THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Ron Graham, D.Ph.

SUBJECT: **Packet Contents for Board Meeting – May 11, 2004**

DATE: May 5, 2004

NOTE: **THE DUR BOARD WILL MEET AT 6:00 P.M.**

Enclosed are the following items related to the May meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – **See Appendix A.**

Update on DUR/MCAU Program **- See Appendix B.**

Long Term Care Consultant Pharmacist Presentation - **See Appendix C.**

Review of Oklahoma State Law and Agency Policy for Adding Categories to the Product Based Prior Authorization Program – **See Appendix D.**

Action Item – Annual Review of Antihypertensives – Vote to Prior Authorize Caduet™ - See Appendix E.

Review and Discuss SSRI's – **See Appendix F.**

Thirty (30) Day Notice of Intent to Prior Authorize/Preferred Drug List for HMG-CoA Inhibitors – **See Appendix G.**

Review and Discuss Antiasthmatics (excluding inhaled corticosteroids) – **See Appendix H.**

FDA and DEA Updates – **See Appendix I.**

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – May 11, 2004 @ 6:00p.m.

Oklahoma Health Care Authority
4545 N. Lincoln Suite 124
Oklahoma City, Oklahoma 73105
Oklahoma Health Care Authority Board Room

AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

1. **Call To Order**
   A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

2. **Public Comment Forum**
   A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

3. **Action Item - Approval of DUR Board Meeting Minutes – See Appendix A.**
   A. April 13, 2004 DUR Minutes
   B. Memorandum of April 13, 2004

Items to be presented by Dr. Browning, Dr. Whitsett, Chairman:

4. **Update on DUR/MCAU Program - See Appendix B.**
   A. Medication Coverage Activity Audit for April 2004
   B. Help Desk Activity Audit for April 2004

Items to be presented by Dr. Woodward, Dr. Lapsley, Dr. Whitsett, Chairman:

5. **Long Term Care Consultant Pharmacist Presentation - See Appendix C.**
   A. Phil Woodward – Oklahoma Pharmacists Association
   B. Margaret Lapsley – Neighbor Care

Items to be presented by Dr. Nesser, Dr. Whitsett, Chairman:

6. **Review of Oklahoma State Law and Agency Policy for Adding Categories to the Product Based Prior Authorization Program – See Appendix D.**
   A. Legislative Laws
   B. OHCA Policy

Items to be presented by Dr. Moore, Dr. Whitsett, Chairman:

7. **Action Item – Annual Review of Antihypertensives – Vote to Prior Authorize Caduet™ – See Appendix E.**
   A. Oklahoma Medicaid Utilization Review
   B. COP Recommendations
   C. Vote on Prior Authorization of Caduet™
   D. Angiotensin II Receptor Blockers and Combo's Utilization Review
   E. COP Recommendations

Items to be presented by Dr.Gorman, Dr. Kim, Dr. Whitsett, Chairman:

8. **Review and Discuss SSRI's – See Appendix F.**
   A. Oklahoma Medicaid Utilization and Economic Review
   B. COP Recommendations

Items to be presented by Dr. Gorman, Dr. Kim, Dr. Whitsett, Chairman:

9. **Thirty (30) Day Notice of Intent to Prior Authorize/Preferred Drug List HMG-CoA Inhibitors (Statins) – See Appendix G.**
   A. Oklahoma Medicaid Utilization and Economic Review
   B. COP Recommendations

Items to be presented by Dr. Flannigan, Dr. Whitsett, Chairman:

10. **Review and Discuss Antiasthmatics (excluding inhaled corticosteroids)- See Appendix H.**
    A. Oklahoma Medicaid Utilization Review
    B. COP Recommendations

11. **FDA and DEA Updates – See Appendix I.**

12. **Future Business**
    A. Hepatitis C Agents Review
    B. Maintenance Drug List - Quantity Limits
    C. Epogen™ / Procrit™ Review
    D. Antibiotic Review
    E. Benzo/Ambien™ Follow-up Review
    F. Vote to PA Provigil™, Synagis™ and Fuzeon™
    G. Narcotics Review
    H. ARB Follow-up Review

13. **Adjournment**

APPENDIX A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of APRIL 13, 2004

BOARD MEMBERS:	PRESENT	ABSENT
Rick G. Crenshaw, D.O.	X	
Dorothy Gourley, D.Ph.	X	
Cathy Hollen, D.Ph.		X
Dan McNeill, Ph.D., PA-C	X	
Cliff Meece, D.Ph.	X	
Dick Robinson, D.Ph., Vice-Chair	X	
James M. Swaim, D.Ph.	X	
Thomas Whitsett, M.D., Chair		X
(VACANT)		
(VACANT)		

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./Clinical Pharmacist	X	
Karen Egesdal, D.Ph./Clinical Pharmacist/OHCA Liaison	X	
Kelly Flannigan, D.Ph./Clinical Pharmacist	X	
Shellie Gorman, Pharm.D./Clinical Pharmacist	X	
Ronald Graham, D.Ph., Manager, Operations/DUR	X	
Chris Kim Le, Pharm.D.; Clinical Pharmacist	X	
Ann McIlvain, Pharm.D.; Clinical Pharmacist	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Carol Peek, Pharm.D.; Clinical Pharmacist	X	
Visiting Pharmacy Student: n/a		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Kristall Bright; Pharmacy Financial Analyst	X	
Alex Easton, M.B.A.; Pharmacy Operations Manager	X	
Mike Fogarty, C.E.O	X	
Lynn Mitchell, M.D., M.P.H, Medical Director	X	
Nancy Nesser, D.Ph., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.		X
Lynn Rambo-Jones, J.D.		X
Rodney Ramsey; Pharmacy Claims Specialist	X	

OTHERS PRESENT:

Pat Evans, Bristol-Myers Squibb
David Dude; Bristol-Myers Squibb
Cristi Davis O'Brien; AstraZeneca
Lana Stewart; Merck
Ann Thompson; Janssen
Scott Bowman; Abbott
Barbara Boner; Novartis
Meg Propes; Eli Lilly
Richard Ponder; Johnson & Johnson
Jorge Nassar; Bristol-Myers Squibb
Mark DeClerk; Eli Lilly
Rebecca Waldrip; Sanofi
Brian Henderson; Aventis
Eric Knam; Pfizer
Darryl Davis; Pfizer
Brett Spencer; Purdue
Angela Menchaca; Amgen
Aliza Tomlinson; Janssen
Holly Jacques; Merck
Charlene Kaiser; Wyeth
Jonathan Klock; GlaxoSmithKline
Ron Schnare; Abbott
Jim Goddard; Shire
Laura Hill; Takeda
Jill Miller; TAP

PRESENT FOR PUBLIC COMMENT:

Dr. Marguerite Enlow; Bristol-Myers Squibb
Curtis Krause; MedImmune

AGENDA ITEM NO. 1: CALL TO ORDER

1A: Roll Call

Dr. Robinson called the meeting to order. Roll call by Dr. Graham established the presence of a quorum.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

2A: Acknowledgement of Speakers and Agenda Item

Dr. Robinson acknowledged Dr. Marguerite Enlow, public comment for Agenda Item No. 10.

Dr. Robinson acknowledged Curtis Krause, public comment for Agenda Item no. 6.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: February 10, 2004 DUR Minutes

Dr. McNeill moved to approve minutes; motion seconded by Dr. Swaim .

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 4: UPDATE ON DUR/MCAU PROGRAM

4A: Medication Coverage Activity Report: March 2004

The March 2004 activity audit noted total number of petitions submitted was 16,138 including super-PA's and special circumstance PA's. Approval/denial/duplicate percentages were indicated on the reports included in the agenda packet for this meeting. Monthly and quarterly reports included in agenda packet; presented by Dr. Browning.

4B: Help Desk Activity Report: March 2004

Total calls for March 2004 numbered 19,232 (81.5% pharmacies, 8.5% clients, 2.1% physicians, 7.9% other). Monthly and quarterly reports included in agenda packet; presented by Dr. Browning.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: VOTE ON NEW P.A. CRITERIA FOR ANTI-ULCERS

Material included in agenda packet; presented by Dr. McIlvain. Board members requested that the Brand name Omeprazole remain a Tier 2 product for now.

Dr. Meece moved to approve; motion seconded by Dr. Gourley.

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: NOTICE OF INTENT TO PRIOR AUTHORIZE SYNAGIS™

Materials included in agenda packet; presented by Dr. Moore.

For Public Comment: Curtis Krause: *I appreciate the opportunity to address the Board. I work for MedImmune, manufacturer of Synagis. There are a couple of things that we'd like to ask the Board . . . to take a look at. One is the inclusion of low birth weights. There is increasing evidence that the mortality . . . associated with low birth weight . . . directly related to increased instance of RSV infection. There is a paper in your packet that addresses that issue and if you'd like additional information . . . get ahold of you. The other situation, we don't have a lot of . . . with what the Board is recommending as prior authorization criteria. They're very consistent with what the AAP recommends. The one thing that we would ask you to consider though is part of the environmental factor is tobacco smoke. Despite our best efforts, we still have a huge problem with pregnant women smoking during pregnancy and there is also information in your packet addressing why we would ask that the Board consider inclusion of tobacco smoking in the house where you have an at-risk baby. Even the bulletin to providers from the Oklahoma Health Care Authority this Spring addresses that issue, so it's obviously still a problem for a lot of areas and we'd like to ask that those two things be included on the criteria. One of the things that's not on this particular slide, there are a lot of States that do include low birth weight as a criteria, as a candidate for the patient to receive Synagis. The*

mortality rate and morbidity rate associated with kids under 2500 grams at birth is fairly significant . . . greater than those kids of above 2500 grams, and that information is in your packet as well. I'd be glad to try to answer any questions anybody has.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 7: **NOTICE OF INTENT TO PRIOR AUTHORIZE CADUET™**
Materials included in agenda packet; presented by Dr. Moore.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: **NOTICE OF INTENT TO PRIOR AUTHORIZE PROVIGIL™**
Materials included in agenda packet; presented by Dr. McIlvain.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **REVIEW & DISCUSS ANTIRETROVIRAL MEDICATIONS FOR HIV**
Materials included in agenda packet; presented by Dr. McIlvain.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 10: **PHARMACOECONOMIC REVIEW OF STATINS**
Materials included in agenda packet; presented by Dr. Gorman. The Board asked for a follow-up review of "Statins" for next month.
For Public Comment, Dr. Marguerite Enlow: *Good evening. For those who I didn't meet last month, I'm Marguerite Enlow a Pharm.D. in the medical science department of Bristol-Myers Squibb. I want to thank you for this opportunity to review with you some of the distinguishing factors about the statin Pravachol, and also to ask for your consideration of Pravachol as a viable option for statin therapy for your Medicaid patients in Oklahoma. Pravachol clinical efficacy in decreasing the risk of cardiovascular events has been proven with three longterm morbidity and mortality trials called the West of Scotland trial, the CARE trial, and the lipid trial, and these trials resulted in FDA approval for indications and primary prevention, hypercholesterolemic patients, to reduce the risk of myocardial infarction, to reduce the risk of cardiovascular revascularization, and cardiovascular death. And also for an indication for secondary prevention in patients with coronary heart disease to reduce the risk of myocardial infarction, revascularization, stroke, transient ischemic attack, total mortality and to slow the rate of atherosclerosis. Perhaps the most important distinguishing feature of Pravachol is its' safety profile. In longterm clinical trials, Pravachol safety and tolerability profile was similar to placebo. In contrast to other agents of this class, Pravachol is not significantly metabolized by the cytochrome P-450 system, and therefore, it offers prescribers and patients statin therapy without concern for drug interactions with the 3A4 isoenzyme system with agents such as the HIV protease inhibitors that could increase the level of the statin, predisposing patients to an increased risk of myopathy and rhabdomyolysis. In addition, it does not interact with the P-450 isoenzyme system of 2C9 that could increase blood levels of other concomitantly administered medications such as Warfarin. In addition to Pravachol's lack of drug interaction with the P-450 system, it has a more favorable profile in terms of liver toxicity, and this is evidenced by the FDA's recommendations for less stringent liver function test monitoring with Pravachol, that being at initiation of therapy, at dose escalation and whenever clinically indicated. The last point I'd like to make is that we've all witnessed in recent years that when a new agent is added to the market, is approved by the FDA, the first couple of years you sometimes see very rare and serious side effects emerge. In the case of Pravachol, it has a proven safety profile that has been tested in over 47,000 patient years in clinical trials, and in over 12 million prescriptions over a 12-year period, and thus its' safety profile has been well characterized and well tested in the real world situation. In closing I'd like to thank you again for this opportunity to ask for your consideration of Pravachol as an option for Medicaid patients in Oklahoma, and I'd also like to open it up if you have any questions for me.*
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 11: **REVIEW & DISCUSS TAMIFLU™**
Materials included in agenda packet; presented by Dr. Browning.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 12: **FDA & DEA UPDATES**
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 13: **FUTURE BUSINESS**
13A: Hepatitis C Agents Review
13B: Maintenance Drug List
13C: Epogen/Procrit Review
13D: SSRI's Economic and Utilization Review
13E: Benzo/Ambien™ Follow-Up Review
13F: Annual Review of Antihypertensives
13G: Review of Anti-Asthmatics
13H: Consultant Pharmacist Presentation
Materials included in agenda packet; submitted by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 14: **ADJOURNMENT**
The meeting was declared adjourned.

The University of Oklahoma
College of Pharmacy
Pharmacy Management Consultants
ORI W-4403; PO Box 26901
Oklahoma City, OK 73190
(405)-271-9039

Memorandum

Date: April 19, 2004

To: Nancy Nesser, DPh, JD
Pharmacy Director
Oklahoma Health Care Authority

From: Ron Graham, DPh
Operations Coordinator / DUR Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of April 13, 2004.

Recommendation 1: Discussion and Vote on New Prior Authorization Criteria For Anti-Ulcers.

Tier 1 Medications

1. Prilosec™ OTC
2. Rx Omeprazole (generic)

Tier 2 Medications

1. Ranitidine (Zantac™) capsules and other forms besides tablets.
2. Rabeprazole sodium (Aciphex™)
3. Esomeprazole magnesium (Nexium™)
4. Lansoprazole (Prevacid™)
5. Pantoprazole sodium (Protonix™)
6. Brand Rx (Prilosec™)

Criteria

1. Tier 1 medications do not require prior authorization.
2. A **14** day trial of Prilosec OTC 40mg. or Rx Omeprazole generic 40mg. daily within the last **60** days is required before a Tier 2 medication can be authorized.
3. There will be no grandfathering after the current prior authorization expires.

MOTION CARRIED.

