

Submitter : Ms. Mary Ellen Kleiman
Organization : National Association of Chain Drug Stores
Category : Pharmacist

Date: 12/05/2007

Issue Areas/Comments

GENERAL

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The National Association of Chain Drug Stores (NACDS) submits the attached November 13, 2007 report by Stephen W. Schondelmeyer, Pharm.D., Ph.D., FAPHA (with exhibits) regarding Average Manufacturer Price and Federal Upper Limits for agency consideration. Due to its size, it will be submitted in multiple submissions of PDF files (more than the 4 originally thought). See Attachments. [SIXTH OF SIX, Part 1]

CMS-2238-FC3-10-Attach-1.PDF

hold at hand



2005 Regional Chain Conference

January 27-30, 2005
The Ritz-Carlton Naples
Naples, Florida

Electronic Prescribing

by

David Medvedeff, PharmD, MBA
Gold Standard





Presented to:
Regional Chain Meeting - NACDS
January - 2005

Agenda



- About Gold Standard
- eMPOWERx, our e-prescribing solution
- Medicaid programs
- Product demonstration

GOLD
STANDARD

Why Medicaid? Why Now?



- Managed Care v. Medicaid
 - Commercial Plans = cost shifting to the patient
 - Government Funded Plans = complex strategies of cost control
- Open Access → Controlled Access
 - PDL's, clinical PA's
 - Brand limits, monthly Rx limits
 - Clinical algorithms = step therapies, "fail first"

Consider the impact on provider recruitment and retention

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– Presenter: David H. Kravitz, PhD, Hermina Sanders Chair in Pharmacy Administration, Sonderegger Research Center, School of Pharmacy, University of Wisconsin, Madison, Wisconsin.



About the Program - FL



- Phase 1:
 - 1000 high volume Medicaid providers
 - Provide Medicaid PDL
 - Provide 60-day patient specific Rx history
 - Drug utilization reports (interaction reports, etc.)
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 - Expand to 3000 total providers
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About the Program - MS



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Duplications of Therapy



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Identifying Doctor Shoppers



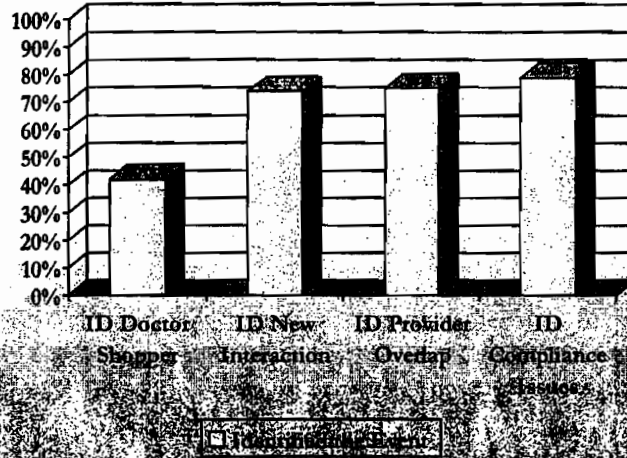
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OS0xxx68	METHADOSE 10MG TABLET	9/26/2003	30	7
OS0xxx68	METHADOSE 10MG TABLET	10/16/2003	30	7
OS0xxx68	OXYCODONE W/APAP 5/325 TAB	10/16/2003	30	7
OS0xxx68	OXYCODONE W/APAP 5/325 TAB	10/27/2003	30	5
OS0xxx68	METHADOSE 10MG TABLET	10/27/2003	30	7
OS0xxx68	OXYCODONE W/APAP 5/325 TAB	10/30/2003	30	5
ME0xxx42	OXYCODONE W/APAP 5/325 TAB	9/22/2003	60	20
ME0xxx42	HYDROCODONE/APAP 10/650 TAB	10/6/2003	60	15
ME0xxx42	HYDROCODONE/APAP 10/650 TAB	11/6/2003	40	10
ME0xxx42	HYDROCODONE/APAP 10/650 TAB	11/17/2003	20	5
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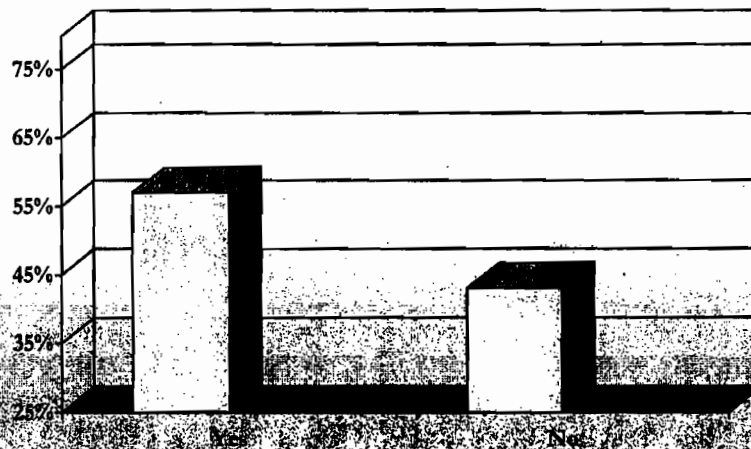
Provider Survey Results Florida Medicaid



