THE UNIVERSITY OF OKLAHOMA

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Ron Graham, D.Ph.

SUBJECT: **Packet Contents for Board Meeting – January 13, 2004**

DATE: January 8, 2004

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

Enclosed are the following items related to the January 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.**

Action Item – Annual Review of Stimulants and Vote on Criteria Change Recommendations – **See Appendix C.**

Annual Review of NSAIDS – **See Appendix D.**

Review and Discuss Atypical Antipsychotic Utilization - **See Appendix E.**

Review and Discuss Forteo™, Calcium Regulators, and Evista™ Utilization – **See Appendix F.**

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

Future Business

Adjournment

Drug Utilization Review Board

(DUR Board)

Meeting – January 13, 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. November 18, 2003 DUR Minutes
   B. November DUR Board Memorandum

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

4. **Update on DUR/MCAU Program - See Appendix B.**
   A. Prospective DUR Quarterly Report for October-November-December 2003
   B. Retrospective DUR Report for September 2003
   C. Medication Coverage Activity Audit for November-December 2003
   D. Help Desk Activity Audit for November-December 2003

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

5. **Action Item – Annual Review of Stimulants and Vote on Criteria Change Recommendations – See Appendix C.**
   A. Oklahoma Medicaid Utilization
   B. Recommended Criteria Changes for Prior Authorization

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

6. **Annual Review of NSAIDS – See Appendix D.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

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

7. **Review and Discuss Atypical Antipsychotic Utilization – See Appendix E.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

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

8. **Review and Discuss Forteo™, Calcium Regulators, and Evista Utilization – See Appendix F.**
   A. Oklahoma Medicaid Utilization
   B. COP Recommendations

9. **FDA and DEA Information Updates – See Appendix G.**
   A. FDA Updates
   B. DEA Updates

10. **Future Business**
   A Antiviral Utilization Review
   B. Anti-Cholesterol Medications
   C. Economic SMAC Report
   D. Annual Antihistamines Review
   E. Annual Anti-Ulcer Medications Review
   F. Synagis Utilization Review

11. **Adjournment**

APPENDIX A

.OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of NOVEMBER 18, 2003

BOARD MEMBERS:	PRESENT	ABSENT
Rick G. Crenshaw, D.O.	X	
Dorothy Gourley, D.Ph.		X
Cathy Hollen, D.Ph.	X	
Thomas Kuhls, M.D.	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	
Greg Tarasoff, M.D.	X	
Thomas Whitsett, M.D., Chair	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Leslie Browning, D.Ph./Clinical Pharmacist	X	
Jack Coffey, Assistant Dean, College of Pharmacy		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	
Elgene Jacobs, Ph.D.; Manager, Research		X
Ann McIlvain, Pharm.D.; Clinical Pharmacist	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Douglas Voth, MD./Dean , College of Pharmacy		X
Visiting Pharmacy Students: R.C. Edwards, Nicole Hazelwood, Thomas Wiseman, Bruce Stephens, Travis Jacobs, Jennifer Sipols	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
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
Kristall Bright, Pharmacy Claims Auditor	X	

OTHERS PRESENT:

Anetta Harrell, Pfizer
Angela Menchaca, Amgen
Jack Cherry, McNeil/JNJ
Candie Phipps, Boehringer Ingelheim
Scott Johnson, Pfizer
Jeff Beck, Baxter
Jon Nickerson, Astra Zeneca
Jeff Tallent, NAMI
Lyn Hosty, Accredo
Mark DeClerk, Lilly
Lane Stewart, Merck
Pat Evans, BMS
Cindy Flesher, BMS
Kristi Dover, Purdue
Greg Hoke, Wyeth
Jack Vaughan, J&J
Tammie Kilpatrick, Astra Zeneca
JoAnne Hargraves, Schering
Curt Griffith, TAP
Peck Clifton, Accredo
Keith Schafer, CNS
Phil Lohec, Sanofi
Becky Alderson, BMS
Brett Spencer, Purdue
Curtis Krause, Medimmune
Erin Landy, Baxter
Greg Hollon, Biovail
Debbie Hayes, Aventis
Jill Miller, TAP
Jeff West, Chiron
Jeannie Gillmore, McNeil Spec.