APPENDIX B

PRIOR AUTHORIZATION ACTIVITY AUDIT

Monthly Totals

MONTH	1999 Total *(approved/ duplicates/ denied)*	2000 Total *(approved/ duplicates/ denied)*	2001 Total *(approved/ duplicates/ denied)*	2002 Total *(approved/ duplicates/ denied)*	2003 Total *(approved/ duplicates/ denied)*	2004 Total *(approved/ duplicates/ denied)*
January	4,124	8,669	9,296	8,427	7,797	15,688
February	3,542	8,077	7,194	6,095	11,272	14,188
March	3,856	7,588	7,748	6,833	10,358	16,138
April	3,867	6,390	7,676	13,381	8,953	15,644
May	3,959	6,711	7,980	12,082	8,589	
June	3,884	6,565	7,249	8,550	8,084	
July	3,523	6,181	8,133	8,775	8,565	
August	10,676	7,183	8,195	9,353	10,213	
September	8,387	6,585	7,438	9,793	9,918	
October	3,863	6,140	7,956	11,584	9,615	
November	3,919	6,961	7,949	7,921	7,201	
December	3,953	6,206	6,385	4,867	7,391	
Calendar Year Total	**57,553**	**83,256**	**93,199**	**107,661**	**107,956**	**61,658**

Activity Audit for

April 01 2004 Through April 30 2004

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Smoking Cess. app.	Smoking Cess. den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	NPA app.	NPA den.	Misc app.	Misc den.	Daily Total
1	9	49	196	28	40	45	0	0	81	24	0	0	11	26	6	10	0	0	6	11	28	7	22	1	0	0	600
2	1	52	200	29	29	45	0	0	60	32	0	0	11	29	0	8	2	3	6	11	27	4	0	2	0	1	552
3	2	24	62	12	16	11	2	0	36	16	0	0	10	18	0	1	2	1	3	5	16	3	0	0	0	1	241
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	5	49	152	20	27	31	0	0	43	16	0	0	10	18	1	6	1	3	5	9	37	8	13	0	0	4	458
6	10	67	270	33	43	49	1	0	82	41	0	0	22	46	4	16	2	6	3	19	45	6	4	1	0	4	774
7	8	51	169	20	34	38	0	0	49	24	0	0	7	33	1	6	2	3	9	12	36	8	20	0	0	0	530
8	10	57	184	26	45	59	0	0	83	20	0	0	20	38	3	16	1	3	5	27	39	19	9	0	1	1	666
9	6	58	141	19	24	48	3	0	77	23	0	0	13	36	1	9	2	3	7	11	31	3	9	0	0	6	530
10	2	15	36	17	3	11	2	0	17	5	0	0	2	4	1	4	0	1	0	2	5	1	0	0	0	0	128
11	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	11
12	6	39	112	21	34	33	0	0	43	22	0	0	11	16	1	4	0	2	2	9	30	6	15	0	0	2	408
13	8	59	194	38	39	56	0	0	79	27	0	0	13	24	1	10	1	0	11	14	33	4	18	0	0	6	635
14	8	45	126	28	36	36	4	1	69	31	0	0	19	16	2	5	2	1	6	10	22	4	8	0	0	1	480
15	8	52	155	36	40	38	3	0	82	34	0	0	25	29	1	8	0	4	5	21	24	8	17	1	0	5	596
16	6	47	136	24	36	43	2	0	81	24	0	0	20	25	3	12	2	3	5	17	39	2	14	0	0	4	545
17	4	15	53	22	8	11	0	0	23	4	0	0	3	16	2	0	0	0	0	6	8	5	0	0	0	1	181
18	1	0	8	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	11
19	5	35	122	25	38	42	1	0	36	14	0	0	5	16	0	8	0	2	2	11	22	3	14	0	1	0	402
20	7	51	169	47	46	65	0	0	56	35	0	0	13	32	3	1	1	4	1	8	27	5	14	1	0	2	588
21	8	45	122	20	29	40	0	0	57	33	0	0	12	21	1	5	0	2	3	10	22	5	6	1	0	3	445
22	9	47	186	25	29	28	6	0	65	37	0	0	6	20	5	7	2	3	3	10	31	6	20	3	0	3	551
23	9	43	134	28	39	39	2	0	66	51	0	0	9	33	3	6	0	1	5	12	19	8	12	2	1	0	522
24	2	5	14	5	8	4	0	0	8	1	0	0	3	5	1	1	0	1	1	2	3	2	0	0	0	0	66
25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	4	33	137	23	31	27	1	0	42	9	0	0	7	11	3	7	0	3	5	7	14	11	19	2	0	2	398
27	11	46	161	35	47	41	0	0	75	30	0	0	15	30	3	10	1	1	3	11	23	7	21	0	0	3	574
28	10	35	129	25	43	39	2	0	69	15	0	0	13	27	2	2	1	1	8	12	20	9	17	1	0	1	481
29	13	51	138	17	38	37	0	0	54	15	0	0	9	24	4	8	1	1	2	6	26	9	30	1	1	3	488
30	9	54	127	35	35	46	0	0	60	26	0	0	9	28	4	7	0	1	3	8	25	9	21	2	0	5	514

Activity Audit for

April 01 2004 Through April 30 2004

Date	Antiulcers app.	Antiulcers den.	Anxiolytic/ Hypnotics app.	Anxiolytic/ Hypnotics den.	Antihistamine app.	Antihistamine den.	Growth Hormones app.	Growth Hormones den.	Stimulant app.	Stimulant den.	Smoking Cess. app.	Smoking Cess. den.	Nsaids app.	Nsaids den.	ACE Inhibitors app.	ACE Inhibitors den.	HTN Combos app.	HTN Combos den.	Calcium Channel Blockers app.	Calcium Channel Blockers den.	Plavix app.	Plavix den.	NPA app.	NPA den.	Misc app.	Misc den.	Daily Total
App.	181		3643		837		29		1493		0		299		56		23		111		652		323		4		
Den.		1124		658		962		1		609		0		621		177		53		281		162		18		58	
Average Length of Approvals in Days	90		92		98		173		268		0		351		360		341		337		302		211		68		

Smoking Cessation	0 PA's for Zyban	0 Total PA's Approved
	0 PA's for Nicotine Patch	0 Unique RID's

Changes to existing PA's	423
Total (Previous Year)	8953

*** Denial Codes**

762 = Lack of clinical information	57.99%
763 = Medication not eligible	3.44%
764 = Existing PA	15.14%
772 = Not qualified for requested Tier	7.13%

SUPER PA's

Early Refill Attempts	70203
Dosing Change	573
lost/stolen/broke	66
Other	100
wrong DS	65

Monthly Totals

	Number	Percent of Total
Approved	7714	49.31%
Additional PA's	8	0.05%
SUPER PA's	804	5.14%
Emergency PA's	6	0.04%
Duplicates	955	6.10%
Incompletes	1363	8.71%
Denied *	4794	30.64%
Total	15644	100.00%

Daily Average of 601.69 for 26 Days

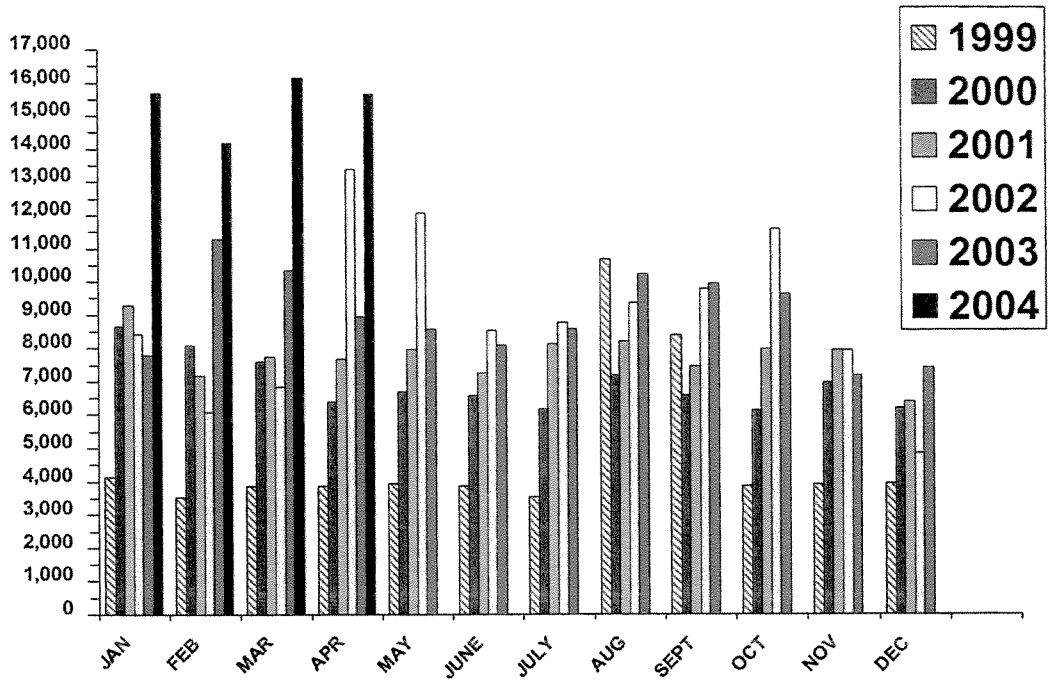
Changes to existing PA's: Backdates, changing units, end dates, etc.

Additional PA's: Done by the help desk (doctor letter responses, PA ran for the wrong person)

Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)

Monthly PA Activity

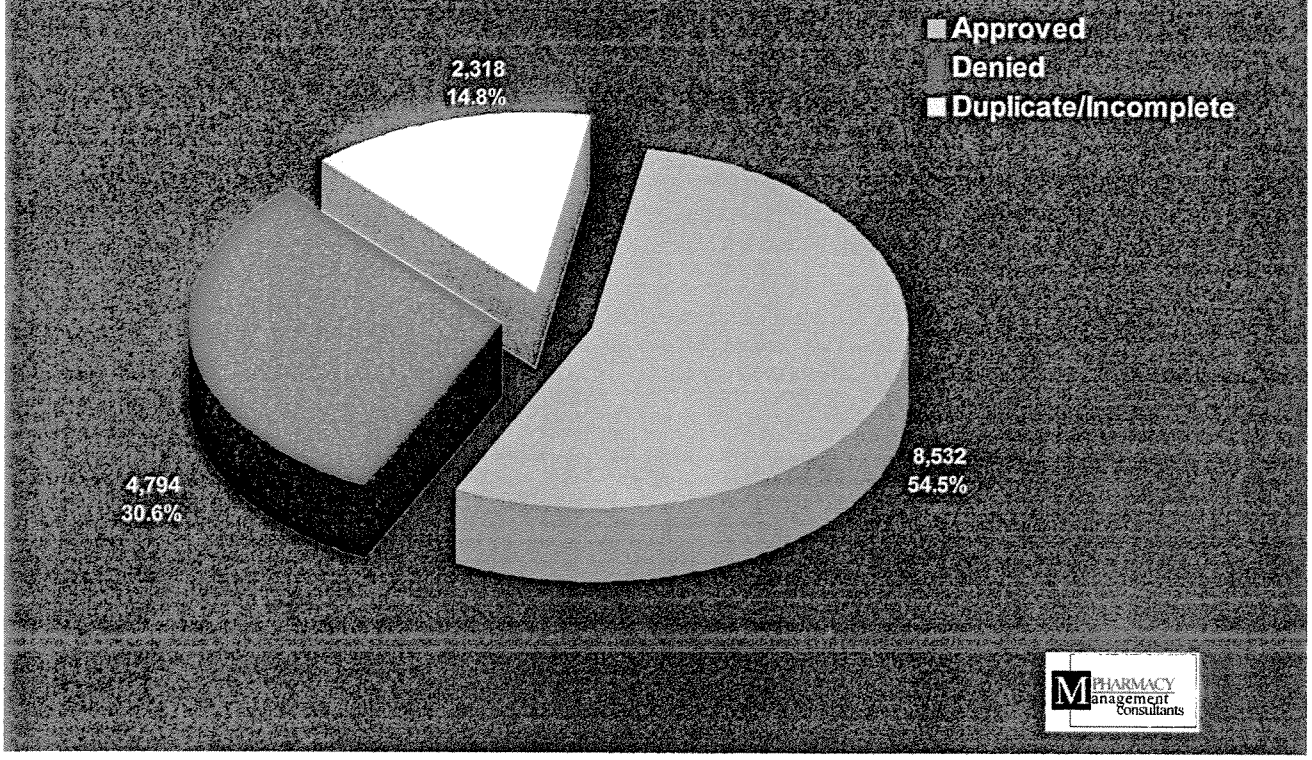
Calendar Years 2000-2004



Monthly PA Activity

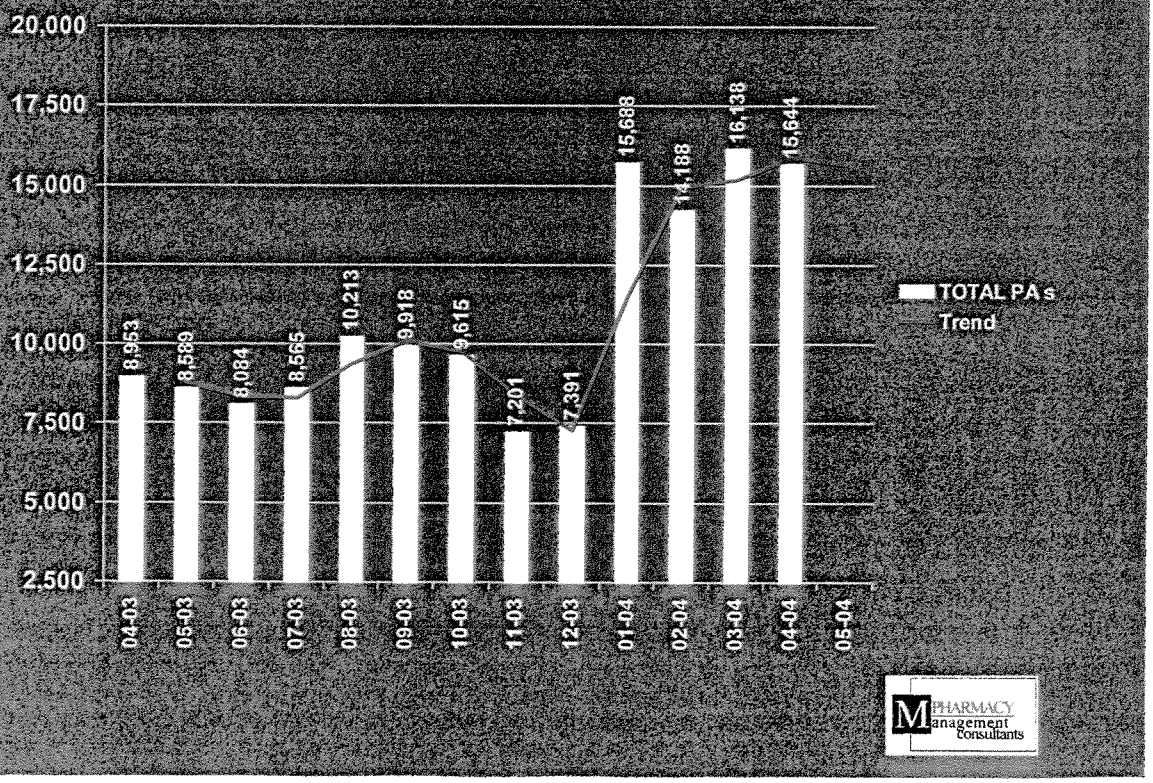
Calendar Years 2000-2004

PRIOR AUTHORIZATION ACTIVITY REPORT
April 2004



PHARMACY Management Consultants

PRIOR AUTHORIZATION REPORT
April 2003 – April 2004



PHARMACY Management Consultants

CALL VOLUME

Monthly Totals

MONTH	1999 Total	2000 Total	2001 Total	2002 Total	2003 Total	2004 Total
January	* 0	3,697	4,905	6,295	23,499	20,498
February	* 0	3,335	4,393	5,049	17,354	16,857
March	* 0	4,157	4,668	5,858	16,081	19,232
April	* 0	3,337	4,556	8,047	12,378	17,660
May	* 0	3,804	5,540	7,586	9,836	
June	* 0	2,820	4,982	6,368	8,917	
July	* 0	3,242	5,465	7,651	12,126	
August	3,883	4,333	6,881	7,629	10,454	
September	2,360	4,015	5,145	8,664	11,449	
October	1,963	4,398	5,912	9,608	12,102	
November	1,721	4,216	6,011	6,627	9,178	
December	2,475	3,804	5,314	11,710	11,461	
Calendar Year Total	**12,402**	**45,158**	**63,772**	**91,092**	**154,835**	**74,247**

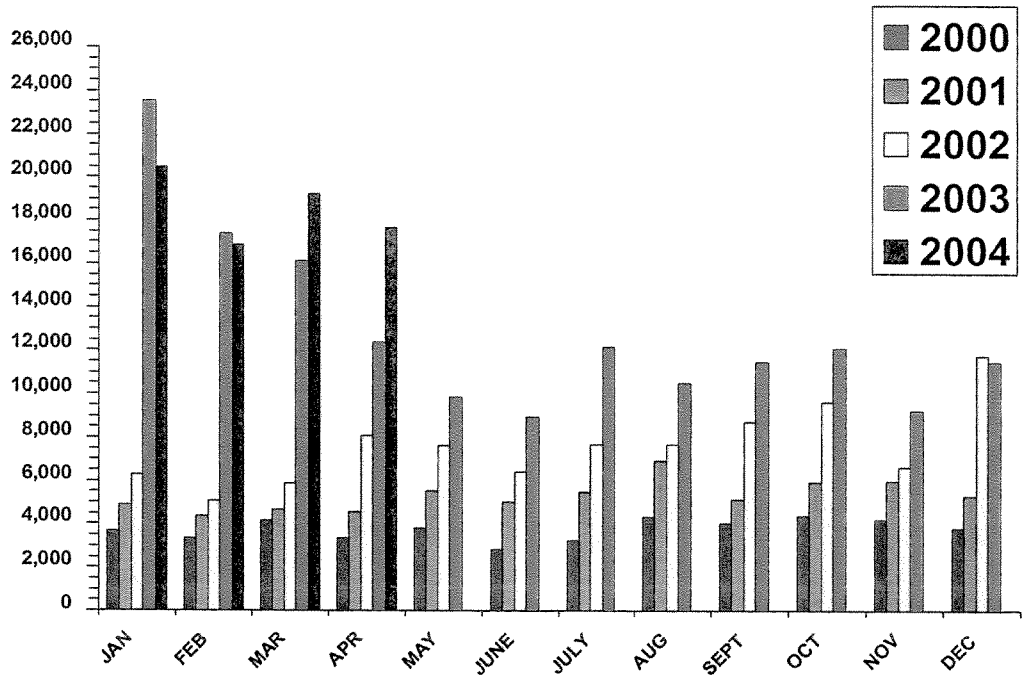
* Help Desk Call Center implemented in August 1999.

