Based on the evidence of scientific research and analysis performed in determining the therapeutic equivalence of brand and generic drug products, the FDA concludes that:

1. Additional testing or examinations, such as drug concentration levels in the bloodstream, are not necessary when a generic drug product is substituted for the brand-name product.
2. Special precautions are not needed when a formulation and/or manufacturing change occurs for a drug product, provided that the change has received approval by the FDA in accordance to applicable laws and regulations.
3. Products evaluated by the FDA and determined therapeutically equivalent as noted in the Orange Book publication, can be expected to have equivalent clinical effect, regardless of whether the product is a brand or generic drug.
4. It is not necessary to consider any one therapeutic class of drug products different from any other class, when the FDA has determined therapeutic equivalence exists for the drug products under consideration.

What if I Observe a Difference between Generic and Brand Drugs that are considered Therapeutically Equivalent?

The FDA has a medical product reporting program called MedWatch that was developed to provide opportunities for health care professionals to voluntarily report adverse events and product problems.

The program is designed to educate professionals about the importance of identifying, monitoring, and reporting adverse events and problems to the FDA concerning drugs, biologicals, medical and radiation-emitting devices, and special nutritional products, and to ensure that new safety information is rapidly communicated to the medical community that would improve patient care. The purpose of the program is to enhance the effectiveness of post-marketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

Prescribers who observe inequivalence in drug products that are considered therapeutically equivalent to innovator drugs should contact the FDA MedWatch program to report the concern. Persons can contact the MedWatch program to report any generic inequivalency problems in the following ways:

1. Contact the MedWatch program by mail using the postage-paid MedWatch form, provided by the FDA or downloaded from their website (www.fda.gov).
2. Contact the MedWatch program by phone at 1-800-FDA-1088.
3. A MedWatch form can be faxed at 1-800-FDA-0178.
4. A MedWatch form can be completed on the internet by accessing the FDA website at www.FDA.gov

Conclusion:

Awareness of the FDA’s commitment to assuring therapeutic equivalence between brand and generic drug products is intended to enhance the confidence of health care providers and patients about the quality, purity, and pharmacological effect of brand and generic drug products. The FDA wants to assure patients an health care professionals that the generic drug products that are available to patients deliver safe and effective drug therapy that is cost efficient.

The Indiana Medicaid DUR Board

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You may contact that Board by e-mail when you access the Indiana Medicaid Website at WWW.IndianaMedicaid.com. Click on the DUR Board link and then select the “How to Contact the Board” button. The page allows you to send comments or questions through e-mail to members of the Board.

DUR Board Calendar

December 8, 2000
9:30 am, Indiana Government Center, South Conference Center Room A
DUR Board Meeting

- Meeting Dates for 2001:**
(Locations to be Announced)
- **March 9, 2001**
 - **June 8, 2001**
 - **September 14, 2001**
 - **December 14, 2001**

For more information call Ms. Karen Baer at (317) 232-4391

IC 16-42-22-7 Medicaid or Medicare prescriptions; substitution of generically equivalent drug product

Sec. 7. If a prescription is filled under the Medicaid program (**42 U.S.C. 1396 et seq.**) or the Medicare program (**42 U.S.C. 1395 et seq.**) the pharmacist shall substituted a generically equivalent drug product unless the words “Brand Medically Necessary” are written in the practitioner’s own writing on the form.

Note: As added by P.L. 2-1993, SEC.25

Pro-DUR Alerts for September 2000

A review of the Pro-DUR alerts that were set during the month of September 2000 disclose interesting trends in prescriptions for patients receiving Non-steroidal anti-inflammatory agents (NSAIDs), and drug therapy compliance for patients with epilepsy, diabetes, high blood pressure, and asthma.

In September, 12,886 claims for NSAIDs were screened to reveal that nearly 5% of them hit a high dose alert. Most of the high dose alerts pertained to prescriptions for ibuprofen and naproxen. High dose alerts were applied to prescriptions for ibuprofen, with daily doses greater than 3.2grams, and naproxen, with daily doses greater than 1.5 grams. Only 7% of the responses to the high dose alerts resulted in cancellations of the prescriptions. Pharmacists overrode 93% of the alerts and dispensed the medications.

Nearly 4.5% of all NSAID prescription claims also hit a therapeutic duplication alert. Therapeutic duplication alerts are issued to NSAID prescriptions when recipients are concurrently prescribed another NSAID product.

Pro-DUR alerts pertaining to late refills were reviewed for September 2000. Late refill alerts on anticonvulsants, oral hypoglycemics, ACE inhibitor/hypotensive agents, and xanthines were reviewed to determine compliance to drug therapy.

Approximately 23% of the 26,958 anticonvulsant prescriptions hit late refill alerts. The majority of drug therapies included divalproex sodium, gabapentin, phenytoin, and carbamazepine. Approximately 19% of the 6,854 oral hypoglycemic prescriptions hit late refill alerts. The majority of drug therapies included glipizide and glyburide. Approximately 18% of the 17,770 ACE inhibitor hypotensive prescriptions hit later refill alerts. The majority of drug therapies included lisinopril, enalapril, and quinapril. And approximately 22% of

the 2,838 xanthine prescriptions hit late refill alerts. The majority of drug therapies included theophylline products.

Late refill alerts are issued when drug refills are dispensed beyond 125% of the days supply dispensed in the previous fill. Usually a late refill occurred when patients had requested their monthly refills a week late or greater.

The total prescription claims used in determining the late refill percentages includes new prescriptions and refills.

Indiana Medicaid Drug Formulary Requirements

Legend drug products included in the Indiana Medicaid Drug Formulary for Traditional Medicaid members meet the following requirements:

1. The manufacturers of the products have rebate agreements with HCFA.
2. Products are not categorized as a DESI 5 or 6.
3. Products are not agents used to promote weight loss, fertility enhancement, or cosmetic purposes.

Top 25 Drugs

The top 25 drug products based on the total dollars spent for first quarter 2000, represented \$22,194,888 in Indiana Medicaid payments to pharmacy providers. Antipsychotic agents topped the list with 6 products attributing to \$5,126,481 in Medicaid payments. Selective Serotonin Reuptake Inhibitors represented 4 products for \$3,038,418 in Medicaid payments. Gastrointestinal agents, Analgesics, and Anticonvulsants were the last 3 groups, representing \$4,501,987, \$2,176,489, and \$1,898,533 in Medicaid payments, respectively.

Top 25 Drugs by the Total Dollars Paid for 2Q2000

Drug Product	Total Claims	Quantity Dispensed	Total Payment
1. Zyprexa 10mg Tablet	6,632	319,066 Tabs	\$2,417,121
2. Prilosec 20mg Capsule	17,705	656,662 Caps	\$2,403,096
3. Recombinate 220-400 Vial	359	2,451,196 U	\$2,219,184
4. Prevacid 30mg Capsule	13,359	484,290 Caps	\$1,676,288
5. Prozac 20mg Pulvule	12,206	562,004 Caps	\$1,303,969
6. Novoseven 48000mcg Vial	137	1,140,875 mcg	\$1,179,887
7. Celebrex 200mg Capsule	11,958	487,960 Caps	\$1,062,940
8. Depakote 500mg Tab EC	6,851	588,381 Tabs	\$837,227
9. Neurontin 300mg Capsule	6,095	632,151 Caps	\$649,730
10. Risperdal 1mg Tablet	5,625	289,005 Tabs	\$641,422
11. Paxil 20mg Tablet	8,063	288,929 Tabs	\$624,970
12. Synagis 100mg Vial	340	832 Vials	\$600,972
13. Claritin 10mg Tablet	9,492	284,504 Tabs	\$590,990
14. Zyprexa 5mg Tablet	2,875	117,375 Tabs	\$587,755
15. Zoloft 100mg Tablet	7,078	276,595 Tabs	\$585,998
16. Vioxx 25mg Tablet	7,932	258,439 Tabs	\$583,303
17. Risperdal 3mg Tablet	2,460	126,147 Tabs	\$546,487
18. Ultram 50mg Tablet	10,895	734,607 Tabs	\$530,246
19. Zoloft 50mg Tablet	6,942	248,329 Tabs	\$523,481
20. Clozaril 100mg Tablet	3,109	164,293 Tabs	\$491,373
21. Lipitor 10mg Tablet	7,621	253,083 Tabs	\$446,567
22. Risperdal 2mg Tablet	2,391	120,456 Tabs	\$442,323
23. Pepcid 20mg Tablet	5,187	254,920 Tabs	\$422,603
24. Lipitor 20mg Tablet	4,551	154,816 Tabs	\$415,380
25. Depakote 250mg Tab EC	5,891	522,971 Tabs	\$411,576



March 2001
Volume 4, Issue 1

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Indiana Medicaid DUR Board
402 West Washington Street
Room W382
Indianapolis, Indiana 46204

Indiana Medicaid Drug Utilization Review Board Newsletter

Identifying Drug and Medical Product Problems and How to Report Them

Drug and medical products enter the healthcare market after thorough pre-market surveillance involving pre-clinical studies with animals and humans. Under the monitoring and oversight of the Food and Drug Administration (FDA), the United States has developed a reputation as having one of the most rigorous approval processes in the world.