PRESENT FOR PUBLIC COMMENT:
(none)

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: Roll Call

Dr. Whitsett called the meeting to order and introduced new Board Member, Dr. Greg Tarasoff. 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

None.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MINUTES**

3A: October 14, 2003 DUR Minutes

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

ACTION: MOTION CARRIED.

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

4A: Retrospective DUR Report: August 2003

Anticonvulsants were selected for retrospective review for August 2003. Pharmacy and physician response was 53% and 66% respectively. Savings related to this DUR run was $13,513. Potential annualized savings total calendar-YTD is $1,164,996. Materials included in agenda packet; presented by Dr. Flannigan.

4B: Medication Coverage Activity Report: October 2003

The October 2003 activity audit noted total number of petitions submitted was 9,615 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. Materials included in agenda packet; presented by Dr. Browning.

4C: Help Desk Activity Report: October 2003

Total calls for October 2003 numbered 12,102 (79.9% pharmacies, 5.6% clients, 2.3% physicians, 12.1% other). Call Volume and Call Log reports were submitted to the Board in the agenda packet for this meeting. Materials included in agenda packet; presented by Dr. Browning.

4D: SoonerCare Plus Update

OHCA press release of 11-6-03 included in agenda packet; presented by Mike Fogarty.

NEWS RELEASE November 6, 2003: Health Care Delivery Changes in Store for Urban Medicaid Patients

Oklahoma City - Increased health care costs and a decision by a health maintenance organization (HMO) to pull out of the state Medicaid program may result in Oklahoma changing its health care delivery for 189,000 Oklahomans on Jan. 1. The program known as SoonerCare Plus may be transitioning to a different form of managed health care. On Oct. 31, Unicare Health Plan of Oklahoma notified the Oklahoma Health Care Authority that they do not intend to renew their managed care contract serving areas of Oklahoma City, Tulsa and Lawton.

"Our first priority is to ensure we meet the needs of our members and the continuity of their care the best we can on Jan. 1," said Mike Fogarty, OHCA chief executive officer. "We are focusing our efforts on the transition of patients and their medical providers for an interim period while another program is expanded to serve these low-income children, pregnant women and individuals with disabilities. "No one will lose health care coverage as a result of Unicare leaving the program." The OHCA board plans to meet Friday to discuss short-term and long-term options. Transitional options are few because of the limited time and resources. The agency may recommend transferring people into a temporary but enhanced fee-for-service system. This means a person will be eligible for care from any willing contracted provider and the state would then pay the provider on a per service basis. It would be enhanced by having agency staff available to help patients find care if needed. After this interim period, the agency will recommend a transition into the state's other managed care system operating successfully in the rural counties. "In this transition comes another opportunity to make some positive changes while focusing on the health care needs of our patients. As we look to a new system, we administer a model program in the rural areas of the state called SoonerCare Choice. We believe the Choice program can be just as, if not more, effective but less expensive to manage with less administrative burden for physicians and other providers." SoonerCare Choice features similar benefits as the SoonerCare Plus program; however, it makes payments directly to physicians and other providers for care rather than through an HMO system. It is a program in which the OHCA contracts directly with providers throughout the state to provide primary health care services and to manage the health needs of their patients. Currently, OHCA provides services for 160,000 people through the SoonerCare Choice program. Under