CALL VOLUME -April 2004

April 04	CALLER					ISSUE					TYPE OF CALL							RESOLUTION						
																				Resolved				
	Call Volume	Physician	Pharmacies	Clients	Other	Eligibility	Claims	PA Issue	SMAC	Other	Regular	Callback	Transferred Pharmacist	Transferred Supervisor	Proactive	ProDUR	Other	Helpdesk Resolved	Helpdesk PA	OHCA	Reversals/ Adjustments	EDS	Customer Service	Provider Contracts
1	901	726	27	80	68	182	363	188	0	168	766	59	3	2	3	63	5	891	2	2	3	0	2	1
2	804	23	625	89	67	162	328	175	1	138	681	58	4	0	2	44	15	777	12	1	2	0	10	2
3	169	0	156	6	7	30	95	13	0	31	161	6	0	1	1	0	0	165	3	1	0	0	0	0
4	50	0	50	0	0	14	31	3	0	2	50	0	0	0	0	0	0	50	0	0	0	0	0	0
5	785	16	615	76	78	161	344	153	3	124	637	66	4	0	2	61	15	772	4	2	3	3	1	0
6	873	33	648	100	92	142	402	161	0	168	734	65	4	0	1	53	16	855	2	2	6	2	6	0
7	714	29	530	92	63	174	269	157	0	114	617	44	1	0	4	23	25	699	6	1	2	0	6	0
8	679	22	520	63	74	185	227	153	1	113	576	52	3	2	2	26	18	634	33	3	4	0	5	0
9	694	21	547	75	51	123	291	145	1	134	586	36	1	1	1	38	31	678	12	0	0	0	4	0
10	138	1	118	8	11	25	72	13	0	28	128	10	0	0	0	0	0	138	0	0	0	0	0	0
11	18	0	15	0	3	5	9	0	0	4	16	0	0	0	0	1	1	18	0	0	0	0	0	0
12	807	16	662	68	61	152	415	127	1	112	705	37	4	0	0	44	17	794	1	2	6	0	3	1
13	766	18	629	68	51	135	411	110	0	110	683	45	1	0	4	26	7	746	7	1	2	0	10	0
14	739	21	561	85	72	125	346	143	1	124	640	51	1	0	1	30	16	728	5	1	5	0	0	0
15	800	9	671	59	61	127	434	117	1	121	703	46	2	0	0	31	18	784	9	1	2	1	2	1
16	697	23	542	82	50	161	312	134	0	90	622	34	3	0	2	24	12	689	2	0	5	0	1	0
17	175	0	159	5	11	41	95	16	0	23	164	10	0	0	1	0	0	175	0	0	0	0	0	0
18	55	0	54	1	0	16	31	2	0	6	55	0	0	0	0	0	0	55	0	0	0	0	0	0
19	825	24	632	89	80	113	439	158	2	113	712	66	1	0	0	36	10	816	0	0	5	1	3	0
20	815	21	663	84	47	133	430	120	0	132	740	31	1	0	2	21	20	801	3	1	3	0	5	2
21	670	15	525	81	49	123	331	127	1	88	590	39	2	0	3	27	9	654	4	0	8	0	3	1
22	801	20	628	65	88	216	287	165	0	133	676	77	1	1	1	28	17	793	2	2	3	1	0	0
23	674	16	533	77	48	125	289	125	0	135	596	37	4	0	4	26	7	661	2	7	4	0	0	0
24	141	0	136	5	0	21	79	7	0	34	134	5	0	0	0	1	1	140	0	0	1	0	0	0
25	48	47	1	0	0	12	26	0	0	10	47	0	0	0	0	0	1	48	0	0	0	0	0	0
26	752	23	615	49	65	146	377	115	0	114	666	38	1	1	4	28	14	725	3	4	9	0	8	3
27	710	27	567	72	44	131	365	114	0	100	642	29	2	0	3	21	13	695	2	3	3	0	4	3
28	795	23	610	85	77	122	402	142	0	129	691	55	1	1	3	33	11	780	2	3	4	0	6	0
29	781	20	638	76	47	97	493	99	1	91	710	39	4	1	0	24	3	778	1	0	1	0	1	0
30	784	24	631	69	60	109	416	128	1	130	707	39	2	1	0	19	16	761	2	5	13	0	3	
Total	17,660	1,218	13,308	1,709	1,425	3,308	8,409	3,110	14	2,819	15,435	1,074	50	11	44	728	318	17,300	119	42	94	8	83	14
Percentage	100.00%	6.90%	75.36%	9.68%	8.07%	18.73%	47.62%	17.61%	0.08%	15.96%	87.40%	6.08%	0.28%	0.06%	0.25%	4.12%	1.80%	97.96%	0.67%	0.24%	0.53%	0.05%	0.47%	0.08%

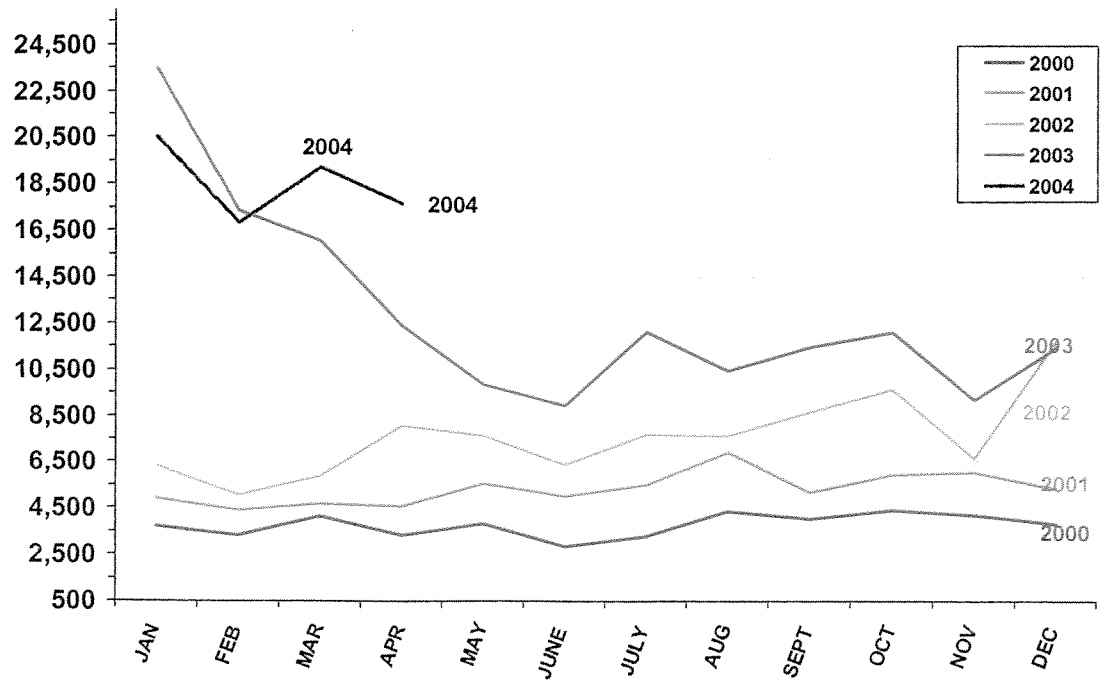
Monthly Call Volume

Calendar Years 2000-2004

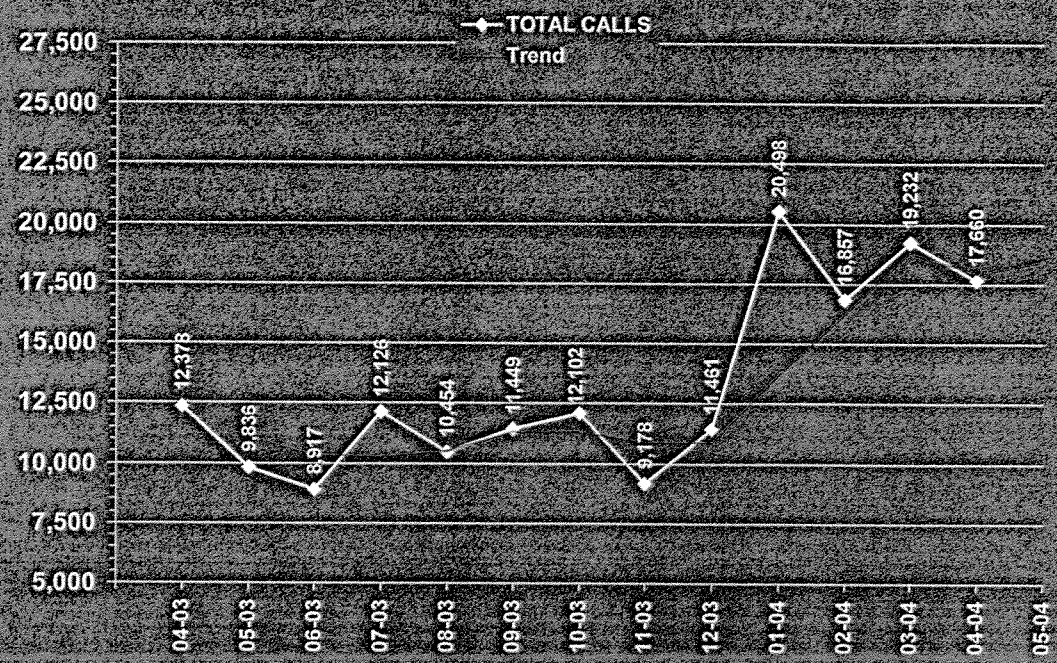


Monthly Call Volume

Calendar Years 2000-2004

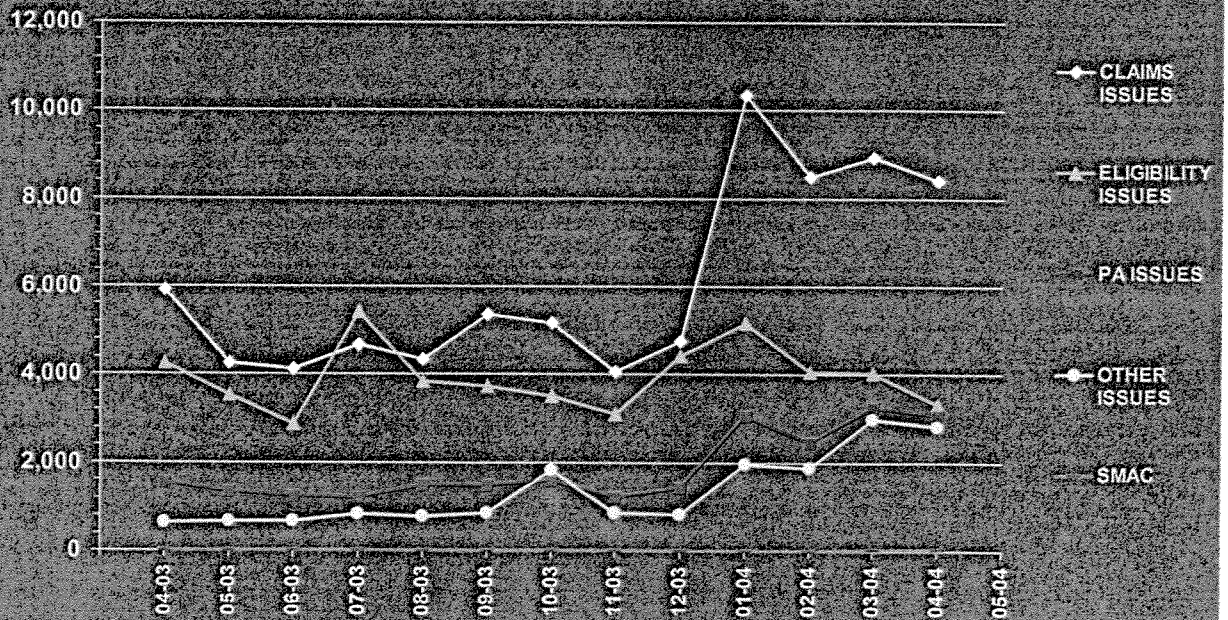


CALL VOLUME MONTHLY REPORT
April 2003 – April 2004



PHARMACY Management Consultants

CALL VOLUME ISSUES
April 2003 – April 2004



PHARMACY Management Consultants

APPENDIX C

Fact Sheet

American Society of Consultant Pharmacists

The American Society of Consultant Pharmacists is the international professional association representing senior care pharmacists, providing leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Senior care pharmacists are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illness.

For millions of senior citizens and individuals with chronic illnesses, consultant pharmacists play a vital role in ensuring optimal drug therapy. In their role as medication therapy experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy. Consultant pharmacists manage and improve drug therapy and improve the quality of life of the senior population and other individuals residing in a variety of environments, including hospitals, nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice, and home- and community-based care.

ASCP supports senior care pharmacy practice and practitioners through the development of standards, guidelines, and policies relevant to geriatric pharmacotherapy and senior care pharmacy; by influencing legislation, regulation, and health care policy to foster and create a favorable professional and business environment for senior care pharmacists; and by encouraging productive and collaborative relationships with other professional organizations, provider groups, and political and lay organizations concerned with the health care of older persons.

Senior Care Pharmacy Facts:

- Today there are 38 million seniors in the United States; by 2030, that number will rise to 75 million.
- Every day in the United States, another 6,000 people reach the age of 65.
- There are 5.5 million seniors with long-term disabilities in the United States. This figure is expected to increase to 10 million by the year 2020, and to 20 million by 2040.
- Life expectancy at age 85 has increased 24% since 1960; and is projected to increase another 44% by 2040, with an accompanying increase in the incidence of conditions such as hip fractures and Alzheimer's disease.