While the purpose of pre-market clinical trials is to establish product safety and efficacy, there are intrinsic limitations that make it difficult for the clinical trials to detect or define the frequency of all important adverse events. Because of the limited exposure of pre-marketed drug and medical products to human subjects in clinical trials, some adverse events are not discovered until the products receive FDA approval and are prescribed to the general public in the post-market environment. The FDA has the regulatory responsibility for ensuring the safety of all marketed medical products. The major changes to the size and nature of the exposed patient population that occur once a medical product is made available for widespread use places great importance on post-marketing surveillance programs sponsored by the FDA for adverse event detection. Health professionals are critical to this process in that the first hint of a potential problem originates with the clinician, who reports the case to the appropriate source.

In an effort to simplify documentation and increase reporting, the FDA developed the MEDWatch program in 1993. The program was designed to emphasize the responsibility of healthcare providers to identify and report adverse events related to the use of medical products. The MEDWatch program encourages health professionals to report serious adverse events and product problems that occur with medical products such as drugs, biologics, medical and radiation-emitting devices, and special nutritional products. The health professional's involvement in this program is strictly voluntary, and entails completion of a one-page form that contains instructions needed for reporting the information pertinent to an adverse event.

Assessment of causality is not required, and suspicion that a medical product may be related to the adverse event is sufficient reason for the health professional to submit a MEDWatch report.

The MEDWatch form includes spaces for the health professional to report details of an adverse event or medical problem, such as a description of the reaction, laboratory information, and information on the patient's medical history. There is space for providing information on suspected drugs, with room for reporting up to two drugs in the event that the adverse event is due to a possible drug interaction. Space for reporting adverse event information on suspect medical devices is also included. Checklists are used throughout the form to categorize details of the adverse event.

The FDA requests that health professionals utilize the MEDWatch form to report any adverse or unusual occurrences with drug or biological products, medical devices, special nutritional products, or any other

product that is regulated by the FDA. The FDA is primarily interested in those events that have serious reactions. Serious events are identified as having one of the following outcomes:

- Death,
- Life-threatening complications,
- Hospitalization,
- Disability,
- Congenital anomaly, or
- Required intervention to prevent permanent impairment/damage.

The health professional should report any adverse event regardless of whether or not they are certain that the product caused the event, and regardless of whether or not they have all the details of the event. All information that is reported is kept in strict confidence by the FDA and that submission of a MEDWatch report does not constitute an admission that the medical personnel or the product caused or contributed to the event. Finally, the MEDWatch form should be used to report any concerns or problems with product quality, performance, or safety that arise from suspected contamination, questionable stability, defective components, and poor packaging or labeling.

Completed MEDWatch reports submitted from health professionals are individually reviewed by FDA health

MEDWatch Program Goals

1. To increase awareness of drug and device-induced disease.
2. To clarify what should (and should not) be reported to the agency.
3. To make it easier to report by operating a single system for health professionals to report adverse events and product problems to the agency.
4. To provide regular feedback to the health care community about safety issues involving medical products.

professional safety evaluators. Special attention is given to those reports that contain serious adverse events that are not noted in the product labeling, as in the case of pharmaceuticals. All other reports are entered into the database for use in aggregate analysis. From the review and research initiated from the reports, the FDA can issue the following actions:

- Publish a “Dear Health Professional” letter, or Safety Alert,
- Require labeling, name, or packaging changes,
- Conduct further epidemiologic investigations,
- Request manufacturer-sponsored post-market studies,
- Conduct inspections of manufacturers’ facilities and records, or
- Work with manufacturers regarding possible withdrawal of a medical products from the market.

The Indiana Medicaid Drug Utilization and Review (DUR) Board is supportive of the MEDWatch program and encourages all prescribing physicians, pharmacists, nurses and other health professionals to actively participate in adverse event reporting. The DUR Board has a special interest in the program because of the “Generic Substitution Law” that impacts the prescribing of pharmacy products for Medicaid members. While significant savings are experienced through the mandatory substitution of generic products in place of brand name products and with the list of products assigned Federal Upper Limits (FUL), provided by the Health Care Finance Administration (HCFA), the Board also encourages prescribers and pharmacists to report experiences with generic drug products that create concerns in product quality, performance, or safety. When a physician or pharmacist observes differences in the pharmacologic effect of a generic drug over its branded drug product in a patient, the health professional should report this concern to the FDA, using the MEDWatch form.

Safety profiles of medical products evolve over their commercial lifetime on the market. Even after several years of market use and experience, new occurrences with the product can be observed that can potentially change the future clinical use of the product in the healthcare market. As a result, it is important to continually monitor all medical products to assess their safety and efficacy in the circumstances for which they are indicated. This continual post-marketing surveillance occurs through the collection of adverse events reported through the MEDWatch program. Health professionals play an important role in the process of post-market surveillance to identify adverse events and report them to the FDA.

What is a Product Problem?

Product problems (defective or malfunctioning) should be reported when there is a concern about the quality, performance, or safety of any medication or device.

Problems with product quality may occur during manufacturing, shipping, or storage. They include product contamination; defective components; poor packaging or product mix-up; questionable stability; device malfunctions; and labeling concerns.

With drugs, the pharmacist is often the first to recognize a product quality problem. Nurses are often the first to recognize a problem with a medical device. Report these suspicions to the FDA through MEDWatch.

Confidentiality of MEDWatch Reports

The patient’s identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter’s identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter’s identity in response to a request from the public, pursuant to the Freedom of Information Act.

How to Report Using the MEDWatch Form

- Just fill in the sections that apply to your report.
- Use Section C for all products except medical devices.
- Attach additional clank pages if needed.
- Use a separate form for each patient.
- Report either to the FDA or the manufacturer (or both).

Mail Completed MEDWatch Form to the Following Address:

MEDWatch
 The FDA Medical Products Reporting Program
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD
 20852-9787

Important Numbers

- 1-800-FDA-0178 to FAX report.
- 1-800-FDA-7737 to report by modem.
- 1-800-FDA-1088 for more information or to report quality problems.
- 1-800-822-7967 for a Vaccine Adverse Event Reporting System (VAERS) form for vaccines.

What Is a Serious Adverse Event???

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported when the patient outcome is:

- **Death** – Report if the patient’s death is suspected as being a direct outcome of the adverse event.
- **Life-Threatening** – Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient’s death.
Example: Gastrointestinal hemorrhage; bone marrow suppression.
- **Hospitalization (Initial or Prolonged)** – Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.
Example: Anaphylaxis; pseudomembranous colitis.
- **Disability** – Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient’s body function/structure, physical activities or quality of life.
Example: Peripheral neuropathy; ototoxicity.
- **Congenital Anomaly** – Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.
Example: Vaginal cancer in female offspring from diethylstilbesterol during pregnancy.
- **Requires Intervention to Prevent Permanent Impairment or Damage** – Report if you suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.
Example: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage.

- Information from FDA MEDWatch Program Packet

The Indiana Medicaid DUR Board

G. Thomas Wilson, B.S. Pharm., J.D.
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Dr. Patricia Treadwell, M.D.
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You may contact that Board by e-mail when you access the Indiana Medicaid Website at WWW.IndianaMedicaid.com. Click on the DUR Board link and then select the "How to Contact the Board" button. The page allows you to send comments or questions through e-mail to members of the Board.