SoonerCare Plus, the Oklahoma Health Care Authority contracts directly with health maintenance organizations (HMOs) to provide medically necessary services to patients living in 16 counties in the urban areas of Oklahoma City, Tulsa and Lawton. OHCA budgeted $222.4 million for the HMO-based program for a six month period beginning Jan. 1, 2004. Federally-mandated actuarial developed rates determined the health plan premiums should be increased to $233.3 million, leaving a difference of about $10.9 million. OHCA made the health plans an offer based on the available budgeted amount. The two remaining HMOs, Heartland Health Plan of Oklahoma operating in Tulsa and Oklahoma City and Prime Advantage Health operating in Lawton, indicated they would renew their respective contracts. These proposed changes do not affect those Medicaid patients living in nursing homes or those people served in the Home and Community Based Waivers such as the Advantage program. "For several years now we have limped along trying to maintain this program for the benefit it was providing our patients. Now we have an opportunity to make positive changes in the best interest of the patients, providers and taxpayers," said Fogarty. After the OHCA board gives its direction to the agency, appropriate letters and notifications will be mailed to beneficiaries and their providers in the coming weeks detailing the transitional information and the resources that will be available.

NEWS RELEASE November 12, 2003, OHCA Opts Not to Renew HMO Contracts

Oklahoma City – News of increased health care costs and a decision by a health maintenance organization (HMO) to pull out of the state Medicaid program prompted the Oklahoma Health Care Authority board to approve a proposal to end its health maintenance organization (HMO) contracts and switch to the state's other managed care system, SoonerCare Choice. This action came after Unicare Health Plan of Oklahoma notified the Oklahoma Health Care Authority that they do not intend to renew their managed care contract serving areas of Oklahoma City, Tulsa and Lawton. The contract expires on Dec. 31. On Jan. 1, the agency will transfer approximately 189,000 people into a temporary but enhanced fee-for-service system. This means a person will be eligible for care from any willing contracted provider and the state would then pay the provider on a per service basis. It would be enhanced by having agency staff available to help patients find care if needed. On or before April 1, the agency will transition members into SoonerCare Choice. Currently operating in 61 counties, SoonerCare Choice features similar benefits as the current HMO managed care system called SoonerCare Plus; however, it makes payments directly to physicians and other providers for care rather than through an HMO system. It is a program in which the OHCA contracts directly with providers throughout the state to provide primary health care services and to manage the health needs of their patients. Currently, OHCA provides services for 160,000 people through the SoonerCare Choice program. Under SoonerCare Plus, the Oklahoma Health Care Authority contracted with three health maintenance organizations (HMOs) to provide medically necessary services to patients living in 16 counties in the urban areas of Oklahoma City, Tulsa and Lawton. OHCA budgeted $222.4 million for the HMO-based program for a six-month period beginning Jan. 1, 2004. Federally-mandated actuarial developed rates determined the health plan premiums should be increased to $233.3 million, leaving a difference of about $10.9 million. OHCA made the health plans an offer based on the available budgeted amount. These changes do not affect those Medicaid patients living in nursing homes or those people served in the Home and Community Based Waivers such as the Advantage program. Letters and notifications will be mailed to affected beneficiaries in the coming weeks detailing the transitional information and the resources that will be available.

NEWS RELEASE November 13, 2003, OHCA Approves Rate Increases for Medicaid Providers