Senior Care Pharmacy

While medications are probably the single most important factor in improving the quality of life for older Americans, the nation's seniors are especially at risk for medication-related problems due to physiological changes of aging, higher incidence of multiple chronic diseases and conditions, and greater consumption of prescription and over-the-counter medications.

The economic impact of medication-related problems in persons over the age of 65 now rivals that of Alzheimer's disease, cancer, cardiovascular disease, and diabetes. Medication-related problems are estimated to be one of the top five causes of death in that age group, and a major cause of confusion, depression, falls, disability, and loss of independence.

For more than a generation, consultant pharmacists have dedicated themselves to protecting the health of our most vulnerable, often forgotten citizens–residents of nursing facilities. Today, the senior care pharmacists ASCP represents are patient advocates for all of our nation's senior population, wherever they reside.

Consultant Pharmacy Practice

Consultant pharmacists are committed to caring for the well-being of each individual, taking into account the complex interrelationships between disease states, nutrition, medications, and other variables. They are essential players on the health care team, and influential decision-makers in all aspects of drug therapy. Consultant pharmacists counsel patients, provide information and recommendations to prescribers and caregivers, review patients' drug regimens, present in-service educational programs, and oversee medication distribution services.

Estimated Annual Cost of Medication Related Problems:

- $76.6 billion among the ambulatory population
- $20 billion in acute-care facilities
- $7.6 billion in nursing facilities

Total annual direct medical cost of medication-related problems in the United States: **$104.2 billion**

In addition to these basic responsibilities, consultant pharmacists provide a wide range of other primary care services to the nation's seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment.

The groundbreaking ASCP-sponsored Fleetwood Project, the preliminary results of which were published in the Archives of Internal Medicine, provides a clear picture of the enormous impact of consultant pharmacist services in achieving optimal therapeutic outcomes and reducing medication-related problems. The Fleetwood study found that consultant pharmacists' drug regimen review services in the nation's nursing facilities improve therapeutic outcomes by 43% and save as much as $3.6 billion annually in costs associated with medication-related problems.

ASCP: Serving the Needs of a Dynamic Profession

The American Society of Consultant Pharmacists was founded in 1969 to represent the interests of its members and promote safe and effective medication therapy for the nation's seniors. The organization has grown dramatically over the past quarter century and its membership continues to diversify.

Today ASCP has chapters in 19 states and Canada, 30 state affiliates, and hundreds of international members in 18 countries. As consultant pharmacists' practice activities expand and diversify, so does their need for innovative programs, information, and resources. ASCP is strongly committed to meeting these needs.

Senior Care Pharmacy Facts:

- Adverse drug reactions are among the top five greatest threats to the health of seniors.
- 28% of hospitalizations among seniors are due to adverse drug reactions.
- 32,000 seniors suffer hip fractures each year due to falls caused by medication-related problems.
- The elderly account for 12.7% of

Government Affairs. ASCP protects the interests of consultant pharmacists and their patients in lobbying and congressional testimony on Capitol Hill, with federal regulatory agencies, and with state legislatures. The Society tracks and analyzes hundreds of legislative and regulatory developments nationwide, and maintains an effective political presence through the ASCP-PAC and the Capitol Fund.

the U.S. population, but consume approximately 34% of total prescriptions.

- On average, individuals 65 to 69 years old take nearly 14 prescriptions per year, individuals aged 80 to 84 take an average of 18 prescriptions per year.

Publications. ASCP members receive several publications, including: *The Consultant Pharmacist*, the Society's award-winning monthly journal, presenting peer-reviewed clinical research, news, and practice management information; ASCP Update, a monthly newsletter focusing on pharmacy news, ASCP programs and initiatives, and state and federal legislative and regulatory developments; and *Clinical Consult* continuing education newsletter, providing in-depth information on a wide range of clinical topics.

Practice Resources. To help consultant pharmacists succeed in a demanding and changing health care environment, ASCP offers a broad array of manuals, texts, videotapes, and software programs. These include resources such as the *Medication Policy and Procedure Manual for Assisted Living* and *Nursing Home Survey Procedures and Interpretive Guidelines: A Resource for the Consultant Pharmacist.*

Traineeships and Research. The ASCP Research and Education Foundation funds, coordinates, and conducts a wide range of traineeships and research programs in long-term care and geriatric health care. Since its inception in 1992, the ASCP Foundation has provided more than $250,000 to fund such programs. The Foundation is currently sponsoring the Fleetwood Project Research Initiative, a landmark study to quantify the impact of consultant pharmacists' services in improving treatment outcomes and reducing health care costs.

Senior Care Pharmacy Facts:

- The number of seniors needing long-term care is projected to rise to 13.8 million by the year 2030; 5.3 million will reside in nursing homes and other long-term care facilities.
- There are more than 1.6 million nursing home beds in the United States; this represents an increase of over 25% since 1980.

Continuing Education. ASCP offers many opportunities for ACPE-accredited continuing education at its midyear conference, annual meeting, and other regional and chapter-sponsored meetings, seminars, and workshops. Click here for more information on upcoming ASCP meetings and conventions.

"Medications are probably the single most important health care technology in preventing illness, disability, and death in the geriatric population."
—J. Avorn. "Medication Use and the Elderly: Current Status and Opportunities. Health Affairs, Spring 1995

America's Senior Care Pharmacists™

modified 02/26/04

American Society of Consultant Pharmacists Home Page

The Consultant Pharmacist's Perspective of Long-Term Care

Interview With Manju T. Beier, PharmD, FASCP
Dr. Beier is Clinical Associate Professor of Pharmacy, The University of Michigan; and President, Geriatric Consultant Resources LLC, Ann Arbor, Michigan.

Q: **How has the role of the consultant pharmacist in long-term care evolved?**

Dr. Beier: Over the course of the last decade, there have been many changes that have affected patient care in the nursing home setting, including the following:

- Guidelines for inappropriate drug therapy and implementation of Beer's criteria addressing inappropriate drugs in the elderly
- Increased attention to psychoactive drugs and their side effects
- Quality indicators for assessing quality of care
- Emphasis on instituting behavioral modification and environmental manipulation as first-line strategies for late-life psychosis

These issues have made pharmacists and other members of the long-term care team focus on providing the best possible care. We have learned the value of having a good clinical rationale for our decisions and documenting the information adequately, which is key for monitoring progress. Patient care has improved in the long-term care environment because some of the regulations and guidelines that have been implemented have forced health professionals to look at issues from a clinical perspective.

Q: **What is the consultant pharmacist's role in the drug regimen review process?**

Dr. Beier: One of the cardinal functions of the consultant pharmacist is having a very good understanding about drug therapy management issues in the frail older population. Performing drug regimen review in a skilled nursing facility (at least once per month) is the only federally mandated function of a pharmacist. However, pharmacists need to focus on having a very comprehensive review of the patient's drug therapy. Unfortunately, because of various time and financial constraints, many pharmacists are only in the long-term care setting once per month and many events transpire between their visits. Therein lies the function of the dispensing pharmacist – when orders are written and faxed to the pharmacy, the dispensing pharmacist needs to be vigilant about questioning any changes (additions or deletions) to the resident's therapy. The dispensing pharmacist, as well as the consultant pharmacist, has an important role in medication management in tandem with the care team.

Q: **What are some of the challenges for the consultant pharmacist in the drug regimen review?**

Dr. Beier: Some important issues include preventing potential drug interactions and recommending the best possible agent from a therapeutic class for an individual resident. For example, if a patient is depressed and it has been decided to use pharmacotherapy, the pharmacist needs to scan the drug regimen and proactively recommend a drug choice that would be best for the patient in terms of morbidity,

drug interactions, and previous experience with medications. This effort takes evaluating the patient, monitoring parameters, and scrutinizing lab profiles.

Consultant pharmacists should be cognizant of available dosage forms, because many patients have swallowing disorders in nursing facilities. Awareness of chewable tablets, oral solutions, and recommending the most appropriate dosage form for the patient may enhance the quality and time for nursing care. These are the issues encompassed in the entire statement of the function of a drug regimen review. The intent is to be proactive, to minimize problems, and to have the most appropriate therapy for that individual. When pharmacists recommend therapy, there needs to be well defined and well-documented therapeutic and toxic endpoints. Many practitioners have now mentioned that the old adage of geriatric pharmacotherapy, "start low and go slow" needs to also include the suffix "but go," because many times we start medication slowly and titrate patients appropriately, but very rarely do we keep titrating upward to tolerance and optimal efficacy. Very often, patients are undermedicated even when the medication is prescribed.

Q: How can the drug review team work best together?

Dr. Beier: The team care concept is particularly apt in the nursing home facility because attending physicians' and pharmacists' presence is somewhat intermittent. Pharmacists may be required to visit the facility once per month, but depending on the complexity of the nursing home setting, visits may range from once to several times per month. Only staff such as certified nursing assistants (CNAs) may know the subtle changes that transpire from day to day and must be included in the team concept, which includes nurses, pharmacists, physicians, social workers, attending physicians, as well as other disciplines, such as dietitians, activity directors, and physician assistants.

Pharmacists need to be vigilant regarding 'consults,' since many times the consulting physician may not be aware of the total care plan and may focus mainly on their specialty. The pharmacist needs to converse with the attending physician, and be more than just a name on a piece of paper. Attending physicians should also get to know their pharmacists – talk on the phone and occasionally go on rounds together. The nurses, depending on the pharmacist's relationship with the facility, increasingly rely on the pharmacist's expertise when they come in to talk about medication management, to see what has changed, and to answer questions. Care conferences and other interdisciplinary team meetings are exceedingly important, and if at all possible, a pharmacist should be present at these meetings to contribute to the care plan in progress.

Q: What is the potential impact of the consultant pharmacist on lowering health care costs and improving care?

Dr. Beier: Although there are increasing financial pressures in today's cost-conscious health care environment, we need to keep the patient's best interest as the focal point. If certain drugs that are part of the formulary are not appropriate for an individual patient, a comparable drug, should be found. We need to streamline therapy, but still work within the parameters of the particular setting.

Many times there are conditions in our frail older patients such as depression, osteoporosis, and heart failure, for which the regimens are not optimized to get the best possible outcomes according to evidence-based medicine. Although not always applicable to older frail patients, we should employ the principles of evidence-based medicine to the benefit of the patient. In the case of osteoporosis, for example, calcium should be a fundamental intake for all patients unless there are contraindications. For heart failure, patients should be on ACE inhibitors and in some cases on beta blockers, barring any contraindications. Again, cost is important and therapies need to be optimized and streamlined. Cost involves not only the acquisition cost of the drug but also includes cost of treating side effects, costs related to lab monitoring, and costs related to lack of efficacy. In essence, it is the total cost of care that is the issue.

Q: **What issues should the consultant pharmacist be sensitive to in working with other members of the LTC team?**

Dr. Beier: One of the important principles is respect for the other members of the long-term care team. We all bring expertise to the table – the attending physician, social worker, physician assistant, nursing staff, medical director, and consultant pharmacist. If we have mutual respect and understanding for the kind of expertise that each member brings, the team will function optimally. When we communicate our recommendations to physicians and medical directors, we should do so in a non-emotional, objective manner, highlighting our clinical rationale with a few key references or a copy of a pivotal article. This way the prescriber knows that the recommendations are not based on regulatory issues only, that there is a clinical rationale as well. This will cultivate more respect for the pharmacist and emphasize the expertise pharmacists bring to the table.

APPENDIX D

28

Title 63. Public Health and Safety

Oklahoma Statutes Citationized

Title 63. Public Health and Safety

Chapter 80

Oklahoma Health Care Authority Act

Section 5030.5 - Drug prior authorization program - Conditions

Cite as: O.S. §, __ __

A. Any drug prior authorization program approved or implemented by the Medicaid Drug Utilization Review Board shall meet the following conditions:

1. The Medicaid Drug Utilization Review Board shall make note of and consider information provided by interested parties, including, but not limited to, physicians, pharmacists, patients, and pharmaceutical manufacturers, related to the placement of a drug or drugs on prior authorization;

2. Any drug or drug class placed on prior authorization shall be reconsidered no later than twelve (12) months after such placement;

3. The program shall provide either telephone or fax approval or denial within twenty-four (24) hours after receipt of the prior authorization request; and

4. In an emergency situation, including a situation in which an answer to a prior authorization request is unavailable, a seventy-two-hour supply shall be dispensed, or, at the discretion of the Medicaid Drug Utilization Review Board, a greater amount that will assure a minimum effective duration of therapy for an acute intervention.

B. In formulating its recommendations for placement of a drug or drug class on prior authorization to the Oklahoma Health Care Authority Board, the Medicaid Drug Utilization Review Board shall:

1. Consider the potential impact of any administrative delay on patient care and the potential fiscal impact of such prior authorization on pharmacy, physician, hospitalization and outpatient costs. Any recommendation making a drug subject to placement on prior authorization shall be accompanied by a statement of the cost and clinical efficacy of such placement;

2. Provide a period for public comment on each meeting agenda. Prior to making any recommendations, the Medicaid Drug Utilization Review Board shall solicit public comment regarding proposed changes in the prior authorization program in accordance with the provisions of the Oklahoma Open Meeting Act and the Administrative Procedures Act; and

3. Review Oklahoma Medicaid specific data related to utilization criterion standards as provided in division (1) of subparagraph b of paragraph 2 of Section 5030.4 of this title.

C. The Oklahoma Health Care Authority Board may accept or reject the recommendations of the Medicaid Drug Utilization Review Board in whole or in part, and may amend or add to such recommendations.

D. The Oklahoma Health Care Authority shall immediately provide coverage under prior authorization for any new drug approved by the United States Food and Drug Administration if the drug falls within a drug class that the Authority has already placed under prior authorization.

E. 1. Prior to a vote by the Medicaid Drug Utilization Review Board to consider expansion of product-based prior authorization, the Oklahoma Health Care Authority shall: 29

a. develop a written estimate of savings expected to accrue from the proposed expansion, and

b. make the estimate of savings available, on request of interested persons, no later than the day following the first scheduled discussion of the estimate by the Board at a regularly scheduled meeting.

2. The written savings estimate based upon savings estimate assumptions specified by paragraph 3 of this subsection prepared by the Authority shall include as a minimum:

a. a summary of all paid prescription claims for patients with a product in the therapeutic category under consideration during the most recent month with complete data, plus a breakdown, as available, of these patients according to whether the patients are residents of a long-term care facility or are receiving Advantage Waiver program services,

b. current number of prescriptions, amount reimbursed and trend for each product within the category under consideration,

c. average active ingredient cost reimbursed per day of therapy for each product and strength within the category under consideration,

d. for each product and strength within the category under consideration, where applicable, the prevailing State Maximum Allowable Cost reimbursed per dosage unit,

e. the anticipated impact of any patent expiration of any product within the category under consideration scheduled to occur within two (2) years from the anticipated implementation date of the proposed prior authorization expansion, and

f. a detailed estimate of administrative costs involved in the prior authorization expansion including, but not limited to, the anticipated increase in petition volume.

3. Savings estimate assumptions shall include, at a minimum:

a. the prescription conversion rate of products requiring prior authorization (Tier II) to products not requiring prior authorization (Tier I) and to other alternative products,

b. aggregated rebate amount for the proposed Tier I and Tier II products within the category under consideration,

c. market shift of Tier II products due to other causes including, but not limited to, patent expiration,

d. Tier I to Tier II prescription conversion rate, and

e. nature of medical benefits and complications typically seen with products in this class when therapy is switched from one product to another.

4. The Board shall consider prior authorization expansion in accordance with the following Board meeting sequence:

30

a. first meeting: publish the category or categories to be considered for prior authorization expansion in the future business section of the Medicaid Drug Utilization Review Board agenda,

b. second meeting: presentation and discussion of the written estimate of savings,

c. third meeting: make formal notice in the agenda of intent to vote on the proposed prior authorization expansion, and

d. fourth meeting: vote on prior authorization expansion.