*Visit the Indiana Medicaid
DUR Board website at
www.indianamedicaid.com*

DUR Board Calendar

March 9, 2001
9:30 am, Indiana Government
Center, South
Conference Center Room A
DUR Board Meeting

June 8, 2001
9:30 am, Indiana Government
Center, South
Training Center Room 5
DUR Board Meeting

September 14, 2001
9:30 am, Indiana Government
Center, South
Conference Center Room C
DUR Board Meeting

December 14, 2001
9:30 am, Indiana Government
Center, South
Conference Center Room A
DUR Board Meeting

For more information call Ms.
Karen Baer at (317) 232-4391

Top 25 Drugs

The Top 25 drug products based on the total dollars spent for third quarter 2000, represented \$21,690,519 in Indiana Medicaid payments to pharmacy providers. This amount is 12% higher than a year ago for third quarter 1999. Antipsychotic agents topped the list with \$5,627,572 in paid Medicaid claims involving 7 drug products. Gastrointestinal agents followed with \$4,795,961 in paid Medicaid claims for 3 drug products. A Gastrointestinal agent, Prilosec, was the number one drug product prescribed for third quarter 2000 with 18,450 paid prescription claims to Medicaid members. Selective Serotonin Reuptake Inhibitors, COX-2 Inhibitors, and Anti-convulsants account for \$3,046,419, \$1,811,987, and \$1,491,893 of the Top 25 totals

Top 25 Drugs by the Total Dollars Paid for 3Q2000

Drug Product	Total Claims	Quantity Dispensed	Total Payment
1. Prilosec 20mg Capsule	18,450	694,112 Caps	\$2,546,005
2. Zyprexa 10mg Tablet	6,698	324,543 Tabs	\$2,467,589
3. Prevacid 30mg Capsule	14,360	522,025 Caps	\$1,808,015
4. Prozac 20mg Pulvule	11,928	543,259 Caps	\$1,289,650
5. Recombinate 220-400 VL	250	1,659,201 IU	\$1,248,233
6. Celebrex 200mg Capsule	12,843	534,843 Caps	\$1,165,198
7. Novoseven 4800mcg Vial	134	1,157,700 mcg	\$1,083,772
8. Depakote 500mg Tab EC	6,966	596,651 Tabs	\$857,812
9. Claritin 10mg Tablet	10,335	307,339 Tabs	\$651,636
10. Risperdal 1mg Tablet	5,571	291,474 Tabs	\$650,839
11. Vioxx 25MG Tablet	8,526	282,514 Tabs	\$646,790
12. Neurontin 300mg Cap	6,094	616,816 Caps	\$634,080
13. Paxil 20mg Tablet	8,184	291,136 Tabs	\$631,206
14. Zolof 100mg Tablet	7,260	286,088 Tabs	\$606,529
15. Zyprexa 5mg Tablet	2,958	120,057 Tabs	\$600,671
16. Risperdal 3mg Tablet	2,525	125,373 Tabs	\$548,052
17. Ultram 50mg Tablet	11,056	748,761 Tabs	\$541,775
18. Zolof 50mg Tablet	6,890	245,742 Tabs	\$519,035
19. Lipitor 10MG Tablet	8,045	268,337 Tabs	\$475,430
20. Oxycontin 40MG Tab SA	1,841	129,213 Tabs	\$470,706
21. Risperdal 2mg Tablet	2,537	127,843 Tabs	\$466,849
22. Clozaril 100mg Tablet	2,868	155,937 Tabs	\$463,857
23. Lipitor 20mg Tablet	4,820	164,208 Tabs	\$445,135
24. Pepcid 20mg Tablet	5,392	265,277 Tabs	\$441,940
25. Seroquel 100mg Tablet	2,774	192,878 Tabs	\$429,714

Summary of Prospective Drug Utilization Review Alerts

During the time period of October 12, 1999 to November 3, 2000, there were 946,422 pro-DUR alerts set from approximately 12 million drug claims submitted to the traditional Medicaid program for legend and non-legend drug products.

Therapeutic Duplication alerts consisted of more than 46% of all pro-DUR alerts, while Drug-Drug Interaction alerts, Early Refill alerts, Late Refill alerts, and High Dose alerts represented 17.6%, 13.7%, 11.9% and 8.1% of all alerts, respectively.

Of the total pro-DUR alerts that were set, approximately 16% of them were cancelled or not responded to by the pharmacist.

The 112,705 Late Refill alerts pertain to prescriptions for anticonvulsants, oral hypoglycemic agents, ACE-inhibitors, and xanthine derivatives that were refill on dates later than 1 week beyond their previous fills supply.

Pro-DUR Alert	Alerts	Overrides
Drug-Drug	166,827	138,401
Early Refill	129,659	100,364
High Dose	76,909	64,983
Late Refill	112,705	99,146
Drug-Disease	20,323	15,274
Drug-Pediatric	2,163	1,905
Drug-Pregnancy	550	508
Therapeutic Dup	437,286	375,968



September 2001
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- 4 Top 25 Drugs
- 4 DUR Board Meeting Dates Now Scheduled Monthly

Indiana Medicaid DUR Board
Room W382
Indiana State Gvmt Center, South
402 West Washington Street
Indianapolis, Indiana 46204

Indiana Medicaid Drug Utilization Review Board Newsletter

Considerations for the Management of Pain with Schedule II Drugs

By Neil Irick, MD
Indiana Medicaid DUR Board

The problems associated with the abuse of Oxycontin[®] have drawn the attention of the media, law enforcement, and healthcare professionals. The picture that is being reported to the public is of addicts who seek to scam prescribers and pharmacists in order to attain supplies of Oxycontin[®] for its heroin-like high. The public is told of situations in which addicts sell portions of their prescription supply to others on the street in order to finance the purchase of additional supplies of Oxycontin[®] at the pharmacy, or support other addictions involving illicit drugs from other street sources. To curb the abuse of the product, some physicians are deciding to tighten up their prescribing of Oxycontin[®], and some states have begun limiting Medicaid reimbursement for the drug. This action has drawn concern from those patients who suffer with chronic pain and who have found Oxycontin[®] able to ease their severe pain for long stretches of time. They are afraid that if the healthcare industry tightens up the prescribing and dispensing of this drug, it might become unavailable to patients who really need it. For these people, Oxycontin[®] allows them to lead fairly normal lives.

Oxycodone, the active ingredient in Oxycontin[®], is one of the oldest of the semi-synthetic opioids. For years, oxycodone (Tylox[®], Percocet[®], Percodan[®], Roxicet[®], etc.) was available in 5 mg strengths and in combination products with acetaminophen or aspirin, which limited the amount of oxycodone that could be

taken. Since the introduction of the new sustained-release forms five years ago, dosages are now strong enough to be effective for a wide range of moderate-to-severe pain etiologies and they do not contain acetaminophen or aspirin. Immediate-release forms of Oxycodone (Percolone[®], Endocodone[®], and Roxicodone[®]) are now available in 5, 15, and 30 mg dosages without acetaminophen or aspirin. The availability of these pure oxycodone dosage forms has drawn the attention of those individuals who seek to abuse and divert schedule II narcotic drugs.

The fear of litigation or censure by regulatory officials due to patient-related fraud and abuse prompts many doctors to avoid prescribing opioids like oxycodone. Prior to the release of federal guidelines concerning trauma, operating, and cancer pain control, it was very easy for doctors to justify the avoidance of opioid use. However, the guidelines have established opioids as essential products for treating certain pain conditions. These guidelines convey to the medical community very specific recommendations about treatment approaches and what medications should be used to treat pain. And while there are no guidelines yet established for the treatment of non-cancer pain, the treatment of non-cancer pain should be no less aggressive than with cancer pain.

Some states employ the use of multiple-copy prescription forms to control the utilization of Oxycontin[®], Duragesic[®], morphine, and other Schedule II drug products. This has led physicians in those states to shift some of their prescribing to Schedule III medications instead in order to avoid using the multiple-copy forms. The multiple-copy prescription forms also presented problems for physicians due to the value

the forms had to the drug seeker. Individuals, who sought to steal forms when they could not get physicians to prescribe their drugs of choice, often targeted physician offices in search of forms kept on countertops or in drawers. Drug seeking individuals would then write phony prescriptions on stolen, blank, multiple-copy prescription forms and present them to pharmacists for dispensing. Physicians who had chosen not to prescribe Schedule II drugs no longer needed to keep multiple-copy prescription forms in their offices and were left with fewer hassles associated with securing the forms and maintaining records. But in doing so, they had limited their ability to effectively treat patients with severe pain conditions.