Application of the Data



Decrease in Pharmacy Calls



What's Next for the Program?



- **Laboratory Data Coordination**
 - Consolidation of lab reports – minimize waste
- **Disease Management Patient Referrals**
 - Communication between case managers and physicians
- **e-Prior Authorization**
 - In planning phase
- **Dissemination of "Best Practice Guidelines"**
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Hold Attraction



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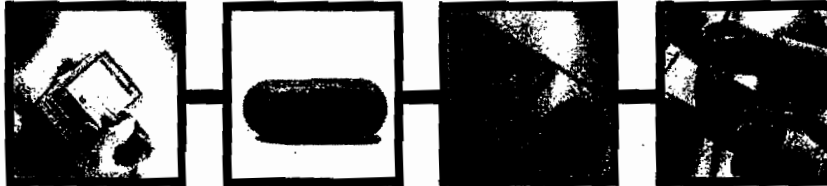
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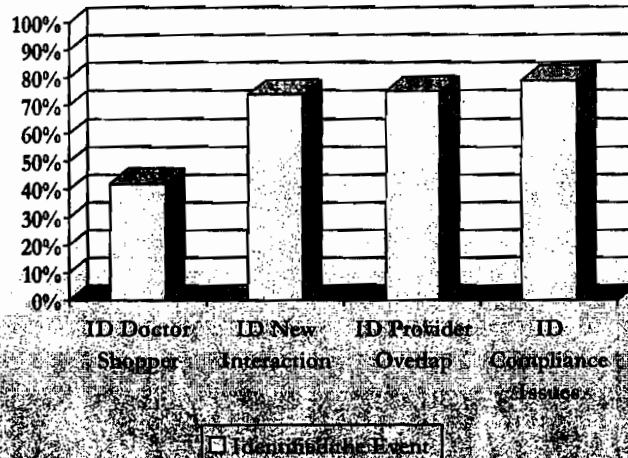
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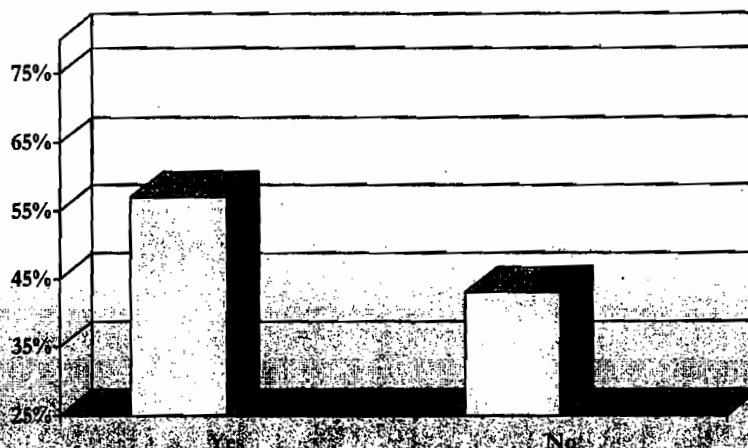
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GO ID
STANDARD