Historical Data

Added by Laws 1999, c. 201, § 5, eff. July 1, 1999; Amended by Laws 2001, SB 134, c. 340 § 1, emerg. eff. June 1, 2001 (superseded document available); Amended by Laws 2002, HB 2763, c. 411, § 2, emerg. eff. June 6, 2002 (superseded document available).

Citationizer© Summary of Documents Citing This Document

Oklahoma Session Laws - 2002

Cite	Name	Level
2002 O.S.L. 411, 2002 O.S.L. 411,	Public health and safety; requiring the Oklahoma Health Care Authority to study the feasibility of implementing one or more disease state management programs. Emergency.	Discussed

Citationizer: Table of Authority

Oklahoma Statutes Citationized, Title 63. Public Health and Safety

Cite	Name	Level
63 O.S. 5030.5 ,	Drug prior authorization program - Conditions	Cited
63 O.S. 5030.5 ,	Drug prior authorization program - Conditions	Cited

oklahoma health care authority

General	Consumer	Provider	Calendar	Search

DUR Policies and Procedures

Meetings

- DUR board meetings will be held on the second Tuesday of each month at the Oklahoma Health Care Authority (OHCA).
- Meeting dates for the calendar year will be on file with the State of Oklahoma Secretary of State. Notice of meeting cancellation will be made to the Secretary of State two weeks prior to the originally scheduled meeting.
- The agenda for the monthly DUR board meeting will be posted on the front door of OHCA, located in the Lincoln Plaza, 4545 N. Lincoln Blvd., Suite 124, Oklahoma City, OK 73105. Posting will be made at least 24 hours prior to the scheduled board meeting.
- DUR board meeting packets will be prepared by the OU College of Pharmacy DUR staff and will be sent to board members via hand delivery, U.S.Mail or Federal Express. Meeting packets will be available for delivery at least five calendar days prior to the meeting.
- Copies of the DUR board meeting packets are available at Kinko's 2125 NW 23rd St, OKC, OK 73107 (405) 528-1955.
- The public comment period will occur at the beginning of each meeting or prior to the relevant agenda item so that the information can be considered in subsequent discussions.
- Parties will be limited to a five-minute period, which may be followed by a question and answer time.
- A total of eight slots for public comments will be available for each meeting.
- Individual speaking periods cannot be combined or yielded.
- Public comment will be limited to statements and/or providing information and is not to be used to direct comments or questions at an individual board member.
- A sign-up sheet will be posted 15 minutes prior to the start of each meeting. Interested parties must provide the organization or group name, the name of the individual who will be speaking, a contact phone number and the topic that will be addressed. Slots will be available on a "first-come, first-served" basis.

This page was last updated: 10/15/2003 14:29:28

APPENDIX E

Prior Authorization Annual Review - Fiscal Year 2003

Antihypertensive Drugs

Oklahoma Medicaid
May 2003

Product Based Prior Authorization - Antihypertensives

Two classes of antihypertensive agents and their associated combination products have been included in Product Based Prior Authorization since April 2002. ACE inhibitors (ACEIs), Calcium Channel Blockers (CCBs), and ACEI/HCTZ combination drugs have two tiers, while ACEI/CCB combinations have only tier-2 medications.

Current Criteria

To qualify for a tier-2 ACEI, CCB, or ACEI/HCTZ, there must be:

- documented failure of a tier-1 drug of the same class (i.e. inadequate clinical response or adverse effect)
- contraindication to the tier-1 drugs
- previous stabilization on the tier-2 drug
- a unique indication for the tier-2 drug which the tier-1 drugs lack

To qualify for a tier-2 ACEI/CCB, there must be

- failure of either a tier-1 ACEI or a tier-1 CCB
- other criteria as above

Calcium Channel Blockers (CCBs)	
Tier 1	**Tier 2**
diltiazem (Cardizem)	nicardipine (Cardene SR)
diltiazem CD (Cardizem CD)	diltazem (Cardizem LA)
diltiazem ER (Cardia XT, Diltia XT)	verapamil (Covera HS)
diltiazem SR (Cardizem SR)	isradipine (Dynacirc)
diltiazem XR (Dilacor XR)	isradipine (Dynacirc CR)
nifedipine (Adalat, Procardia)	nimodipine (Nimotop)
nifedipine CC (Adalat CC)	amlodipine (Norvasc)
nifedipine ER	felodipine (Plendil)
nifedipine XL (Nifedical XL, Procardia XL)	nisoldipine (Sular)
nicardipine (Cardene)	diltiazem (Tiazac, Taztia XT)
verapamil (Calan, Isoptin, Verelan)	bepridil (Vascor)
verapamil SR (Calan SR, Isoptin SR)	verapamil (Verelan PM)

ACE Inhibitors	
Tier 1	**Tier 2**
captopril (Capoten)	quinapril (Accupril)
enalapril (Vasotec)	perindopril erbumine (Aceon)
enalapril AT (Vasotec IV)	ramipril (Altace)
lisinopril (Prinivil, Zestril)	benazepril (Lotensin)
	trandolapril (Mavik)
	moexipril (Univasc)

ACE/HCTZ Combinations	
Tier 1	**Tier 2**
captopril/HCTZ (Capozide) enalapril/HCTZ (Vasoretic) lisinopril/HCTZ (Prinzide) lisinopril/HCTZ (Zestoretic)	quinapril/HCTZ (Accuretic) moexipril/HCTZ (Uniretic) benazepril/HCTZ (Lotensin HCT) fosinopril/HCTZ (Monopril HCT)

ACE/CCB Combinations	
Tier 1	**Tier 2**
	enalapril/felodipine (Lexxel) benazeparil/amlodipine (Lotrel) trandolapril/verapamil (Tarka)

Fiscal Year '03 Changes

No changes occurred in this category between FY 2002 and FY 2003. Since July 1, 2003, moexipiril (Univasc) and isradipine (Dynacirc CR) have been moved from tier-2 to tier-1. Benazepril and Benazepril/HCTZ (Lotensin and Lotensin-HCT) were moved to tier 1 May 1, 2004.

Utilization

For the period of July 2002 through June 2003, a total of 36,642 clients received antihypertensive drugs from the PBPA categories through the Medicaid fee-for-service program.

Drug Category	*Total # of Clients*	*# of Claims*	*Total # of Units*	*Total # of Days*	*Total Costs*	*$/Unit*	*Per Diem*
ACE Inhibitors							
Tier 1 7/1/02-6/30/03	**18,568**	**96,905**	**4,810,613**	**3,606,212**	**$2,330,738.83**	**$0.50**	***$0.67***
7/1/01 – 6/30/02	*16,319*	*85,347*	*4,030,584*	*2,889,742*	*$2,981,543.40*	*$0.79*	*$1.10*
Tier 2 7/1/02-6/30/03	**4,123**	**22,141**	**1,082,212**	**885,257**	**$1,175,266.56**	**$1.13**	***$1.38***
7/1/01 – 6/30/02	*8,388*	*43,104*	*1,871,016*	*1,555,523*	*$1,777,912.33*	*$1.01*	$1.22
ACE Inhibitor/HCTZ Combinations							
Tier 1 7/1/02-6/30/03	**2,005**	**9,905**	**507,114**	**410,008**	**$423,240.28**	**$0.88**	***$1.09***
7/1/01 – 6/30/02	*2,066*	*10,600*	*489,341*	*401,175*	*$474,368.84*	*$1.04*	$1.26
Tier 2 7/1/02-6/30/03	**348**	**1,794**	**83,810**	**72,995**	**$81,248.40**	**$1.00**	***$1.15***
7/1/01 – 6/30/02	*650*	*3,158*	*138,760*	*121,154*	*$117,703.70*	*$0.91*	$1.04
Calcium Channel Blockers							
Tier 1 7/1/02-6/30/03	**12,430**	**66,316**	**3,172,428**	**2,577,857**	**$3,287,999.21**	**$1.07**	***$1.32***
7/1/01 – 6/30/02	*11,861*	*63,499*	*2,867,666*	*2,274,183*	*$2,957,404.21*	*$1.10*	$1.38
Tier 2 7/1/02-6/30/03	**5,945**	**33,407**	**1,490,913**	**1,323,880**	**$2,294,995.24**	**$1.59**	***$1.79***
7/1/01 – 6/30/02	*10,052*	*56,083*	*2,251,463*	*1,999,900*	*$3,261,479.57*	*$1.54*	$1.74
ACE Inhibitor/Calcium Channel Blocker Combinations							
Tier 2 7/1/02-6/30/03	**1,452**	**8,049**	**397,862**	**332,504**	**$757,022.29**	**$1.96**	***$2.35***
7/1/01 – 6/30/02	1,813	10,192	454,079	381,062	$765,760.84	$1.79	$2.14

Total Cost FY '03	**$10,359,510.81**
Total Cost FY '02	*$12,336,172.89*
Total Claims FY '03	**238,517**
Total Claims FY '02	*271,982*
Total Clients FY '03	**36,642**
Total Clients FY '02	*38,054*
Total Days FY '03	**9,208,713**
Total Days FY '02	*9,622,739*
Per Diem FY '03	**$1.16**
Per Diem FY '02	*$1.37*

Total petitions submitted in for this category for FY '03:

	ACE	CCB	HTN	Total
Approved	1,133	1,499	654	3,286
Denied	1,882	2,080	525	4,487
Incompletes	270	273	86	629
Total	3,285	3,852	1,265	**8,402**

Claims were reviewed to determine the age/gender of the clients.

Age	Female	Male	Totals
0 to 9	39	77	116
10 to 19	224	178	402
20 to 34	843	382	1225
35 to 49	2111	1547	3658
50 to 64	5044	2690	7734
65 to 79	10022	3395	13417
80 to 94	7985	1382	9367
95 and Over	661	62	723
Totals	**26929**	**9713**	**36642**

Recommendations

The college of pharmacy has the following recommendation(s) for Fiscal Year 2004:

1. Continue to move drugs from tier-2 to tier-1 as they become available as generic and have a SMAC applied.
2. Add Caduet (amlodipine/atorvastatin) to Tier-2 Calcium Channel Blockers.

Caduet® (Atorvastatin/Amlodipine)
Intent to Prior Authorize
Oklahoma Medicaid
May, 2004

Recommendations for Prior Authorization Criteria

Caduet will be placed in the Product Based Prior Authorization program as a tier-2 calcium channel blocker. Approval would require:

1. An FDA approved diagnosis from each drug category (CCB and HMG-CoA Reductase inhibitor)
2. A documented failed trial of a tier-1 CCB (diltiazem, verapamil, nicardipine, isradipine (Dynacirc CR), or nifedipine).
3. Concurrent use of an HMG-CoA reductase inhibitor.
4. Patients currently using both Norvasc and Lipitor will be encouraged to switch to the appropriate strength of Caduet.

Angiotensin II Receptor Blockers – Utilization

Angiotensin II Receptor Blockers (ARBs)							
Fiscal Year	**Total # of Clients**	**# of Claims**	**Total # of Units**	**Total # of Days**	**Total Costs**	**$/Unit**	**Per Diem**
7/1/02-6/30/03	**5,226**	**25,384**	**1,152,824**	**1,017,559**	**$1,665,086.15**	**$1.48**	***$1.68***
7/1/01 – 6/30/02	*4,329*	*24,408*	*1,015,492*	*877,923*	*$1,327,339.56*	*$1.39*	$1.61
Change vs previous year	*897↑*	*976↑*	*1,373,321↑*	*139, 636↑*	*$337,746.59↑*	*$0.09↑*	$0.07↑
% change	*20.7%↑*	*4%↑*	*13.5%↑*	*15.9%↑*	*25.4%↑*	*6.5%↑*	4.3%↑

ARB-HCTZ Combinations							
Fiscal Year	**Total # of Clients**	**# of Claims**	**Total # of Units**	**Total # of Days**	**Total Costs**	**$/Unit**	**Per Diem**
7/1/02-6/30/03	**2,953**	**15,102**	**694,444**	**630,553**	**$1,109,369.16**	**$1.64**	***$1.81***
7/1/01 – 6/30/02	*2,505*	*13,724*	*561,196*	*508,355*	*$804,114.38*	*$1.53*	$1.69
Change vs previous year	*448↑*	*1378↑*	*133,248↑*	*122,198↑*	*305,254.78↑*	*0.11↑*	0.12↑
% change	*17.9%↑*	*10%↑*	*23.7%↑*	*24%↑*	*38.0%↑*	*7.2%↑*	7.1%↑

Angiotensin II Receptor Blockers with & without Hydrochlorothiazide (HCTZ)
Medicaid Utilization 7/1/02 – 6/30/03

Angiotensin II Receptor Blockers (ARBs)							
	Total # of Clients	**# of Claims**	**Total # of Units**	**Total # of Days**	**Total Costs**	**$/Unit**	**Per Diem**
tacand (candesartan) 4 mg	4	14	630	630	$812.14	$1.35	$1.35
acand (candesartan) 8 mg	26	122	4760	3796	$6,199.26	$1.36	$1.71
Atacand (candesartan) 16 mg	405	1255	57745	49563	$75,327.83	$1.34	$1.57
Atacand (candesartan) 32 mg	367	1010	51133	47838	$88,663.73	$1.79	$1.91
Teveten (eprosartan) 400 mg	13	41	1900	1400	$1,858.08	$0.98	$1.33
Teveten (eprosartan) 600 mg	60	149	6416	5932	$8,030.87	$1.26	$1.36
Avapro (irbesartan) 75 mg	28	90	3644	2878	$4,996.99	$1.42	$1.81
Avapro (irbesartan)150 mg	1006	3315	148553	128397	$211,088.37	$1.47	$1.70
Avapro(irbesartan) 300 mg	420	1105	50460	52134	$85,071.72	$1.75	$1.69
Cozaar(losartan) 25 mg	344	1039	44332	38622	$62,308.81	$1.43	$1.64
Cozaar (losartan) 50 mg	2059	6366	302690	247037	$413,564.53	$1.40	$1.72
Cozaar (losartan)100 mg	553	1398	64204	61513	$119,522.44	$1.89	$1.98
Benicar (olmesartan) 5 mg	221	3	91	91	$,117.56	$1.91	$1.29
Benicar (olmesartan) 20 mg	21	631	25466	24538	$30,564.64	$1.22	$1.26
Benicar (olmesartan) 40 mg	91	220	9532	10172	$11,295.32	$1.21	$1.13
Micardis (telmisartan) 20 mg	12	33	1004	1088	$1,452.64	$1.45	$1.33
Micardis (telmisartan) 40 mg	212	598	14044	22551	$32,664.31	$1.41	$1.50
Micardis (telmisartan) 80 mg	226	627	27386	26198	$39,831.39	$1.50	$1.56
Diovan (valsartan) 80 mg cap	20	38	1880	1480	$1,954.17	$1.25	$1.35
Diovan (valsartan) 160 mg cap	51	96	4541	4038	$6,117.44	$1.40	$1.58
Diovan (valsartan) 40 mg tab	8	13	620	575	$754.44	$1.22	$1.31
Diovan (valsartan) 80 mg tab	1225	3924	168953	152910	$233,445.88	$1.41	$1.56
Diovan (valsartan) 160 mg tab	1020	3060	141384	122858	$207,816.35	$1.51	$1.74
Diovan (valsartan) 320 mg tab	105	237	11434	11299	$21,627.24	$1.91	$1.93

ARB/HCTZ Combinations	Total # of Clients	# of Claims	Total # of Units	Total # of Days	Total Costs	$/Unit	Per Diem
.tacand HCT 16/12.5 mg	85	244	1,119	10,629	$19,905.99	$1.79	$1.88
Atacand HCT 32/12.5 mg	139	382	18,489	17,362	$33,022.54	$1.82	$1.94
Teveten HCT 600/12.5 mg	6	9	3,311	341	$3,487.57	$1.27	$1.27
Teveten HCT 600/25 mg	1	1	90	90	$112.05	$1.25	$1.25
Avalide 150/12.5 mg	344	1,082	50,539	43,961	$84,713.86	$1.72	$1.97
Avalide 300/12.5 mg	220	697	31,244	30,335	$56,029.06	$1.87	$1.93
Hyzaar 50/12.5 mg	1,383	4,455	204,736	176,643	$279,385.80	$1.40	$1.62
Hyzaar 100/25 mg	1,123	3,419	149,416	144,828	$273,769.42	$1.88	$1.95
Micardis HCT 40/12.5 mg	35	103	4,816	4,066	$6,257.81	$1.34	$1.59
Micardis 80/12.5 mg	118	356	14,505	13,163	$22,843.95	$1.61	$1.77
Diovan HCT 80/12.5 mg	580	1,710	76,762	70,969	$114,307.84	$1.53	$1.65
Diovan HCT 160/12.5 mg	836	2,515	120,614	107,764	$195,994.85	$1.66	$1.86
Diovan HCT 1660/25 mg	79	229	11,683	10,402	$22,593.25	$1.94	$2.18

Recommendations

The college of pharmacy recommends the ARBs be brought back for review and a vote on establishing a prior authorization/preferred drug list.