Because Indiana does not use multiple-copy prescription forms, physicians should understand the importance of securing all prescription blanks and keeping them away from patients.

The purpose of this article is to share what considerations must be taken by prescribers and pharmacists in order to manage opioid treatment for moderate-to-severe pain conditions. Measures can be employed that allow doctors and pharmacists to identify and discourage drug-seeking behaviors while freely treating pain with opioid products.

Know the Law

The most important thing that a prescribing physician of Schedule II drug products should know is the law of the particular state in which the physician practices. Some states have laws that itemize those things that must be in the medical record for complete compliance in prescribing Schedule II drugs. Federal law, on the other hand, only requires the physician to document the presence of the condition that requires the use of opioid medications, and that the physician is not treating an addiction. For treating addictions, a physician is required to have a special license, often called a “methadone license” that must be renewed annually. Physicians who do not have a “methadone license” are not prevented from treating pain in patients who have

a history of, or are being treated for addiction. However, the physician is required to coordinate the pain treatment closely with the physician who is overseeing the patient’s addiction.

While some state laws are very explicit about what information must be in the medical record in order to prescribe Schedule II pain medications, documentation should be the appropriate mechanism that assures the physician that the right things are being done for the proposed treatment. Table A contains a partial list of information that many states require.

Is the Patient an Addict?

Correctly diagnosing addiction in a patient is difficult to do and requires honest answers by the patient to questions concerning attributes of addiction:

- Is the patient’s lifestyle focused on the acquisition of particular drugs?
- Is there evidence of the use of illicit substances recently and on a regular basis?
- Is the patient compulsively using the medication despite harm from

the drug?

- Is there an improvement in the quality of life with the use of the drug?

If the answer is “yes” to the first three questions and “no” to the last questions, addiction specialists who are aware of the appropriate uses of opioids should evaluate the patient. Consultation and evaluation of these individuals at an early phase can save mountains of worry later.

Determinants of the risk of addiction are easily assessed. Documentation in the record should include the patient’s personal and family history of alcoholism, drug use and abuse, and the presence of a personal history with major depression. A positive response to any of the questions about their history does not preclude the appropriate use of opioids in the patient’s treatment. In the case of the patient with cancer or AIDS, it would be harsh to withhold opioids from these patients because of increased risk of developing an addiction. One would simply monitor a patient with these risks more closely than the patient with no risks.

Table A

Documentation Required in Many States

History and Physical	Includes the use of illicit substances, all meds used for treatment of pain and allergies. Includes pain regimens tried in the past that had failed.
Treatment Plan & Goals	Establish early with clear-cut objectives to guide therapy. Includes goals that are tailored to the patient’s medical condition. Includes a window of time for achievement of goals.
Consultation	Includes a record of who referred the patient to you. Should indicate if the patient was self-referred.
Records	Includes copies of records from previous doctors who have treated the patient. Includes all prescriptions that were written or telephoned.
Follow-up Visits at Appropriate Intervals	Plan to see the patient more frequently as the regimen is initiated; less frequent as you are more comfortable and familiar with the patient. Includes medication-monitoring visits.
Medications Management Agreement	Includes itemized expectations of the patient by the prescriber.
Outcome Documentation	Includes documented improvements in functions, mood, and quality of life.

Under-treatment of a legitimate pain syndrome that results in drug-seeking behaviors was documented first in cancer patients. The syndrome of pseudo-addiction is now one of the most difficult with which to deal, and more common than we are led to believe. Because of the under-treatment with opiates, patients will often appear to be behaving as addicts. They will typically be going to more than one physician and pharmacy. They may be buying medications on the street, or getting other patients' medications. They may hoard their medication. One of the most difficult things to do with this type of patient is to give them an increase of their medication for a period of three to four days. This, however, may be the only test of whether the patient actually improves. If you have documented a valid pain complaint, the patient has legitimate records to substantiate a chronic painful condition, and the patient has no addiction risks, it is safe and legal to try opioids in that situation. If you are uncomfortable, get a consult. If a consult is not available, you could use a urine drug screen to confirm that the patient is not using marijuana, cocaine, or other street drugs prior to starting an opioid. If the patient improves with a small test period of three to seven days, then document the successful outcome of the trial period, and try to continue the same regimen. It is not uncommon for the initial stabilization regimen to require several months. During this time, give the patient leeway for determining a role in the dosing to meet his actual needs. However, it is important that you maintain control of the process. If this simply becomes a venue for "ordering drugs," then you are not in control. However, if there is consensus that medication or regimen change will benefit the patient, then it is appropriate to do so.

Materials for Managing the Chronic Pain Patient

The following documents are important tools for managing the treatment of chronic pain patients. Use of these tools will assist the health care professional in

determining the patient's cooperation and compliance to therapy as well as provide documentation that is supportive of therapy changes and treatment successes.

The **Medication Management Agreement** is an agreement that is signed by the patient and is used to set the ground rules for treatment. The Medication Management Agreement is the best offense and defense that physicians have against improper use of the medication by the patient. The agreement establishes the responsibility and accountability of the patient for the medication prescribed. Limitations established in the agreement are not negotiable from patient to patient and must be equally applied to all patients in the practice to avoid misunderstandings and frustration. The rules in the agreement should be written to be reasonable and enforceable. The purpose of the agreement is to make it very clear that deviation from the rules, or the law, will not be tolerated. The agreement includes the name, address, and telephone number of the pharmacy that will fill all the patient's opioid prescriptions and stresses the importance of using one pharmacy. Strict adherence to rules of the Medication Management Agreement avoids any possible increase in scrutiny of your practice by law enforcement because you only prescribe in the manner established in the agreement.

The **Encounter Form** is used to help document the progress of the patient's pain medication regimen. The form is used to chart information gathered during routine follow-up office visits. Types of information kept on this form include reporting the worst level of pain experienced, least level of pain experienced, percentage of pain relief from the regimen, things the patient does to help control the pain, and side effects.

The **Medication Record** is a document that summarizes the patient's pain medication regimen. It contains information one would need immediately to help with a problem without a thorough knowledge of the

patient. Information provided on this form includes demographic data, other doctors caring for this patient, diagnoses, procedures related to care, and a thorough accounting of all prescription drugs being used, when they were prescribed and how the patient takes them. The name, phone number, and address of the patient's pharmacy should also be on the form so that the contact with the pharmacist is facilitated. The Medication Record is also useful in facilitating patient chart reviews by regulatory officials, making it easier for them to see exactly what has been done and what is missing from the record.

Using opioid drug products to treat severe pain necessitates thorough documentation and monitoring of drug treatment regimens in patients with pain and an understanding of the law and requirements affecting the use of these agents. Physicians and pharmacists can successfully treat patients in pain without feeling that regulatory officials are looking over their shoulders. Likewise, good patient management will lessen the chance of being targeted by patients with addictions and drug-seeking behaviors.



Drug/Drug Interactions Involving Clonidine and Beta-Adrenergic Blocking Agents

During the twelve-month period October 1, 1999, through September 30, 2000, 4869 pro-DUR alerts were issued from 37,392 prescription drug claims for clonidine. The pro-DUR alerts were issued due to potential drug/drug interactions in patient profiles containing clonidine together with a beta-adrenergic blocking agent.

Patients taking beta-adrenergic blocking agents and clonidine together are at risk of severe adverse events related to sympathetic activity and rapid rises in blood pressure within 24 to 72 hours upon the immediate discontinuation of clonidine. The action of beta-adrenergic blocking agents neutralizes the vasodilatory effect of beta₂-adrenergic receptors. When clonidine is immediately stopped, neurotransmitters are released that stimulate alpha-adrenergic receptors to cause vasoconstriction, while the beta₂-adrenergic receptor remains neutralized. Besides the rapid blood pressure rise, other symptoms may include tremor, insomnia, nausea, vomiting, flushing, and headaches.

Any attempt to discontinue clonidine in patients with concurrent treatment using a beta-adrenergic agent, such as tapering the clonidine dose over a period of time, has not avoided the hypertensive syndrome. It is recommended that to prevent the syndrome, labetalol be used preventively or that the beta-adrenergic agent be discontinued well in advance of stopping the clonidine therapy.