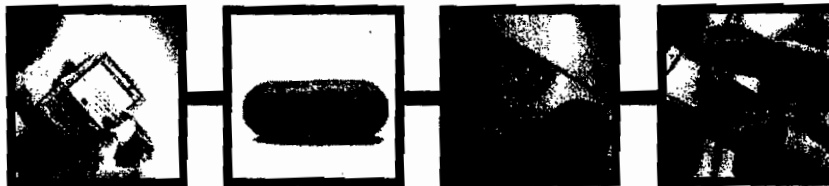
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CMS-2238-FC3-14-Attach-1.PDF

Exhibit 9

**DDD™ Annual Class-of-Trade Analysis 2003
IM Health**

The 2003 DDD Annual Class-of-Trade Analysis examines the 10 channels of business across the retail and non-retail pharmaceutical market. It provides statistics relative to market share, growth and overall trends for the past seven years. The Analysis also highlights and reports prescription sales as tracked by IMS Retail Method-of-Payment™.

The dollars used in the Class-of-Trade Analysis (unless otherwise stated) are based on *wholesale acquisition cost (WAC)* – those set by each pharmaceutical manufacturer. These prices do not reflect rebates, discounts or charge backs. Direct sales, as reflected in this analysis, are only for those manufacturers who participate in and provide direct sales data to IMS.

As part of IMS's Sales Force Effectiveness offerings, DDD is the industry's premier source of pharmaceutical sales intelligence. Tracking subnational, direct and indirect sales information for pharmaceutical products across all retail and non-retail classes of trade — DDD provides comprehensive insight and accurate assessment of pharmaceutical product sales.

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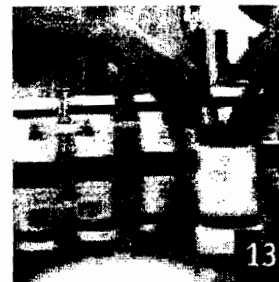
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DDD Class-of-Trade Analysis



12

**Payment of Prescriptions
by Managed Care**



13

Definitions



SUMMARY

Driven by consumer demand, the pharmaceutical industry reached annual sales of \$233 billion in 2003. Fueled by strong sales across the top 10 therapy classes and the introduction of 21 new molecular entities (up from 17 in 2002), the industry overall grew at 8.8 percent. While this growth rate is slower than previous years, it is most telling considering the multitude of environmental factors influencing the U.S. market.

As in the recent past, the pharmaceutical industry is under the constant scrutiny of the government, media and the general public with politicians, health plans, and employers implementing new strategies to curtail drug spend. Further impacting growth is the reimportation of pharmaceutical products from Canada. Increasingly, brand products are moving to over-the-counter (OTC) status. And, switching from branded to generic products continues (growing by 9.2 percent on a total dispensed prescription basis in 2003).

The U.S. economy, tenuous at best, and marred by an unemployment rate of six percent (the highest it's been since 1995), also affected overall drug sales. Due to lack of disposable income, consumer polls indicate that patients are opting for non-compliance with

recommended therapy treatments, including, cutting doses and ignoring prescription orders altogether.

In 2003, in spite of the many environmental factors and a slowed overall growth rate across the ten classes of trade, several channels fared well. Chain pharmacies and hospitals, the leaders within the retail and non-retail channels respectively, both achieved market share growth in 2003 – this after experiencing a decline in the previous year. Chain stores led all channels with a 28.3 percent market share, followed by hospitals with a 15.3 percent share, and mail service now up to 14.9 percent. This is good news for the chains and hospitals whose market share growth has fluctuated in recent years. As for mail service, while its growth rate has slowed somewhat, down from an average of 26% over the previous four years, its market share increase remains impressive.