APPENDIX F

Pharmacoeconomic Review of the SSRIs

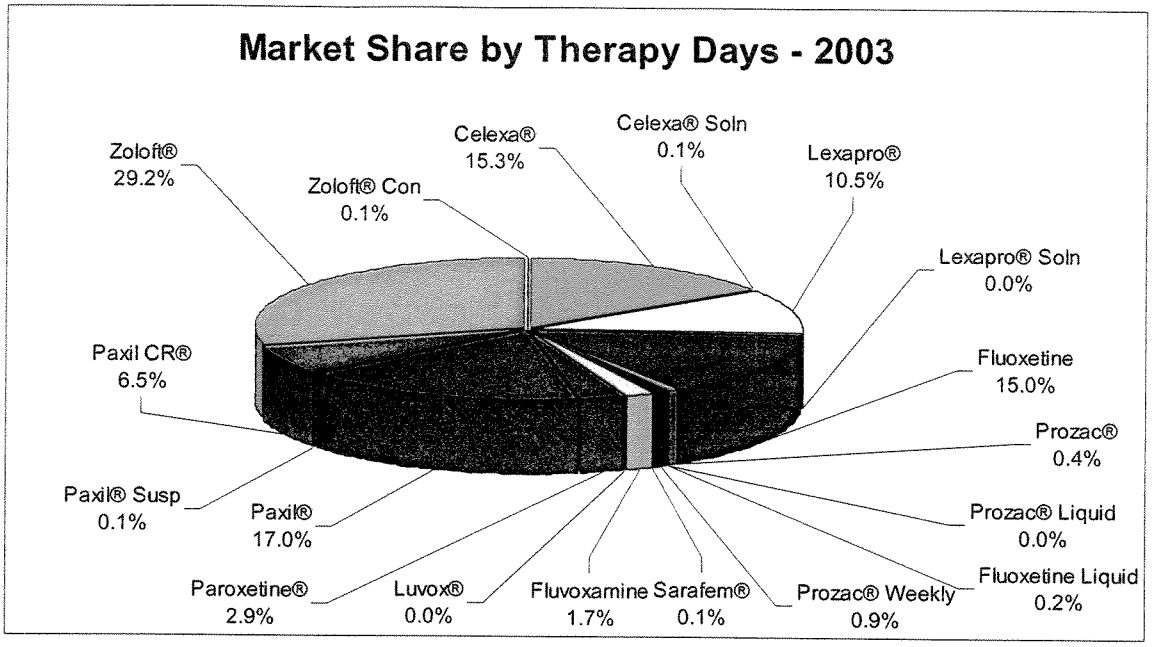
Oklahoma Medicaid
May 2004

Utilization

For the period of January 2003 through December 2003, a total of 37,902 clients received selective serotonin reuptake inhibitors (SSRI) products through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Unit/ Day	Total Cost	Total Clients	Per Diem
Celexa®	27,753	1,047,718	964,698	1.09	$ 2,416,348.67	6,433	$ 2.50
Celexa® Soln	159	41,345	3,705	11.16	$ 17,980.54	38	$ 4.85
Lexapro®	19,067	687,642	663,384	1.04	$ 1,452,565.99	6,882	$ 2.19
Lexapro® Soln	47	11,985	1,245	9.63	$ 5,007.53	20	$ 4.02
Fluoxetine	26,643	1,265,158	950,446	1.33	$ 1,118,869.50	7,924	$ 1.18
Prozac®	645	38,715	25,159	1.54	$ 110,443.12	229	$ 4.39
Fluoxetine Liquid	434	66,660	11,076	6.02	$ 44,367.04	103	$ 4.01
Prozac® Liquid	46	7,170	1,286	5.58	$ 5,679.88	29	$ 4.42
Prozac® Weekly	1,899	10,911	59,423	0.18	$ 218,211.14	426	$ 3.67
Sarafem®	96	3,525	3,265	1.08	$ 5,810.07	45	$ 1.78
Fluvoxamine	3,327	203,505	108,001	1.88	$ 181,954.36	643	$ 1.68
Luvox®	42	2,026	1513	1.34	$ 3,082.41	27	$ 2.04
Paroxetine®	4,868	200,215	182,803	1.10	$ 474,359.01	2,865	$ 2.59
Paxil®	29,052	1,164,402	1,075,770	1.08	$ 3,111,487.63	7,745	$ 2.89
Paxil® Susp	199	64,447	5,380	11.98	$ 32,537.84	74	$ 6.05
Paxil CR®	11,015	458,172	413,491	1.11	$ 1,192,364.31	4058	$ 2.88
Zoloft®	51,055	2,127,044	1,847,320	1.15	$ 5,128,599.49	13,172	$ 2.78
Zoloft® Con	142	10,270	4,400	2.33	$ 10,126.65	39	$ 2.30
Total	176,489	7,410,910	6,322,365		$ 15,529,795.18		$2.46

Total Cost Calendar Year '03	**$15,529,795.18**
Total Cost Calendar Year '02	*$15,152,739.50*
Total Claims Calendar Year '03	**176,489**
Total Claims Calendar Year '02	*186,500*
Total Clients Calendar Year '03	**37,902**
Total Clients Calendar Year '02	*36,118*
Total Days Calendar Year '03	**6,322,365**
Total Days Calendar Year '02	*6,207,075*
Per Diem Calendar Year '03	**$2.46**
Per Diem Calendar Year '02	*$2.44*



Age and Gender CY02

Age	Female	Male	Totals
0 to8	342	597	939
9 to 17	2,949	2,791	5,740
18 to 34	5,081	1,330	6,411
35 to 49	4,246	1,903	6,149
50 to 64	3,993	1,447	5,440
65 to 79	4,542	1,372	5,914
80 to 94	4,256	881	5,137
95 and Over	347	41	388
Totals	**25,756**	**10,362**	**36,118**

Age and Gender CY03

Age	Female	Male	Totals
0 to8	333	593	926
9 to 17	3,076	2,978	6,054
18 to 34	5,560	1,456	7,016
35 to 49	4,645	2,123	6,768
50 to 64	4,233	1,552	5,785
65 to 79	4,604	1,364	5,968
80 to 94	4,166	855	5,021
95 and Over	325	39	364
Totals	**26,942**	**10,960**	**37,902**

For the period of January 2003 through December 2003, a total of 12,359 clients had medical claims with the following diagnoses.

ICD-9 Code	Description	Clients with Diagnosis	% of Clients (n=12,359)
296*	MDD, Single Episode	4,777	38.65 %
300.01	Panic Disorder	505	4.09 %
300.02	Generalized Anxiety Disorder	954	7.72 %
300.23	Social Phobia	62	0.50 %
300.3	Obsessive-Compulsive Disorder	293	2.37 %
307.51	Bulimia	10	0.08 %
308.3	Acute Stress Reaction	86	0.70 %
309.81	Prolonged Posttraumatic Stress Disorder	1,791	14.49 %
311**	Depressive Disorder, Not Elsewhere Classified	7,681	62.15 %
625.4	Premenstrual Dysphoric Disorder (PMDD)	42	0.34 %

*Includes all subgroups.
**1,684 clients had diagnoses of both MDD and DD NEC. Combined diagnosis equal 87.18% of these clients.

Recommendations

The college of pharmacy recommends the SSRIs be brought back for further review and vote on establishing a prior authorization/preferred drug list.

APPENDIX G

Thirty (30) Day Notice of Intent to Prior Authorize/Preferred Drug List
HMG-CoA Inhibitors (Statins)

Oklahoma Medicaid
May 2004

Review of Available Products

% LDL Reduction Target[1]	Generic Name	Brand Name	Dosage Forms Available	Usual Adult Dose	Indications	% 2003 Market Share	Cost Ratio[2]	% LDL Reduction	LDL Ratio[1]	Cost/ LDL Ratio[3]
High to Moderate	**Rosuvastatin**	Crestor®	5, 10, 20, 40 mg Tabs	10-40 mg QD	1-3, 5	0.22	2.51	45 - 63	1.89	1.33
	Atorvastatin	Lipitor®	10, 20, 40, 80 mg Tabs	10-80 mg QD	1-5	**50.53**	2.63	39 - 60	1.74	1.51
	Simvastatin	Zocor®	5, 10, 20, 40, 80 mg Tabs	5-80 mg QHS	1-5,7	31.50	2.98	26 - 47	1.28	2.33
Moderate to Low		Mevacor®	10, 20, 40 mg Tabs	10-80 mg QHS or divided doses	1-2,6-7	0.13	2.36	35 - 37	1.26	1.87
		Altocor®	10, 20, 40, 60 mg XR Tabs	10-80 mg QHS or divided doses	1-2, 6-7	0.54	1.53	30 - 40	1.23	1.24
	Lovastatin	Lovastatin[4]	10, 20, 40 mg Tabs	10-80 mg QHS or divided doses	1-2, 6-7	1.94	1.98	28 - 37	1.14	1.74[5] (0.93)[5]
	Pravastatin/Aspirin	Pravigard PAC®[6]	20/81 & 325, 40/81 & 325, 80/81 & 325 mg Tabs	40-80 mg QD	1-4,6,7	0.01	4.48	22 - 37	1.04	4.31
	Pravastatin	Pravachol®	10, 20, 40 80 mg Tabs	40-80 mg QD	1-4,6,7	10.79	1.61	22 - 37	1.04	1.55
Low	**Lovastatin/Niacin**	Advicor®	20/500, 750, 1000 mg Tabs	20/1000 mg QHS	1-2	0.27	1.71	30	1.05	1.63
	Fluvastatin	Lescol® & Lescol XL®	20, 40 mg Caps & 80 mg XL Tabs	20-80 mg QHS or divided doses	1-2,7	4.07	1.00	22 - 35	1.00	1.00

[1]Based on the midpoint for labeled LDL reduction percentages.
[2]Cost Ratio does not reflect an actual dollar amount.
[3]Cost/LDL Ratio = Cost Ratio / LDL Ratio.
[4]SMAC for lovastatin initiated 11/03.
[5]Projected Cost/LDL Ratio for lovastatin based on current SMAC and previous utilization = 0.93.
[6]No utilization of the 80/81 or 80/325 mg tablets occurred during CY '03. Indications for aspirin not included.

Indications:

1. Primary hypercholesterolemia (Includes heterozygous familial and nonfamilial hypercholesterolemia)
2. Mixed dyslipidemia (Includes Fredrickson types IIa and IIb)
3. Hypertriglyceridemia (Includes Fredrickson type IV)
4. Primary dysbetalipoproteinemia (Includes Fredrickson type III)
5. Homozygous familial hyperlipidemia
6. Primary prevention coronary events
7. Secondary prevention cardiovascular event(s)

Recommended Preferred Drug List

The following preferred drug list has been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of clients. This list was determined based on FDA approved indications, LDL reduction target ranges, Cost/LDL ratio, and current client usage. The college of pharmacy recommends this list to the Drug Utilization Review board for approval before referral to the Oklahoma Healthcare Authority for final limitations or additions based on cost effectiveness.

1. Lescol and Lescol XL
2. Lovastatin (generic only)
3. Lipitor

The following criteria are recommended for approval of a non-preferred product:

1. Previous failure to achieve desired LDL reduction with a preferred statin - defined by at least 6-8 weeks of continuous therapy at standard to high dose.
2. Previous stabilization on non-preferred medication.
3. Documented increased risk for drug interactions. Specifically: concurrent immunosuppressant therapy, HIV antiretroviral therapy, and therapy with other potent inhibitors of CYP450 system.
4. Documented adverse effect or contraindication to the preferred products.

The college of pharmacy recommends the Statins be brought back for a vote on establishing this prior authorization/preferred drug list.

APPENDIX H

Asthma Utilization (excluding inhaled corticosteroids)

January 2003 to December 2003

Oklahoma Medicaid
May 2004

NAEPP Asthma Guidelines (see attached Quick Reference)

The guidelines were revised in July 2002. This revision made inhaled corticosteroids the preferred treatment for long-term control of all types of asthma, except for mild intermittent asthma. Bronchodilators, theophylline, and leukotriene agents are either adjunctive or alternate choices.

Utilization – January 2003 to December 2003

For the period of January 2003 to December 2003 a total of 55,860 clients received asthma medications through the Medicaid fee-for-service program. The chart below is a summary of the utilization. A detailed chart is at the end of this report.