DUR Board Meeting Dates Now Scheduled Monthly

The Indiana Medicaid Drug Utilization Review (DUR) Board has changed the frequency of when meetings are conducted. Because of concerns associated with the increasing drug costs for pharmacy benefits in the Medicaid program, the DUR Board will meet monthly to review and advise the State on new programs that are being designed and implemented to help control the cost of pharmacy services, while maintaining the high level of care to Medicaid members.

Each month the Board will meet to review and discuss proposed programs related to pharmacy services and involving prior authorization, formulary review and management, and drug utilization reviews.

TOP 25 Prescription Drugs Ranked by Claims Paid For First Quarter 2001

Rank	Drug Name	Paid Claims	Paid Units	Amount Paid
1	Prevacid 30mg Capsule	28,669	985,656	\$3,563,791
2	Prilosec 20mg Capsule	22,078	837,257	\$3,021,923
3	Celebrex 200mg Capsule	20,983	841,698	\$1,921,017
4	Zithromax 250mg Tablet	20,702	126,003	\$821,183
5	Albuterol 90mcg Inh Refill	17,058	332,044	\$353,311
6	Hydrocodone/APAP 5/500	16,849	645,395	\$126,713
7	Prozac 20mg Pulvule	16,830	714,862	\$1,818,096
8	Furosemide 40mg Tablet	16,744	768,627	\$92,703
9	K-DUR 20mEq Tablet SA	15,373	825,521	\$453,166
10	Ultram 50mg Tablet	15,242	1,029,349	\$794,244
11	Zolof 50mg Tablet	14,161	480,108	\$1,048,592
12	Amoxicillin 250mg/5ml Susp	13,536	2,161,487	\$100,586
13	Claritin 10mg Tablet	13,360	382,799	\$870,617
14	Vioxx 25mg Tablet	13,228	429,741	\$1,026,890
15	Acetaminophen 325mg Tablet	12,407	855,098	\$58,106
16	Potassium Cl 10mEq Cap SA	12,051	838,392	\$211,538
17	Paxil 20mg Tablet	11,709	398,404	\$914,431
18	Depakote 500mg Tablet EC	11,451	970,717	\$1,461,031
19	Lipitor 10mg Tablet	11,332	367,872	\$675,832
20	Norvasc 5mg Tablet	11,307	382,822	\$497,843
21	Premarin 0.625mg Tablet	11,255	377,766	\$243,596
22	Risperdal 1mg Tablet	11,026	524,584	\$1,258,196
23	Zolof 100mg Tablet	10,964	413,310	\$910,273
24	Zyprexa 10mg Tablet	10,707	502,417	\$3,982,158
25	Propoxy-N/APAP 100-650 Tb	10,462	492,648	\$159,903

Brian Musial joined the Board as a new member and was present at the July 13, 2001 DUR Board meeting. Brian is a licensed pharmacist employed with American Drug Stores as the Manager of Provider Relations. Brian replaces the seat left vacant by Hamid Abaspour's resignation from the Board in December 2000.

The Board is currently composed of four physicians, four pharmacists, a pharmacologist, and a representative of the Office of Medicaid Policy and Planning for the state of Indiana that serves as an ex-officio nonvoting member of the Board.

The members currently serving on the DUR Board are as follows:

G. Thomas Wilson, B.S. Pharm., J.D.
Chairperson

Patricia Treadwell, M.D.
Vice Chairperson

Marc Shirley, R.Ph.
OMPP Representative

Thomas Bright, M.D.
Neil Irick, M.D.

John J. Wernert, M.D.

Terry Lindstrom, Ph.D.

Thomas A. Smith, P.D., M.S.

Paula J. Ceh, Pharm.D.

Brian Musial, R.Ph.

Dates, locations, and agendas for upcoming meetings are published on the DUR Board Web site. The Web site also allows readers to submit comments to the Board via e-mail. To access the DUR Board Web site, go to the Medicaid Web site at www.IndianaMedicaid.com. Click on Departments, found on the top bar of the Indiana Health Coverage Program's Homepage, to pull down the menu containing the DUR Board link. Once on the DUR Board Homepage, readers can browse through the folder sections located on the left hand side of the page.

DUR Board Meeting Dates:

- **September 14, 2001**
- **October 12, 2001**
- **November 9, 2001**
- **December 14, 2001**

ATTACHMENT 5

Indiana Medicaid policy mandates substitution of a generically equivalent drug for a prescribed brand name drug, unless the prescribing practitioner properly indicates “brand medically necessary”. The following statutory information is provided to further clarify Indiana’s generic substitution policy.

Generic Substitution Law

Indiana Code 16-42-22 Drugs: Generic Drugs is presented in its entirety for your reference:

16-42-22-1 "Brand name" defined

Sec. 1. As used in this chapter, "brand name" means the proprietary or trade name selected by the drug manufacturer and placed upon a drug or the drug's container, label, or wrappings at the time of packaging. *As added by P.L.2-1993, SEC.25.*

16-42-22-3 "Customer" defined

Sec. 3. As used in this chapter, "customer" means the individual for whom a prescription is written or the individual's representative. *As added by P.L.2-1993, SEC.25.*

16-42-22-4 "Generically equivalent drug product" defined

Sec. 4. (a) As used in this chapter, "generically equivalent drug product" means a drug product:

- that contains an identical quantity of active ingredients in the identical dosage forms (but not necessarily containing the same inactive ingredients) that meet the identical physical and chemical standards in The United States Pharmacopoeia (USP) described in IC 16-42-19-2, or its supplements, as the prescribed brand name drug; and
- if applicable, for which the manufacturer or distributor holds either an approved new drug application or an approved abbreviated new drug application unless other approval by law or of the federal Food and Drug Administration is required.
 - A drug does not constitute a generically equivalent drug product if it is listed by the federal Food and Drug Administration on July 1, 1987, as having actual or potential bioequivalence problems.

As added by P.L.2-1993, SEC.25. Amended by P.L. 239-1999, SEC.4.

16-42-22-4.5 "Practitioner" defined

Sec. 4.5. As used in this chapter, "practitioner" means any of the following:

- A licensed physician.

- A dentist licensed to practice dentistry in Indiana.
- A podiatrist licensed to practice podiatric medicine in Indiana.
- An optometrist who is:
 - licensed to practice optometry in Indiana; and
- An advanced practice nurse licensed and granted the authority to prescribe legend drugs under IC 25-33.

As added by P.L.2-1993, SEC.25. Amended by P.L. 239-1999, SEC.5.

16-42-22-5 "Substitute" defined

Sec. 5. As used in this chapter, "substitute" means to dispense a generically equivalent drug product in place of the brand name drug product prescribed by the practitioner. *As added by P.L.2-1993, SEC.25.*

16-42-22-5.5 Authorization to substitute only generically equivalent drug products

Sec. 5.5. Nothing in this chapter authorizes any substitution other than substitution of a generically equivalent drug product. *As added by P.L.239-1999, SEC.6.*

16-42-22-6 Prescription forms

Sec. 6. Each written prescription issued by a practitioner must have two (2) signature lines printed at the bottom of the prescription form, one (1) of which must be signed by the practitioner for the prescription to be valid. Under the blank line on the left side of the form must be printed the words "Dispense as written". Under the blank line on the right side of the form must be printed the words "May substitute". *As added by P.L.2-1993, SEC.25.*

16-42-22-8 Substitution of generically equivalent drug product in non-Medicaid or Medicare prescriptions

Sec. 8. For substitution to occur for a prescription other than a prescription filled under the traditional Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program (42 U.S.C. 1395 et seq.), the practitioner must sign on the line under which the words "May substitute" appear; and the pharmacist must inform the customer of substitution. This section does not authorize any substitution other than substitution of a generically equivalent drug product. *As added by P.L.2-1993, SEC.25. Amended by P.L. 239-1999, SEC.7.*

16-42-22-9 Transcription of practitioner's oral instructions to pharmacist

Sec. 9. If the practitioner communicates instructions to the pharmacist orally, the pharmacist shall indicate the instructions in the pharmacist's own handwriting on the written copy of the prescription order. *As added by P.L.2-1993, SEC.25.*

16-42-22-10 "Brand Medically Necessary" Traditional Medicaid or Medicare prescriptions

Sec. 10. (a) If a prescription is filled under the traditional Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall substitute a generically equivalent drug product and inform the customer of the substitution if the substitution would result in a lower price unless:

- the words "Brand Medically Necessary" are written in the practitioner's own writing on the form; or
- the practitioner has indicated that the pharmacist may not substitute a generically equivalent drug product by orally stating that a substitution is not permitted.
 - If a practitioner orally states that a generically equivalent drug product may not be substituted, the practitioner must subsequently forward to the pharmacist a written prescription with the "Brand Medically Necessary" instruction appropriately indicated in the physician's own handwriting.
 - This section does not authorize any substitution other than substitution of a generically equivalent drug product

As added by P.L.2-1993, SEC.25. Amended by P.L. 239-1999, SEC.8.