Once again, based on DDD dollars, mass merchandisers and healthcare plans had negative growth rates and associated decreases in market share. This holds true for the miscellaneous channel as well, whose market share dropped by a full one percent.

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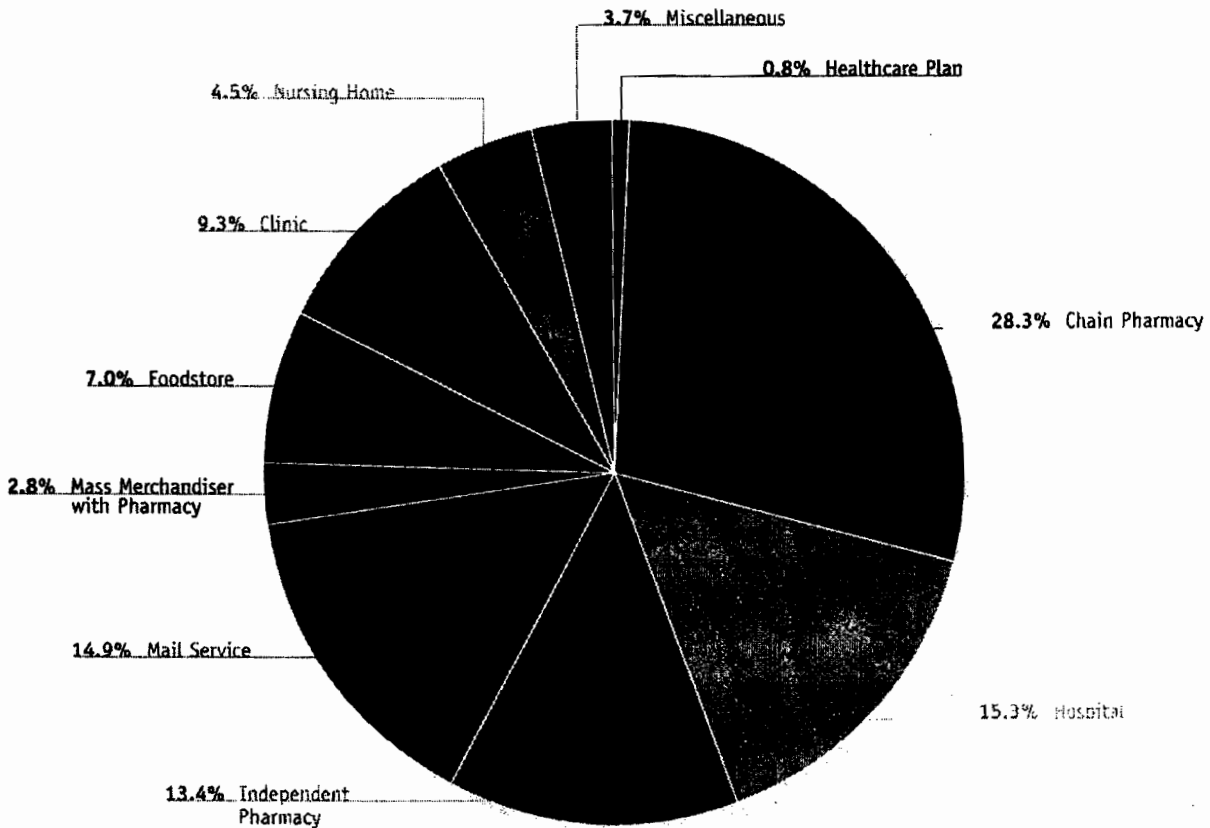
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DDD MARKET SHARE TRENDS