Drug	# of Claims	Total Units	Total Days	Total Cost	Total Clients	Per Diem CY 2003	Per Diem CY 2002
Ipratropium Nebs/Powder	7,249	1,235,980	113,966	$ 464,785.72	2,160	$ 4.08	$ 6.66
Atrovent® MDI/Refills	3,695	92,279	95,038	$ 268,442.47	1,116	$ 2.82	$ 2.60
Albuterol MDI/Refills/HFA	52,078	1,125,761	1,146,913	$ 916,872.06	24,333	$ 0.80	$ 0.98
Albuterol Oral	12,329	1,473,246	229,051	$ 252,019.78	7,804	$ 1.10	$ 1.09
Albuterol Nebs	29,463	4,526,388	485,541	$ 630,017.84	15,172	$ 1.30	$ 1.42
Albuterol Powder	4	1,080	82	$ 1,632.36	2	$ 19.91	$ 5.08
Xopenex® Nebs	8,451	1,275,736	118,292	$ 963,841.67	3,590	$ 8.15	$ 7.43
Metaproterenol Oral	381	53,407	5,587	$ 5,205.80	296	$ 0.93	$ 0.81
Metaproterenol Nebs	50	6,153	752	$ 1,285.55	20	$ 1.71	$ 1.90
Metaproterenol MDI	228	4,829	5,544	$ 10,812.79	82	$ 1.95	$ 1.82
Maxair® MDI	663	12,108	18,528	$ 61,737.38	302	$ 3.33	$ 2.85
Terbutaline Oral	1,241	79,784	21,813	$ 41,714.46	762	$ 1.91	$ 1.77
Terbutaline Inj	21	802	400	$ 15,918.60	5	$ 39.80	$ 23.83
Foradil®	1,083	66,549	32,149	$ 84,734.53	337	$ 2.64	$ 2.09
Serevent® MDI/Diskus	5,113	164,019	134,687	$ 467,227.04	2,293	$ 3.47	$ 3.39
Epinephrine Inj	14	182	260	$ 84.31	12	$0.71	$0.98

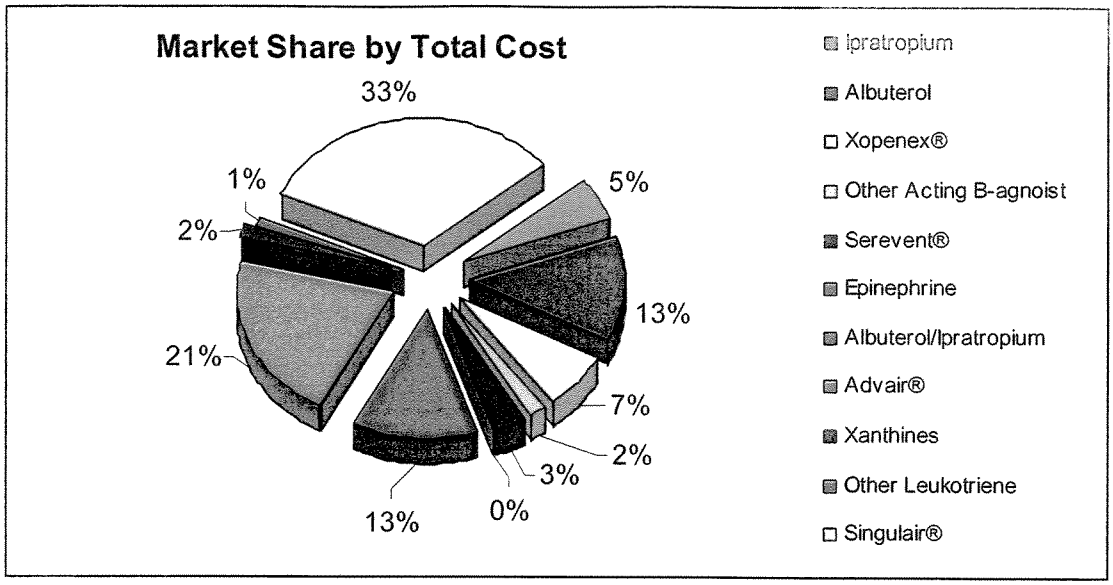
DuoNeb® Soln	4,436	1,046,921	81,279	$ 625,549.64	1,527	$7.70	$6.99
Combivent® MDI	14,434	313,290	353,432	$ 1,125,918.52	4,419	$3.19	$2.73
Advair®	21,165	1,295,306	618,306	$ 2,872,221.45	7,518	$4.65	$4.16
Aminophylline – all	87	13,334	1,784	$ 922.03	22	$0.52	$0.34
Dilor®	11	695	172	$ 735.47	4	$4.28	$2.98
Theophylline – all	8,142	827,001	295,001	$ 220,368.54	2,190	$0.75	$0.69
Zyflo®	64	6,740	1,760	$ 5,380.90	7	$3.06	$2.97
Singulair®	41,737	1,578,019	1,566,448	$ 4,368,799.35	14,135	$2.79	$2.50
Accolate®	1,683	110,978	57,634	$ 130,801.41	58	$2.27	$2.06
Totals	**214,122**	**15,296,558**	**5,382,463**	**$ 13,535,472.37**	**55,860***	**$ 2.51**	**$ 2.28**

*Total number of non-duplicated clients

Total Cost 12 month period	**$13,535,472.37**
Total Cost Previous 12 months	*$12,156,127.30*
Total Claims 12 month period	**214,122**
Total Claims Previous 12 months	*229,344*
Total Clients 12 month period	**55,860**
Total Clients Previous 12 months	*53,781*
Per Diem 12 month period	**$2.51**
Per Diem Previous 12 months	*$2.28*

Claims were reviewed to determine the number of claims per client and the age of the clients.

Age	Female	Male
0 to 9	9,812	13,656
10 to 19	5,236	5,235
20 to 34	2,963	511
35 to 49	2,494	1,107
50 to 64	3,322	1,654
65 to 79	4,083	1,920
80 to 94	2,768	787
95 and over	261	51
Totals	**30,939**	**24,921**



Cost Drivers and Possible Ways to Contain Cost

Singulair® – 33% of Market Share

At the May 2003 DUR Board Meeting, the Board voted on and approved a motion to require a prior authorization for Singulair® use in allergic rhinitis. Implementation of this PA has been delayed due to the required steps needed for a rule change. The PA is currently slated to start 7/1/04.

The chart below gives a comparison of the daily cost of therapy for all the leukotriene medications. This category may be an area to consider for product based prior authorization (PBPA). An in-depth clinical analysis and estimated economic impact would be needed prior to recommendation of a PA.

	Cost/day
Zyflo 600mg tab	$ 3.12104
Singulair 4mg granules	$ 2.75440
Singulair 4mg chew tab	$ 2.75440
Singulair 5mg chew tab	$ 2.75440
Singulair 10mg tab	$ 2.75440
Accolate 10mg tab	$ 2.44170
Accolate 20mg tab	$ 2.44170

Advair® – 21% of Market Share

	Flovent® Diskus Cost/Inhal	Serevent® Diskus Cost/Inhal	Total Cost	Advair® Diskus Cost/Inhal
Fluticasone/Salmeterol 100-50 mcg	$0.98985	$1.48573	$2.47558	$1.89346
Fluticasone/Salmeterol 250/50 mcg	$1.37690	$1.48573	$2.86263	$2.39668
Fluticasone/Salmeterol 500/50 mcg	$2.75380*	$1.48573	$4.23953	$3.31012

*Flovent does not come in 500mcg so 2-250mcg must be used

The use of the combination product, Advair®, is more cost effective than using the Flovent® plus Serevent®. The combination product also decreases the total number of inhalations needed per day, hopefully increasing client compliance.

Albuterol/Ipratropium Products – 13% of Market Share

	Combivent® MDI (103-18mcg/inhalation)	Albuterol (90mcg/inhalation)	Atrovent® (18mcg/inhalation)
Cost per MDI	$58.86	$6.26	$56.19
Cost per inhalation	$0.2943	$0.0313	$0.28095
Total cost per inhalation	$0.2943	$0.31225	

The cost difference in utilizing the combination product versus the individual components used together may not favor of Combivent® greatly; however, approximately equivalent doses of these products would take 8 inhalations of Combivent® per day compared to 16 inhalations of albuterol plus Atrovent®. Compliance with this high number of inhalations could be a problem. Additionally, Combivent® delivers a slightly higher dose of albuterol than an albuterol MDI.

	DuoNeb® Soln (0.5-2.5mg/3ml)	Albuterol Soln (2.5mg/3ml dose)	Ipratropium Soln (0.5mg/2.5ml)
Cost per dose	$1.83039	$0.19878	$0.2567
Total	$1.83039	$0.45548	

The cost ingredient analysis shows that the combination product is approximately four times more expensive than the individual ingredients combined. The total amount spent for DuoNeb® for CY'03 was $625,549.64. While a savings could be realized if the generic ingredients were used instead of the combination

product, it would increase the total volume of medication and amount of time the client would spend with the nebulizer.

Xopenex® (levalbuterol) - 7% of Market Share

Levalbuterol is the R-enantiomer of racemic albuterol. This enantiomer is responsible for all bronchodilating activity of commercially available albuterol. Medicare (CMS) reimburses for Xopenex® at the same rate as for albuterol due to it having "no clinical advantage over albuterol". Medicaid paid almost $1 million for this Medication for CY'03. Prior authorization of this medication may be an option to contain costs. However, an in-depth clinical analysis in comparison to albuterol, along with an estimated economic impact would be needed to draw any meaningful conclusions.

Recommendations

The Oklahoma Health Care Authority is currently phasing in quantity limits previously voted on by the DUR Board. This along with tighter restrictions on dispensing brand when generic is available should help curb cost increases in this area. Other strategies to consider are possible PA of leukotriene agents and levalbuterol.

Detailed Utilization for CY'03

	Total Claims	Total Units	Total Days	Clients	Total Paid
Central Acting Bronchodilator					
Ipratropium Neb	7,248	1,235,860	113,936	2,159	$464,479.72
Ipratropium Powder	1	120	30	1	$306.00
Ipratropium MDI	3,690	92,209	94,953	1,164	$268,256.22
Ipratropium MDI Refill	5	70	85	2	$186.25
Short Acting Beta-Agonists					
Albuterol MDI	49,593	1,097,360	1,094,211	23,217	$795,860.92
Albuterol MDI Refill	239	6,851	6,043	126	$5,658.33
Albuterol Rot Cap	2	200	28	2	$73.04
Albuterol Tab 2mg	517	42,780	14,623	189	$4,692.19
Albuterol Tab 4mg	877	66,584	26,863	207	$9,922.20
Albuterol Tab ER 4mg	1,812	119,583	58,507	496	$112,440.82
Albuterol Tab ER 8mg	329	24,617	12,198	86	$44,712.05
Albuterol Syrup 2mg/5ml	8,794	1,219,682	116,860	6,826	$80,252.52
Albuterol Neb 0.083%	22,007	4,168,290	359,286	11,107	$481,803.10
Albuterol Neb 0.5%	6,319	201,174	109,586	3,310	$70,371.88
Albuterol Neb 0.63mg/3ml	542	73,810	8,283	343	$36,839.78
Albuterol Neb 1.25mg/3ml	595	83,114	8,386	412	$41,003.08
Albuterol Powder	4	1,080	82	2	$1,632.36
Albuterol Aer HFA	2,244	21,350	46,631	988	$115,279.77
Levalbuterol Neb 0.31mg	1,007	162,769	17,707	591	$123,404.82
Levalbuterol Neb 0.63mg	4,822	689,754	67,297	2,195	$520,844.39
Levalbuterol Neb 1.25mg	2,622	423,213	33,288	804	$319,592.46
Metaproterenol Tab 10mg	32	3,781	929	5	$1,237.73
Metaproterenol Syrup 10mg/5ml	349	49,626	4,658	291	$3,968.07
Metaproterenol Neb 0.4%	24	2,568	311	10	$608.10
Metaproterenol Neb 0.6%	25	3,565	427	9	$644.49
Metaproterenol Neb 5%	1	20	14	1	$32.96
Metaproterenol MDI	228	4,829	5,544	82	$10,812.79
Pirbuterol MDI	663	12,108	18,528	302	$61,737.38
Terbutaline Tab 2.5mg	656	44,443	11,725	390	$19,982.67
Terbutaline Tab 5mg	585	35,341	10,088	372	$21,731.79
Terbutaline Inj 1mg/ml	21	802	400	5	$15,918.80
Long-Acting Beta Agonists					
Formoterol Aer Cap	1,083	66,549	32,149	337	$84,734.53
Salmeterol MDI	3,148	48,049	78,883	1,418	$298,548.97
Salmeterol MDI Refill	97	1,456	2,697	54	$8,772.44
Salmeterol Diskus	1,868	114,514	53,107	821	$159,905.63
Epinephrine					
Epinephrine Inj mg/ml	14	182	260	12	$184.31
Combination Bronchodilators					
Albuterol/Ipratropium Nebs	4,436	1,046,921	81,279	1,527	$625,549.64
Albuterol/Ipratropium MDI	14,434	313,290	353,432	4,419	$1,125,918.52
Fluticasone/Salmeterol Diskus 100-50	9,050	548,388	265,426	3,551	$1,002,787.21

Fluticasone/Salmeterol Diskus 250-50	9,121	561,076	264,644	3,085	$1,285,518.76
Fluticasone/Salmeterol Diskus 500-50	2,994	185,842	88,236	882	$583,915.48
Xanthine Bronchodilators					
Aminophylline Inj 25mg/ml	4	94	68	2	$17.37
Aminophylline Soln 105mg/5ml	29	7,745	565	11	$487.87
Aminophylline Tab 100mg	4	240	28	1	$22.28
Aminophylline Tab 200mg	50	5,255	1,183	8	$394.51
Dyphylline Elixir 160mg/15ml	1	180	12	1	$29.64
Dyphylline Tab 200mg	1	30	10	1	$30.76
Dyphylline Tab 400mg	9	485	150	2	$675.07
Theophylline Cap CR 100mg	43	2,413	1,542	10	$1,103.41
Theophylline Cap CR 200mg	187	12,980	7,037	51	$8,181.24
Theophylline Cap CR 300mg	333	23,265	12,834	66	$17,605.97
Theophylline Cap ER 125mg	13	1,020	405	7	$400.97
Theophylline Cap ER 200mg	554	44,639	17,970	135	$19,431.75
Theophylline Cap ER 300mg	714	53,382	24,724	171	$26,732.54
Theophylline Cap ER 400mg	216	15,445	9,991	63	$16,273.42
Theophylline Elixir 80/15ml	96	173,083	1,749	27	$2,293.39
Theophylline Soln 80/15ml	1	630	7	1	$18.77
Theophylline Tab 125mg	10	660	330	1	$318.06
Theophylline Tab 250mg	68	5,300	2,401	14	$3,814.16
Theophylline Tab CR 100mg	102	8,701	2,907	26	$1,397.78
Theophylline Tab CR 200mg	1,043	84,394	34,004	298	$14,944.44
Theophylline Tab CR 300mg	2,004	154,007	66,828	466	$31,627.09
Theophylline Tab CR 400mg	301	19,512	13,638	109	$19,457.72
Theophylline Tab CR 450mg	0	0	0	0	$0.00
Theophylline Tab CR 600mg	168	8,828	8,087	63	$12,686.89
Theophylline Tab ER 100mg	26	1,370	574	10	$266.50
Theophylline Tab ER 200mg	838	65,494	27,609	218	$11,678.63
Theophylline Tab ER 300mg	1,605	128,076	56,356	403	$25,817.83
Theophylline Tab ER 450mg	80	6,377	2,762	14	$3,127.65
Theophylline Tab SR 300mg	10	1,000	200	1	$621.00
Theophylline Tab TD 200mg	8	660	240	3	$116.86
Theophylline Tab TD 300mg	22	1,736	790	7	$794.97
Leukotriene Agents					
Zileuton Tab 600mg	64	6,740	1,760	7	$5,380.90
Montelukast Gran 4mg	281	8,681	9,264	199	$24,183.23
Montelukast Chew 4mg	8,048	263,906	265,316	3,118	$739,888.65
Montelukast Chew 5mg	13,013	458,711	449,470	4,588	$1,278,905.97
Montelukast Tab 10mg	20,395	846,721	842,398	6,230	$2,325,821.50
Zafirlukast Tab 10mg	54	3,320	1,860	19	$3,963.91
Zafirlukast Tab 20mg	1,629	107,658	55,774	319	$126,837.50
Totals	**214,122**	**15,296,558**	**5,382,463**		**$13,535,472.37**

Stepwise Approach for Managing Infants and Young Children (5 Years of Age and Younger) With Acute or Chronic Asthma

Classify Severity: Clinical Features Before Treatment or Adequate Control	Symptoms/Day Symptoms/Night	Medications Required To Maintain Long-Term Control Daily Medications
Step 4 Severe Persistent	Continual Frequent	■ Preferred treatment: – **High-dose inhaled corticosteroids** AND – **Long-acting inhaled beta$_2$-agonists** AND, if needed, – Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)
Step 3 Moderate Persistent	Daily > 1 night/week	■ Preferred treatments: – **Low-dose inhaled corticosteroids and long-acting inhaled beta$_2$-agonists** OR – **Medium-dose inhaled corticosteroids.** ■ Alternative treatment: – Low-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline. If needed (particularly in patients with recurring severe exacerbations): ■ Preferred treatment: – **Medium-dose inhaled corticosteroids and long-acting beta$_2$-agonists.** ■ Alternative treatment: – Medium-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline.
Step 2 Mild Persistent	> 2/week but < 1x/day > 2 nights/month	■ Preferred treatment: – **Low-dose inhaled corticosteroid (with nebulizer or MDI with holding chamber with or without face mask or DPI).** ■ Alternative treatment (listed alphabetically): – Cromolyn (nebulizer is preferred or MDI with holding chamber) OR leukotriene receptor antagonist.
Step 1 Mild Intermittent	≤ 2 days/week ≤ 2 nights/month	■ No daily medication needed.