16-42-22-11 Substitution of generic drugs; identification of brand name drug

Sec. 11. If under this section a pharmacist substitutes a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label must identify the brand name drug for which the substitution is made and the generic drug. The identification required under this subsection must take the form of the following statement on the drug container label, with the generic name and the brand name inserted on the blank lines: " Generic for ". *As added by P.L.2-1993, SEC.25. Amended by P.L.186-1993, SEC.1.*

16-42-22-12 Identification of manufacturer or distributor of dispensed drug product on prescription

Sec. 12. The pharmacist shall record on the prescription the name of the manufacturer or distributor, or both, of the actual drug product dispensed under this chapter. *As added by P.L.2-1993, SEC.25.*



P R O V I D E R B U L L E T I N

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A U G U S T 1 0 , 2 0 0 1

**To: All Indiana Health Coverage Programs Physicians,
Podiatrists, Dentists, Hospitals, Clinics, Mental
Health Providers, and Pharmacies**

**Subject: Implementation of Prior Authorization Requirement
for Brand Medically Necessary Drugs**

Note: The information in this bulletin about prior authorization and payment methodology, may vary for practitioners and providers rendering services to members enrolled in the risk-based managed care (RBMC) delivery system.

Policy Change

Effective September 4, 2001, a prescriber's indication of "brand medically necessary" for a prescribed drug will require prior authorization. What this means is that, if a prescriber chooses to specify "brand medically necessary" for a drug, he or she must obtain prior authorization for that brand name drug before the pharmacist can be paid for the brand name drug. This action implements Medicaid rule 405 IAC 5-24-8, *Prior Authorization; brand name drugs*.

405 IAC 5-24-8 Prior authorization; brand name drugs

Authority: IC 12-8-6-5: IC 12-15-1-10: IC 12-15-21-2

Affected: IC 12-13-7-3: IC 12-15

Sec. 8. a) Prior authorization is required for a brand name drug that:

- (1) Is subject to generic substitution under Indiana Law; and
- (2) The prescriber has indicated is "brand medically necessary" either orally or in writing on the prescription or drug order.
 - (b) In order for prior authorization to be granted for a brand name drug in such instances, the prescriber must:

- (1) indicate on the prescription or drug order, in the prescriber's own handwriting, the phrase "brand medically necessary"; and
- (2) seek prior authorization by substantiating the medical necessity of the brand name drug as opposed to the less costly generic equivalent.

The prior authorization number assigned to the approved request must be included on the prescription or drug order issued by the prescriber or relayed to the dispensing pharmacist by the prescriber if the prescription is orally transmitted. The office may exempt specific drugs or classes of drugs from the prior authorization requirement, based on cost or therapeutic considerations. Prior authorization will be determined in accordance with the provisions of 405 IC 5-3 and 42 U.S.C. 1396r-8(d)(5). (*Office of the Secretary of Family and Social Services; 405 IAC 5-24-8; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3346; filed Sep 27, 1999, 8:55 a.m.: 23 IR 319*)

Background Information

The basis for this action is the Food and Drug Administration (FDA)'s position that therapeutically equivalent generic drugs have the same effect in the body as their more expensive brand name counterparts. Therefore, it does not make sense for a tax-funded drug benefit to subsidize the additional cost of brand-name drugs when less expensive, equally effective, generic equivalents can be used. The prior authorization system will be used to allow prescribers to substantiate what constitutes the *medical necessity* of a given brand name drug, when the prescriber chooses to write "brand medically necessary."

The Office of Medicaid Policy and Planning (OMPP) strives to employ prior authorization only in circumstances in which it is clearly warranted to do so. That would include utilization control, cost control, or ensuring quality of care. Over the past two years, Indiana Medicaid reimbursed an estimated extra three million dollars associated with uncontrolled "brand medically necessary." That is three million dollars of additional tax dollars expended for brand name drugs, when therapeutically equivalent, less expensive generics could have been used, simply because "brand medically necessary" overrode otherwise applicable payment levels to the pharmacy. At a time when Medicaid faces unsustainable cost increases, we would be remiss not to implement this reasonable and practical program policy that many other states have already adopted.

Prior Authorization is required only for those drugs that have an established federal upper limit (FUL), maximum allowable cost (MAC), and an "AA" or "AB" rated generic equivalent. The following drugs are excluded from the PA requirement:

- Coumadin®
- Dilantin®

- Lanoxin®
- Premarin®
- Provera®
- Synthroid®
- Tegretol®

How The Process Will Work

Prescribers

In the past, if you wrote a prescription for a substitutable brand name drug for an Indiana Medicaid beneficiary signed on the “Dispense as Written” line, and wrote “brand medically necessary” across the face of the prescription, the pharmacist dispensed the prescribed brand name drug and was paid for it. You were not asked what constituted the medical necessity of the more expensive brand name drug as opposed to generic equivalents. As of September 4, 2001, should you chose to continue to write “brand medically necessary” for such drugs, you will have to document the medical necessity for the brand name drug (as opposed to the generic) through the prior authorization process. A description of that process, and how it meets applicable state and federal requirements for drug prior authorization programs, is found below.

Pharmacists

If after September 4, 2001, you receive a prescription for a substitutable brand name drug that is subject to federal MAC limits and that prescription has “brand medically necessary” specified, you will not be able to get paid for the prescribed brand name drug unless the prescriber has obtained prior authorization. If your request is filed point-of-sale (POS) you will know whether or not prior authorization has been obtained if the claim denied. You may receive a call from a prescriber asking you for the National Drug Code (NDC) of the drug for which he or she is seeking prior authorization; if you can assist the member by providing this information, it will facilitate his or her being able to obtain prior authorization for the drug, and thus assist you in getting paid for what is being prescribed. Bear in mind that, ultimately, it is the prescribing physician’s responsibility to initiate and obtain prior authorization for instances in which he or she opts to specify “brand medically necessary.”

Description Of The Prior Authorization Process

Prior Authorization for Brand Medically Necessary will be granted in cases where documentation indicates the following.

- *Allergic reaction to excipients in the generic products* – If multiple generics are available, a history of trials of generics from multiple companies must exist.
- *A therapeutic failure to the generic product* – A history of documented previous purchases will be reviewed to determine dosing and compliance issues.
 - Prescribers and pharmacists are encouraged to report experiences with generic drug products that create concerns in product quality, performance, or safety.
 - When a physician or pharmacist observes differences in the pharmacologic effect of a generic drug over its branded drug product in a patient, the health professional is asked to report this concern to the Federal Drug Administration, using the MEDWatch form.
 - If the concern immediately above is the rationale for request of a branded drug, a copy of the MEDWatch form or alternative reporting system submitted to the Federal Drug Administration (FDA) must accompany the prior authorization (PA) request. (One may also call 1-800-FDA-1088 to obtain MedWatch forms.)

Note: Patient requests for brand name drugs will not be approved.

Drugs subject to FUL are listed in the *Indiana Health Coverage Programs (IHCP) Provider Manual* in *Chapter 9*. Additions and deletions are published in IHCP banner page articles and bulletins.

Prior Authorization Process

To obtain approval, the physician must send the following.

- An *Indiana Prior Authorization Request* form (PA Request). A form may be downloaded from www.indianamedicaid.com. The following must be included on or with the form:
 - The 11-digit NDC for the requested drug must be included as the “Service Code Required.”
 - The medical necessity for a brand name drug must be documented in the “Clinical Summary.” Alternatively, a letter explaining the need for generic substitution exemption may be attached to the prior authorization request.
 - A copy of the MEDWatch form or alternate reporting system submitted to the FDA, if applicable.
- Prior authorization approval generally effective for a one-year supply.

The PA Request and other documentation or letters should be mailed or faxed to the Health Care Excel (HCE) Prior Authorization (PA) Department. PA requests also be called to the HCE Department. However, telephone approvals can only be given for one month and a PA Request will need to be completed as described above and faxed or mailed to the HCE PA Department.