Color Key	
Chain Pharmacy	[Color swatch]
Mass Merchandiser with Pharmacy	[Color swatch]
Mail Service	[Color swatch]
Independent Pharmacy	[Color swatch]
Foodstore with Pharmacy	[Color swatch]
Hospital	[Color swatch]
Nursing Home	[Color swatch]
Miscellaneous	[Color swatch]
Clinic	[Color swatch]
Healthcare Plan	[Color swatch]

Across all channels, market share for 2003 remained relatively level. Only the mail service and clinic channels experienced notable growth of over one half of one percent. However, even for mail service, the change in market share has fallen off pace from its impressive growth over the past four years. Chain store pharmacies and hospitals, the leaders in the retail and non-retail channels (respectively), each showed an increase in 2003, rebounding from a market share decline in 2002. Market share for all other channels, with the exception of nursing homes, which was up slightly, fell for the year.



DDD MARKET SHARE TRENDS 1997-2003

Market share trends for 2003 were disappointing for the majority of distribution channels. Consistent with previously reported trends, five distribution channels (healthcare plans, miscellaneous, independent pharmacies, foodstores with pharmacies and mass merchandisers) experienced declining market share. Hospitals, nursing homes and chain pharmacies showed modest growth. Once again this year, mail service and clinics fared the best achieving the greatest market share gains.

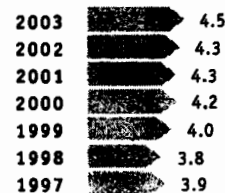
Chain Pharmacy



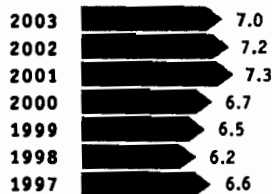
Independent Pharmacy



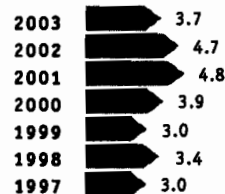
Nursing Home



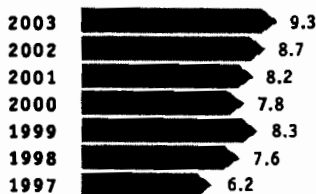
Foodstore with Pharmacy



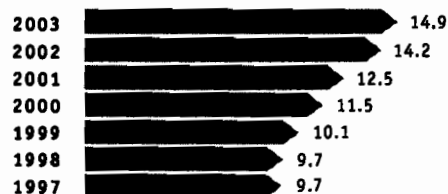
Miscellaneous



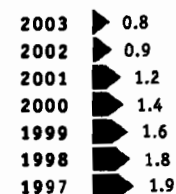
Clinic



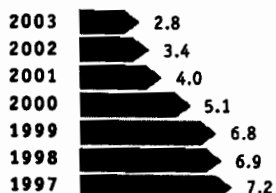
Mail Service



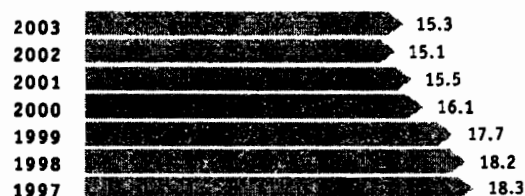
Healthcare Plan



Mass Merchandiser with Pharmacy



Hospital





DDD DOLLAR SALES 2003 vs 2002

Indicative of the industry overall, growth rates in general slowed across all channels with several channels showing negative results. For example, since 1999, mail service has experienced an average growth rate of 26 percent, significantly higher than 2003 where the growth rate was just over 14 percent. Chain pharmacies, hospitals and nursing homes all showed double digit increases in DDD dollars. Mass merchandisers, healthcare plans and the miscellaneous channels realized negative growth.