Quick Relief
All Patients

- Bronchodilator as needed for symptoms. Intensity of treatment will depend upon severity of exacerbation.
  - Preferred treatment: **Short-acting inhaled beta$_2$-agonists** by nebulizer or face mask and space/holding chamber
  - Alternative treatment: Oral beta$_2$-agonist
- With viral respiratory infection
  - Bronchodilator q 4–6 hours up to 24 hours (longer with physician consult); in general, repeat no more than once every 6 weeks
  - Consider systemic corticosteroid if exacerbation is severe or patient has history of previous severe exacerbations
- Use of short-acting beta$_2$-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term-control therapy.

Step down
Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.

Step up
If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.

Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night
- Minimal or no exacerbations
- No limitations on activities; no school/parent's work missed
- Minimal use of short-acting inhaled beta$_2$-agonist
- Minimal or no adverse effects from medications

Note

- The stepwise approach is intended to assist, not replace, the clinical decisionmaking required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs.
- There are very few studies on asthma therapy for infants.
- Gain control as quickly as possible (a course of short systemic corticosteroids may be required); then step down to the least medication necessary to maintain control.
- Minimize use of short-acting inhaled beta$_2$-agonists. Overreliance on short-acting inhaled beta$_2$-agonists (e.g., use of approximately one canister a month even if not using it every day) indicates inadequate control of asthma and the need to initiate or intensify long-term-control therapy.
- Provide parent education on asthma management and controlling environmental factors that make asthma worse (e.g., allergies and irritants).
- Consultation with an asthma specialist is recommended for patients with moderate or severe persistent asthma. Consider consultation for patients with mild persistent asthma.

Stepwise Approach for Managing Asthma in Adults and Children Older Than 5 Years of Age: Treatment

Classify Severity: Clinical Features Before Treatment or Adequate Control	Symptoms/Day Symptoms/Night	PEF or FEV_1 PEF Variability	Medications Required To Maintain Long-Term Control Daily Medications
Step 4 Severe Persistent	Continual Frequent	≤ 60% > 30%	■ **Preferred treatment:** – **High-dose inhaled corticosteroids** AND – **Long-acting inhaled $beta_2$-agonists** AND, if needed, – Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)
Step 3 Moderate Persistent	Daily > 1 night/week	> 60% – < 80% > 30%	■ **Preferred treatment:** – **Low-to-medium dose inhaled corticosteroids and long-acting inhaled $beta_2$-agonists.** ■ Alternative treatment (listed alphabetically): – Increase inhaled corticosteroids within medium-dose range OR – Low-to-medium dose inhaled corticosteroids and either leukotriene modifier or theophylline. If needed (particularly in patients with recurring severe exacerbations): ■ **Preferred treatment:** – **Increase inhaled corticosteroids within medium-dose range and add long-acting inhaled $beta_2$-agonists.** ■ Alternative treatment (listed alphabetically): – Increase inhaled corticosteroids within medium-dose range and add either leukotriene modifier or theophylline.
Step 2 Mild Persistent	> 2/week but < 1x/day > 2 nights/month	≥ 80% 20–30%	■ **Preferred treatment:** – **Low-dose inhaled corticosteroids.** ■ Alternative treatment (listed alphabetically): cromolyn, leukotriene modifier, nedocromil, OR sustained-release theophylline to serum concentration of 5–15 mcg/mL.
Step 1 Mild Intermittent	≤ 2 days/week ≤ 2 nights/month	≥ 80% < 20%	■ No daily medication needed. ■ Severe exacerbations may occur, separated by long periods of normal lung function and no symptoms. A course of systemic corticosteroids is recommended.

Quick Relief
All Patients

- Short-acting bronchodilator: 2–4 puffs **short-acting inhaled $beta_2$-agonists** as needed for symptoms.
- Intensity of treatment will depend on severity of exacerbation; up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed. Course of systemic corticosteroids may be needed.
- Use of short-acting $beta_2$-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term-control therapy.

Step down
Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.

Step up
If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.

Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night
- Minimal or no exacerbations
- No limitations on activities; no school/work missed
- Maintain (near) normal pulmonary function
- Minimal use of short-acting inhaled $beta_2$-agonist
- Minimal or no adverse effects from medications

Note

- The stepwise approach is meant to assist, not replace, the clinical decisionmaking required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs (PEF is % of personal best; FEV_1 is % predicted).
- Gain control as quickly as possible (consider a short course of systemic corticosteroids); then step down to the least medication necessary to maintain control.
- Minimize use of short-acting inhaled $beta_2$-agonists. Overreliance on short-acting inhaled $beta_2$-agonists (e.g., use of approximately one canister a month even if not using it every day) indicates inadequate control of asthma and the need to initiate or intensify long-term-control therapy.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g., allergens and irritants).
- Refer to an asthma specialist if there are difficulties controlling asthma or if step 4 care is required. Referral may be considered if step 3 care is required.

APPENDIX I

Savings From Generic Drugs Purchased at Retail Pharmacies

Generics have long offered a safe and inexpensive alternative to many brand-name drugs. Using average national retail price data from IMS Health's National Prescription Audit *Plus*™, we calculate the per-day drug costs for several different hypothetical patients. We show that the drug costs per day can fall by 14 to16 percent if patients use generics instead of branded drugs, depending on their medical needs. Patients whose needs can be fully satisfied with generics could enjoy reductions of 52 percent in the daily costs of their medications.

For this analysis we use the average national retail price of drugs in brick-and-mortar pharmacies (i.e. chain, independent and foodstore pharmacies, excluding internet, mail order and long-term care pharmacies), a measure that averages pharmacies' revenues from uninsured customers, insured customers, and Medicaid beneficiaries alike. This measure of average national retail price would generally be lower than the retail prices paid by the uninsured. Our use of this measure implies that the savings are interpretable as total cost savings—including to Medicaid and insurance companies—and not necessarily out-of-pocket savings to patients.

We examine six hypothetical patients, and calculate two costs for each patient. The first cost estimate is for the case where all drugs are branded products. The second cost estimate is for the case where the patient buys generic versions if they are available. The six hypothetical patients include one who is prescribed only off-patent products, two who are prescribed only on-patent products, and three that are prescribed a mix of both.

Table 1 below lists the specific drugs and strengths. Using dosing information also presented below, we

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calculate average daily drug costs from prescription price data for the first quarter of 2004, taken from IMS's NPA *Plus*^{TM} data on brick-and-mortar retail pharmacies. For example, the average price of a 5 mg pill of Norvasc is $1.62, so that the average daily drug costs (including costs to all third party payers) for this daily dose of Norvasc would be $1.62.

This analysis includes several caveats. First, these hypothetical patients are chosen to be illustrative and thus may not be fully representative of the medical needs of a given individual or population. Second, generic prices available to the average consumer may be significantly lower than the median prices reported here. While the median prices are less influenced by outliers than arithmetic means, averages weighted by volume may be a better measure of the price that the typical consumer pays. Weighted averages would give greater importance to manufacturers with high sales volumes relative to smaller manufacturers. Since the low-price manufacturers are likely to sell larger volumes of drugs, the weighted average price may be less than the median price reported here. Finally, savings from generics will increase as more patents expire. For example, FDA approved a generic competitor to Paxil at the end of the period when these price data were collected, so patient #2 may enjoy some savings in the future.

The maximum savings occur when the most generics are prescribed (Scenario 1), and no savings can occur when only on-patent products are prescribed (Scenarios 2 and 3). This can occur when all drugs available with the desired active ingredient in a given dosage form are patented. However, even when generic drugs make up only a portion of the drugs prescribed, savings of 14-16 percent can be realized (Scenarios 3-6).

Table 1: Potential Savings From Generic Drugs

Hypothetical Patient	Conditions	Drugs (Brand Name/Generic where available)	Dosing(1)	Retail Cost Per Day (all brand)(2)	Retail Cost Per Day (brand/generic where available) (3)	Generic Savings ($)	Generic Savings (% of total spending)
Scenario #1	**Market Basket Total**			**$5.79**	**$2.77**	**$3.02**	**52.1%**
	Asthma	(Ventolin/albuterol) (4)	2 puffs every 4-6 hours as needed	$1.44	$0.69	$0.75	52.3%
	Hypertension	(Prinivil/lisinopril)	20 mg per day	$1.16	$0.60	$0.57	48.5%
	Diabetes	(Glucophage/metformin)	850 mg twice daily	$2.81	$1.29	$1.52	54.1%
	Congestive Heart Failure	(Lasix/furosemide)	40 mg per day	$0.38	$0.20	$0.18	47.1%

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Scenario #2	**Market Basket Total**			**$12.13**	**$12.13**	**$0.00**	**0.0%**
	Osteoarthritis	Celebrex	200 mg per day	$3.03	$3.03	$0.00	0.0%
	Hypercholesterolemia	Zocor	40 mg per day	$4.54	$4.54	$0.00	0.0%
	Depression	Paxil	20 mg per day	$2.93	$2.93	$0.00	0.0%
	Hypertension	Norvasc	5 mg per day	$1.62	$1.62	$0.00	0.0%
Scenario #3	**Market Basket Total**			**$16.05**	**$16.05**	**$0.00**	**0.0%**
	Schizophrenia	Zyprexa	10 mg per day	$9.76	$9.76	$0.00	0.0%
	Hypercholesterolemia	Lipitor	40 mg per day	$3.55	$3.55	$0.00	0.0%
	Depression	Zoloft	50 mg per day	$2.74	$2.74	$0.00	0.0%
Scenario #4	**Market Basket Total**			**$8.13**	**$6.93**	**$1.20**	**14.7%**
	Anti-coagulant	(Coumadin/warfarin)	2.5 mg per day	$0.87	$0.58	$0.30	33.8%
	Hypertension	(Vasotec/enalapril)	20 mg per day	$1.71	$0.81	$0.90	52.8%
	Osteoarthritis	Vioxx	25 mg per day	$3.00	$3.00	$0.00	0.0%
	Osteoporosis	Fosamax	70 mg per week	$2.55	$2.55	$0.00	0.0%
Scenario #5	**Market Basket Total**			**$14.25**	**$11.98**	**$2.27**	**15.9%**
	Asthma	(Ventolin/albuterol) (3)	2 puffs every 4-6 hours as needed	$1.44	$0.69	$0.75	52.3%
	Diabetes	(Glucophage/metformin)	850 mg twice daily	$2.81	$1.29	$1.52	54.1%
	Diabetes	Actos	30 mg per day	$5.45	$5.45	$0.00	0.0%
	Hypercholesterolemia	Pravachol	40 mg per day	$4.55	$4.55	$0.00	0.0%
Scenario #6	**Market Basket Total**			**$11.32**	**$9.50**	**$1.82**	**16.1%**
	Hypertension/mild congestive heart failure	(Zestril/lisinopril)	20 mg per day	$1.28	$0.60	$0.68	53.1%
	Coronary artery disease; congestive heart failure	(Toprol XL/metoprolol)	200 mg per day/ 100 mg twice a day	$1.96	$0.82	$1.14	58.2%
	Hypercholesterolemia	Lipitor	40 mg per day	$3.55	$3.55	$0.00	0.0%
	Acid Reflux	Aciphex	20 mg per day	$4.53	$4.53	$0.00	0.0%

(1) All medication is taken once per day unless otherwise noted.

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(2) Prices are average retail prices in brick-and-mortar pharmacies (i.e. chain, independent and foodstore pharmacies, excluding internet, mail order and long-term care pharmacies) across all payer types (cash-only, Medicaid and other 3rd party payers) for the first quarter of 2004.
(3) Generic prices are calculated in the same fashion using the median price among generic manufacturers. A weighted average price would have been preferable, but no prescription volume data were available at the time by which to weight the different manufacturers.
(4) Patients using albuterol are assumed to need 7 puffs on an average day.
Data Source: IMS Health, National Prescription Audit *Plus*™; 1st Quarter 2004; extracted April 2004; analysis conducted by the FDA.

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FDA News

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Agency Guidances Promote Comprehensive Efforts to Minimize Risks While Preserving the Benefits of Medical Products

The Food and Drug Administration (FDA) is announcing the availability of three draft guidances to help industry develop risk management activities when needed for some drugs and biological products. The documents, entitled "Premarketing Risk Assessment," "Development and Use of Risk Minimization Action Plans," and "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment," address safety issues that can arise throughout a product's entire lifecycle, including its development, the review and approval process, and after it is available on the market.

"These draft documents are part of much broader, ongoing, and comprehensive efforts by our agency to provide guidance to industry on measures that can be used to minimize the risks while preserving the benefits of medical products," said Dr. Lester M. Crawford, the Acting Comissioner of Food and Drugs. "These guidances, when finalized, will help safeguard the health of our consumers and patients."

The draft guidances were produced in part to fulfill FDA's commitment to certain risk management performance goals agreed to when the Prescription Drug User Fee Act was reauthorized in June 2002. They are based on three concept papers released on March 7, 2003, and on comments the agency received in and following a subsequent public workshop.

The draft guidances describe additional safety testing, monitoring, and interventions that may be helpful in selected circumstances and address premarket risk assessment; the development, implementation, and evaluation of risk minimization action plans (called RiskMAPs); and good pharmacovigilance practices and assessment of reported adverse events.

For example, the draft guidance on premarket risk assessment focuses on measures sponsors might consider during the later stages of clinical development of products that are known to, or might, present special safety issues. The recommended risk assessment strategies for such cases can include long-term controlled safety studies, enrollment of diversified patient population, and phase 3 trials with multiple dose levels.

The draft guidance on development and use of RiskMAPs describes how industry can address specific risk-related goals and objectives. This guidance also suggests various tools to minimize the risks of drug products. The draft guidance on heightened postmarketing vigilance identifies recommended reporting and analytical practices involving adverse events associated with high-risk drug and biological products.

In releasing these draft guidances, FDA seeks comments on its efforts to help industry increase both product benefits and safety without undue burdens on product developers,

health care practitioners, and patients. As new products are developed, FDA recommends that sponsors seek to identify risk signals as early as possible in a product's development cycle, evaluate them, and communicate and manage them as thoroughly and efficiently as possible.

The agency invites written or electronic comments on the draft guidances. The comment period closes on Tuesday, July 6, 2004. FDA is specifically soliciting public comment on how to best characterize the types and levels of risk that might suggest the need for a risk management plan. General comments on agency guidance documents are welcome at any time.

The draft guidances, when finalized, will represent the agency's current thinking on these topics. They will not create or confer any rights for or on any person and will not be binding on FDA or the public.

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Federal Register Notice *(May 5, 2004)*

- Premarketing Risk Assessment
- Development and Use of Risk Minimization Action Plans
- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

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U.S. Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

"This may be the most important prescription I've ever written."

- Richard Carmona, M.D., M.P.H.
Surgeon General of the United States

This resource is also available as a public service announcement in PDF format

If you take over-the-counter drugs, remember that these are strong medicines. Follow Dr. Carmona's prescription: Before you use an over-the-counter medicine, read the directions on the label carefully. Then follow those directions exactly. If you have any questions, ask your pharmacist or other health care professional.

Remember, always Be MedWise.

The Be MedWise Prescription for Taking Over-the-Counter Medicines with Care

Richard H. Carmona, M.D., M.P.H.,
Surgeon General of the United States

When selecting on over-the-counter (nonprescription) medicine, always read the instructions and warnings on the product label. If you want more information, talk to your pharmacist or doctor.

Some questions to ask:

- What over-the-counter (OTC) medicines are available for the symptoms I want to treat?
- How much of this OTC medicine should I take at a time?
- How often should I take this OTC medicine?
- Howe many days in a row should I use this medicine to treat my symptoms?
- What other medicines (OTC and prescription), herbal products or dietary supplements should I avoid while taking this OTC medicine?

Remember, OTC drugs are serious medicines that should be taken with care. That is why it is so important to **Be MedWise** when buying and taking OTC medicines