Health Care Excel, Prior Authorization Department
P.O. Box 531520
Indianapolis, IN 46253-1520
Fax Number: (317) 347-4537
Telephone: (317) 347-4511 or (800) 457-4518

Pharmacy Claims Processing

Prescription claims for brand name drugs requiring prior authorization will deny by the IndianaAIM claims processing system with a message that prior authorization is required. The pharmacist may then take three possible courses of action.

- Contact the prescriber to get the order changed so a generic drug may be substituted.
- Contact the prescriber and ask he or she submit a PA request.
- Give the prescription back to the patient so he or she can return to the prescribing practitioner.

If the claim is denied and there is an emergency, the prescriber cannot be reached, or the prescription is presented after normal business hours at the HCE PA Department (including week-ends and holidays), a 72-hour supply (*Sec. 1927 (d) 42 USC 1396r-8, "OBRA '90"*) of the drug may be dispensed by the pharmacy at no risk to the pharmacy. Prescriptions meeting these criteria may be dispensed in a sufficient amount to provide medication to the patient until the HCE PA Department can review the PA request.

Claim instructions for emergency situations, situations when the prescribing physician is unavailable, or instances when the HCE PA Department is closed are as follows:

- The pharmacist may use the "06" indicator in the Brand Field Locator on the Drug Claim Form if the prescriber has written "brand medically necessary" in his or her own hand-writing or met other requirements of *IC 16-42-22-10* for "Brand Medically Necessary" Medicaid or Medicare prescriptions.
- The correct number of day's supply (less than or equal to three) would need to be included on the pharmacy claim form.
- If the package size is for greater than three days and cannot be broken, the pharmacist may also dispense the medication at no risk to the pharmacy. However, the claim must be held until PA is obtained for the package size. Prescriptions presented on holiday weekends and filled for more than three days will need to be handled in the same manner.
 - Information may be placed on the PA Request accompanied by the prescription and faxed to the HCE PA Department. A PA number will then be faxed back to the pharmacy.

- Alternatively, the PA Department may be called during business hours, 7:30 a.m. – 6 p.m., Central Standard Time, Monday through Friday.

Prescribers should bear in mind that if they choose to write “brand medically necessary” on their prescriptions and do not initiate the required prior authorization request, it could result in the patient encountering difficulties in obtaining their medication. The mutual goal should be to ensure that patients receive less expensive, therapeutically equivalent generic products whenever feasible and reasonable, while allowing for payment of more expensive brand name products if there are true and valid, documented medical reasons for use of the brand name product.

Further Information

Questions about this bulletin may be directed to the Health Care Excel Medical Policy Department at (317) 347-4500.

ATTACHMENT 6

The projected pro-DUR savings calculation reflects only those claims that were submitted electronically. If an alert is triggered upon submission of a claim, the pharmacist must respond to the alert in order to receive payment for the claim. The response is captured electronically. By responding to the alert, the claim may be adjudicated, and the pharmacist would thereby dispense the medication.

The responses captured on the pro-DUR report 0014A summarize the actions taken by pharmacists when presented with pro-DUR alerts in the course of dispensing prescriptions to Indiana Medicaid recipients. The codes 1A, 1B and 1G are override codes and would not produce any program savings since no changes in the dispensed prescription took place. A pharmacist who overrides an alert with a code 1A, 1B, or 1G, after having been presented the alert, determines to his best professional judgement, with or without the communicated judgement of the prescriber, that the benefits of dispensing the medication outweigh the potential risks associated with the alert. However, alerts 1C, 1D, 1E and 1F are adjustments made to the prescription in response by the pharmacist to the pro-DUR alert. The response could produce program savings if the action taken by the pharmacist prevented an adverse drug-related event or enhanced the effectiveness of the patient's drug therapy. Still, a change documented by these codes could also reflect an increase in program costs if the result was the utilization of a more costly drug therapy even though the potential for an adverse drug-related event was minimal. The savings or added expense may be marginal, but the potential of this cost savings/expense should be acknowledged. Therefore, calculating this amount with the data available would be difficult at best.

Reviewing the DUR-0011 report provides a more solid foundation for calculating savings to the program attributed to the POS/pro-DUR functionality.

A "cancellation" response to a pro-DUR alert indicates that the pharmacist cancelled the claim and did not dispense the medication. The total number of cancellations for FFY2001 was 367.

A "non-response" to an alert indicates that the pharmacist did not respond to the alert. If a pharmacist does not respond to a pro-DUR alert within three days, the claim is denied, and no program funds are expended. However, the claim may have been resubmitted after this three-day period and no alert triggered (i.e. early refill alert may not be triggered and the medication was dispensed). Conversely, another alert may have been triggered and the pharmacist properly responded and dispensed the medication. Thus, it is a logical assumption that a percentage of the non-responses were not dispensed and savings to the State Medicaid program were incurred. The total number of non-responses to pro-DUR alerts for FFY2001 was 126,051.

If one assumes that fifty percent of the non-responses were not subsequently dispensed, the POS/pro-DUR system would have resulted in 63,026 prescriptions not being dispensed.

The latest data available that reflects both drug program expenses and the number of prescriptions dispensed is information from the FFY2001 claim data. From this data, we discover that \$562,596,087 was paid for pharmacy services to Indiana Medicaid recipients for 12,181,187 prescriptions. An average price per prescription of \$46.19 is calculated and includes both legend and OTC drug formulary product claims.

\$46.19 - Average prescription drug price.
367 - Number of POS/pro-DUR cancellations.
63,026 – Non-responses to pro-DUR alerts.

Estimated program savings attributable to POS/pro-DUR = \$ 2.93 million.

If an estimated 30% of non-responses are calculated as non-dispensed prescriptions, the program still has an estimated saving of \$1.76 million.

The estimated retro-DUR savings reflect interventions that occurred six to nine months earlier. Therefore, Board activity from FFY2000 would be reflected in the FFY2001 report as well as Board actions taken in FFY2001. Additionally, not all FFY2001 Board activity will be reflected in the current annual report. As retro-DUR processes continue, the savings will accrue from therapy changes effected in multiple prior quarters, thus resulting in a compounding of savings.

It is the responsibility of the pharmacist at EDS to interface with the OMPP, the Indiana Medicaid DUR Board, and Eagle Managed Care in coordinating and reporting the DUR activities of Indiana Medicaid. The retro-DUR savings reflected in this report are developed from an outcomes analysis performed on patient profiles and physician prescribing patterns during December 2001. The following is a summary of those outcomes that are attributed to the retro-DUR activities for FFY2001:

FFY 1Q2001 (10/1/00-12/31/00)

Purpose of Study:

The purpose of the study was to identify prescribers that exhibit a prescribing pattern of selecting Azithromycin, Zyxon, or a flouroquinolone as first line agents for antimicrobial therapy.

Intervention Results:

Patient profiles were reviewed and identified. The profiles were then grouped by prescribers, and the prescribers were ranked in order of highest to lowest occurrence. The top 248 prescribers who exhibited the highest number of patient-related occurrences for the month were selected for intervention. Out of a total of 9,353 prescriptions identified, 2,573 were addressed in interventions to the prescribers. There were 1846

instances where azithromycin was being utilized as a first-line therapy, 724 for fluoroquinolones and 3 for linezolid.

Responses

94 physicians responded to the intervention packets (38%):

- 57 agreed with the recommendation and would consider first-line antibiotic agents for common bacterial infections. However, 29 would continue therapy for these patients.
- 37 physicians, including the 29, who agreed with the recommendation, chose to continue use with the second or third-line agents.
- 10 physicians responded that these are no longer or never have been their patients.

Basis for Cost Analysis

Antibiotics

2573 prescriptions, 248 physicians

- 1846 azithromycin interventions @ 32.37 (avg cost) = \$59,755
- 724 fluoroquinolone interventions @ 74.29 (avg cost) = \$53,786
- 3 linezolid interventions = \$2,846
- Total cost = \$116,387

Comparison to Dec 2001 data

Comparing the same 248 physicians, 213 physicians continued to write for 2nd line antibiotics.

2566 total prescriptions

- 2104 azithromycin prescriptions @ 35.77 (avg cost) = \$75,260
- 462 fluoroquinolone prescriptions @ 72.43 (avg cost) = \$33,463
- No linezolid prescriptions
- Total cost = \$108,723

Total cost savings \$7,664 per month.