CLASS OF TRADE	2003 (000)	2002 (000)	Growth Rate %
Chain Pharmacy	\$65,966,763	\$59,928,028	10.1%
Independent Pharmacy	\$31,282,187	\$29,193,817	7.1%
Mail Service	\$34,726,306	\$30,412,912	14.2%
Mass Merchandiser with Pharmacy	\$6,557,910	\$7,248,063	-9.5%*
Foodstore with Pharmacy	\$16,336,659	\$15,429,904	5.9%
TOTAL Retail	\$154,869,825	\$142,212,724	8.9%
Hospital	\$35,599,732	\$32,220,315	10.5%
Clinic	\$21,555,751	\$18,629,455	15.7%
Nursing Home	\$10,367,451	\$9,171,616	13.0%
Miscellaneous	\$8,713,417	\$9,983,178	-12.7%
Healthcare Plan	\$1,914,586	\$1,929,052	-0.7%
TOTAL Non-Retail	\$78,150,937	\$71,933,616	8.6%
TOTAL	\$233,020,762	\$214,146,340	8.8%

* Growth rate is underestimated due to limited data access.

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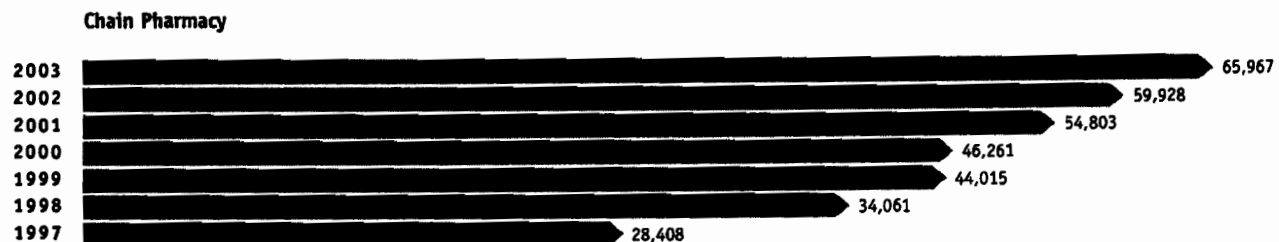
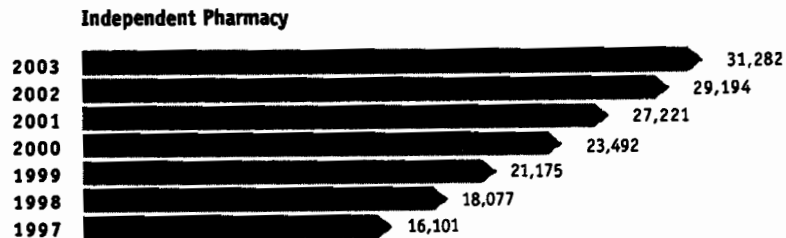
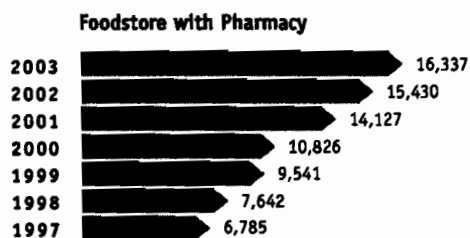
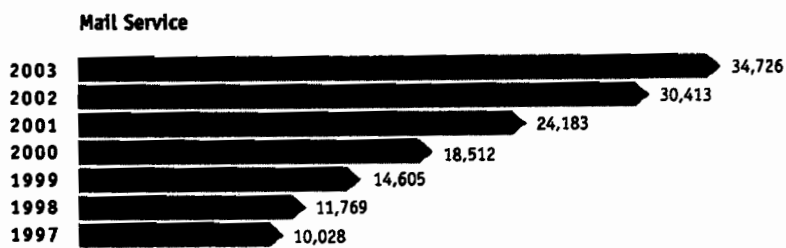
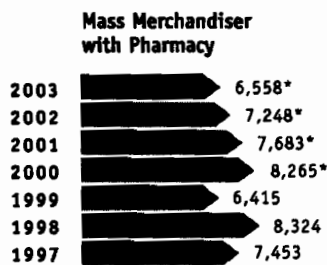
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RETAIL SALES DOLLAR TRENDS 1997-2003

All five of the retail channels, except for mass merchandisers, realized gains in dollar trends. Chain pharmacies led the pack followed by the mail service channel. Sales for independent pharmacies and foodstores with pharmacies increased consistent with previous years. Total retail sales increased by \$12 billion over 2002 to nearly \$155 billion in 2003.

