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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

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

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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