FFY 2Q2001 (1/1/2001-3/31/2001)

Purpose of Study:

The purpose of the study was to identify patient profiles that contain BID dosing of Proton Pump Inhibitors (PPIs) for greater than 90 days and/or identify dosages higher than recommended by the manufacturer for maintenance therapy.

Intervention Results:

Letters were sent to 204 physicians whose 571 patients were receiving prescriptions for twice daily PPI therapy. (583 interventions)

The letter encouraged the initiation of lifestyle modifications, antacids, and/or the utilization of Histamine 2 receptor blockers or proton pump inhibitors at the lowest

effective dose. It promoted the recommended dosing for PPIs in acute GERD therapy, and in chronic, long-term GERD therapy maintenance.

Patients unresponsive to low doses of PPIs may be given higher dose therapy for 8 weeks. However, low doses should be attempted after 8 weeks of high dose treatment.

Responses

257 responses (44%) were received from 100 physicians (49%):

- For 74 patients, physicians agreed with the recommendations
- for 22 patients, physicians would attempt lifestyle modifications along with once daily PPI therapy
- for an additional 59 patients, physicians would consider once daily PPI therapy
- For 125 patients, physicians chose to continue current twice daily therapy:
- 16 patients were receiving PPIs once daily
- 39 patients were no longer receiving care from these physicians
- 9 physicians report that these recipients were not their patients

Basis for Cost Analysis

PPI twice daily therapy

- 583 interventions (571 patients) and 204 physicians
- 583 prescriptions @ \$ 233 avg cost = \$ 135,839
- Cost savings by using once daily therapy 583 @ \$117= \$68,211

Comparison to Dec 2001 data

- Of the 571 patients, 312 continue to receive a PPI twice daily
- 334 prescriptions (43% reduction) @ \$233 = \$77,822
- 109 recipients receiving 123 prescriptions for once daily @ \$117= \$14,391
- Cost savings for these patients of \$43,626
- Of the 204 physicians, 157 continue to prescribe twice daily PPI therapy for a period of at least 90 days
- 347 patients
- 370 prescriptions (37% reduction) with a total cost of \$83,743.
- Approximately 20% (117) will continue to receive once daily therapy
- 117 @ \$117= \$13,642
- Total cost originally =\$135,839
- Total cost Dec 2001= \$97,385

Total cost savings \$38,454 per month.

FFY 3Q2001 (4/1/2001-6/30/2001)

Purpose of Study:

The purpose of the study was to examine pharmacy claims where the indicator “Brand Medically Necessary” was provided on the claim, allowing the higher brand-name price to pay in situations affecting Federal Upper Limits (FUL).

Intervention Results:

Out of the 6,678 prescription episodes identified with “Brand Medically Necessary” overrides, 117 Physicians were identified who were responsible for four, or more, BMN prescriptions, or greater than \$400 per month in BMN prescription costs. (407 patients pertaining to 698 prescriptions). The total cost for these prescriptions was \$58,259.

Letters were not mailed due to the fact that brand products now require prior approval. However, cost analyses were done to compare the effect of prior authorization for brand products.

Basis for Cost Analysis

Claims were reviewed on subsequent months to determine if prescribing patterns had changed due to the prior authorization requirement for brand medically necessary. A summary of the monthly analyses is provided below:

September

Data from September for the same physicians were compared to our original data (June).

- Results: 100 of the 117 original physicians wrote for 541 BMN prescriptions for 363 patients. The total cost was \$55,141.
- For these top physicians, there were savings of \$3,118 as compared to June.

October

Data for October for the same physicians were again compared to the original data.

- Results: 80 of the 117 original physicians wrote for 335 BMN prescriptions for 219 patients. The total cost was \$40,676.
- For these top physicians, there were savings of \$17,583 as compared to June.

Also, looking at overall generic use of all medications and all physicians, there appears to be a decreasing trend:

Month	Total Cost Savings Potential BMN	Total Number of claims for month	Cost savings/ # of claims
August	\$144,258	593,270	.2431
September	\$103,565	611,736	.1693
October	\$ 78,142	813,149	.0961

November	\$ 54,683	640,513	.0853
December	\$ 66,840	692,144	.0965

The cost savings is calculated using the potential cost savings related to BMN requests:

- \$0.2431 x 12 million claims = \$2.92 million per year potential cost savings in June 2002.
- \$0.092 (avg of Oct, Nov, and Dec) x 12 million claims = \$ 1.1 million per year potential cost savings after PA was implemented.

Total Cost savings is estimated at \$1.82 million per year.

FFY 4Q2001 (7/1/200-9/30/200)

Purpose of Study:

The purpose of the study was to identify medication profiles of patients 65 years of age and older who were receiving a benzodiazepine drug product for over 60 days.

Intervention Results:

349 patients, age 65 or older, were identified as receiving a benzodiazepine drug for a period of at least 60 days. 295 physicians received intervention packets for a total of 356 interventions.

Responses

187 responses (53%) were received from 162 physicians (55%)

- For 83 patients, physicians agreed with the recommendation and would re-evaluate benzodiazepine therapy.
- Physicians would discontinue benzodiazepine therapy for 10 patients.
- For 10 patients, physicians agreed with the recommendation to change to a non-benzodiazepine hypnotic.
- For 79 patients, physicians chose to continue the current therapy for the following reasons:
 1. Effective medication
 2. Patients are stable
 3. Patients tolerate well

Basis for Cost Analysis

The total monthly cost for benzodiazepine prescriptions for the patients identified in the study was \$ 9,572.

Comparison: Jan 2002 Claims Data

266 of the 314 patients (decrease of 15%) continue with benzodiazepine therapy with a cost of \$ 6,965 for savings of \$2,607 or a 27% decline.

RetroDUR Intervention Summary

Interventions	Letters	Number of physicians responding	Number of Interventions	Number of Responses	Response Rate	% agreeing to change	Potential cost savings per month	Predicted cost savings per month	Actual cost savings per month	Annualized cost savings
2 nd line antibiotics	248	94	2573	936	36%	30%	\$116,387	\$34,916	\$ 7,664	\$91,968
PPI BID therapy	204	100	583	257	44%	28%	\$ 68,211	\$19,099	\$38,454	\$461,448
Benzodiazepines in elderly	302	109	365	125	34%	40%	\$ 9,572	\$ 3,829	\$ 2,607	\$31,284
Total	754	303	3521	1318	37%	31%	\$194,170	\$57,844	\$48,725	\$584,700

Overall, the retro-DUR activities performed for FFY2001 revealed that 754 intervention packets were sent to physicians concerning 3512 interventions. The response rate received from physicians that were mailed intervention packets requesting feedback was approximately 48%. Approximately 31% of the time, the responding physicians agreed to the recommendations communicated in the intervention packets. The total estimated program savings for the retro-DUR program for FFY2001 was \$584,700, and included retro-DUR analysis of three out of four quarters for FFY2001. The estimated average amount of cost savings per intervention is estimated to be \$535. This figure is calculated using the estimated cost savings involving retro-DUR activities for FFY2001 and dividing that into an extrapolation of the agreement percentage from the prescriber responses to the total number of interventions performed.

The most significant savings experienced in SFY2001 involved the reduction in prescribers requesting brand medically necessary for branded drug products that have generic equivalents with lower cost. During June 2001, the potential cost savings for moving from branded to generic product per claim was calculated at \$0.2431. After implementation of prior authorization for brand medically necessary requests, the utilization of brand medically necessary requests decreased over subsequent months, as evident in the decrease of the potential cost savings associated with the remaining BMN occurrence to \$0.092 per claim. As a result, the calculated annual savings associated with the PA program is \$1.82 million.

Conclusion:

The estimated cost savings attributed to POS/pro-DUR for FFY2001 is \$2.93 million. This assumes that 50% of the cancellations and non-responses were not subsequently dispensed. The estimated cost savings attributed to retro-DUR for FFY2001 is \$584,700. The estimated cost savings attributed to all DUR activity for FFY2001 is \$3,514,700.

Neither the pro-DUR nor the retro-DUR savings reflect any potential program savings from hospitalizations and emergency room visits or primary care giver visits that may have been avoided. The cost savings are an estimate of the drug expenditures that the Indiana Medicaid program did not incur. Realistically, the savings to the program would far exceed the drug savings indicated.