Total Retail Sales in \$ Millions	
2003	154,870
2002	142,213
2001	128,017
2000	107,356
1999	95,750
1998	79,873
1997	68,774



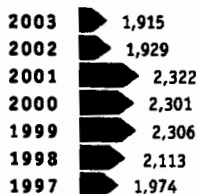
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NON-RETAIL SALES DOLLAR TRENDS 1997-2003

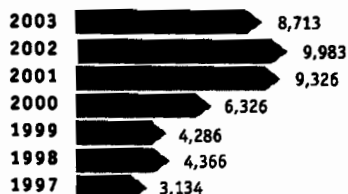
Total Non-Retail Sales in \$ Millions	
2003	78,151
2002	71,934
2001	65,744
2000	54,095
1999	50,385
1998	40,641
1997	34,486

Hospitals, clinics and nursing homes had increases in DDD dollars, but at a more modest rate than the leading retail channels. Healthcare plans continued to decline, and the miscellaneous channel, which in recent years had shown increases, also experienced a decrease in dollars. For 2003, the non-retail market, which has historically shown variability in dollar trends, achieved over \$78 billion in sales, up from \$71 billion in 2002.

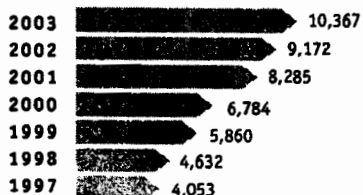
Healthcare Plan



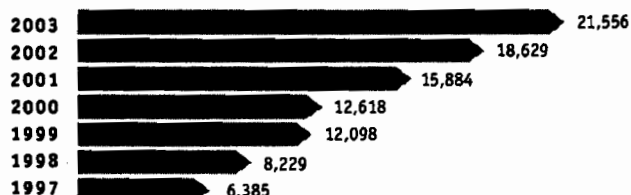
Miscellaneous



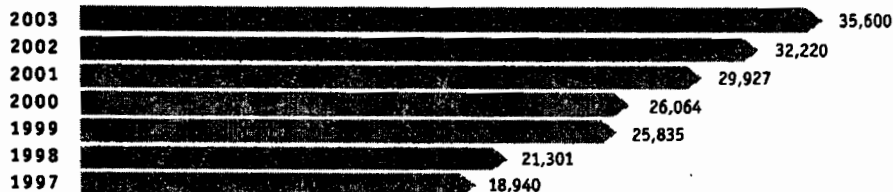
Nursing Home



Clinic



Hospital



CLASS-OF-TRADE DOLLAR GROWTH

Dollar growth by outlet varied significantly for each of the classes of trade with three channels showing negative growth — mass merchandisers, healthcare plans and the miscellaneous channels. Hospitals, clinics, nursing homes, and chain pharmacies all showed steady growth. Foodstores with pharmacies, mail service and independents realized a decline.

Class	Growth in \$ Millions 2003 vs. 2002	Dollar Increase Per Outlet (\$ actual)
Chain Pharmacy	\$6,039	\$304,692
Hospital	\$3,380	\$338,271
Clinic	\$2,927	\$46,482
Independent Pharmacy	\$2,088	\$116,563
Mail Service	\$4,313	\$11,784,153
Miscellaneous	-\$1,270	-\$129,923
Mass Merchandiser with Pharmacy	-\$690	-\$141,626
Foodstore with Pharmacy	\$907	\$90,882
Nursing Home	\$1,195	\$221,419
Healthcare Plan	-\$14	-\$11,966