Oklahoma City – On the heels of a proposal by Governor Brad Henry and legislative leaders, the Oklahoma Health Care Authority board approved rate increases paid to nursing homes, hospitals, doctors and ambulance services that provide care to more than 500,000 Medicaid beneficiaries each month. At its monthly meeting, the board unanimously approved the use of $34 million in federal relief funds to increase nursing home rates by 7 percent and inpatient hospital rates by 5 percent. Evaluation and management services provided by physicians and other providers will be increased equal to 90 percent of the Medicare fee schedule, up from 72 percent. New rates are effective on Jan. 1, 2004. It is estimated the federal relief funds could support this rate increase for at least 18 months. "Increasing provider rates to appropriate and adequate levels continues to be a priority of this board and this agency. We must be able compete in the health care market. This increase will help the state maintain our network of providers and give us the opportunity to attract new providers," said Ed McFall, board chairman. The rate increase also restores co-payments for beneficiaries who are dually eligible for both Medicaid and Medicare. For example, Medicare pays 80 percent of the cost of an ambulance trip to the hospital. Before the rate was reduced two years ago, Medicaid paid a portion of the remaining 20 percent for persons with both Medicaid and Medicare coverage. As approved today, Medicaid will pay for half of the patients' remaining co-payment. "We believe these increases are the best use of this remaining pool of federal funds. The support of Governor Henry and legislative leaders demonstrates that this initiative is a priority. It is critical to pay responsible rates to ensure access to health care for Oklahomans who cannot afford the cost," said McFall. In other action, the board approved an increase in the number of prescriptions available for adults. After Jan. 1, the SoonerCare and the fee-for-service program will pay for up to six prescriptions per month for each eligible adult. However, the benefit will be limited to a maximum of three brand prescriptions. Currently, the adults in the SoonerCare program are limited to three paid prescriptions per month. The SoonerCare and fee-for-service program does not include adults living in nursing homes or adults in other Medicaid "waiver" programs. The board also removed restrictions covering smoking

cessation products. After Jan. 1, providers can prescribe the use of smoking cessation products such as nicotine patches without filing a prior authorization request.

4E: DUR Board Meeting Dates for 2004

Presented by Dr. Graham: DUR Board Meeting dates for 2004 are: January 13, February 10, March 9, April 13, May 11, June 8, July 13, August 10, September 13, October 12, November 9, and December 14.

ACTION: NONE REQUIRED.

AGENDA ITEM NO. 5: REVIEW & VOTE ON QUANTITY LIMITATIONS ADDITIONS

Materials included in agenda packet; presented by Dr. Moore. Two migraine medications and one nausea medication are included as additions to quantity limitations list.

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

ACTION: MOTION CARRIED.

AGENDA ITEM NO. 6: REVIEW & DISCUSS FACTOR PRODUCTS UTILIZATION

Materials included in agenda packet; presented by Dr. Flannigan. OHCA will prepare an RFP through Central Purchasing in the future and the DUR Board will be advised of results.

ACTION: NONE REQUIRED.

AGENDA ITEM No. 7: REVIEW & DISCUSS CURRENT CRITERIA FOR PRIOR AUTHORIZATION OF STIMULANTS

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

Dr. MCILVAIN: Reviewed packet materials and explained to the Board Members that this is not an action item but questionable prescribing habits of some physician providers were causing a great deal of concern amongst pharmacy providers and COP Prior Authorization Unit pharmacists. The COP is looking to the DUR Board for some guidance in dealing with these extremely high stimulant doses to Medicaid Clients.

Dr. MEECE: Suggested there may be some drug diversion going on.

Dr. WHITSETT: Twice the FDA recommended maximum dose seems to be quite liberal.

Dr. TARASOFF: Recommended not moving the acceptable dose to twice the FDA maximum because it would allow the other 97% of clients to reach a higher threshold also while the problem is only with about 3% of clients taking stimulants.

Dr. WHITSETT: Asked OHCA legal if it is OK for the DUR Board to ask for personal information concerning the death of a client and what policies are needed to make recommendations to review records. Mr. Fogarty will investigate further the procedures for following up on available client information.

Dr. CRENSHAW: Asked if we have to allow doses above mfg recommended dosage.

Dr.GRAHAM: There are always exceptions and in the past if the physician provided information to justify higher dosing than normal then it was allowed.

Dr.CRENSHAW: Can't we do this like we did the other . . .is this a specialist that's prescribing this or family practice doctor.

Dr. MCILVAIN: Some are pediatricians, some are psychiatrist (not Board certified, not on AMA website), considers himself a psychiatrist.

Dr. CRENSHAW: If above recommended dosage, couldn't we make a recommendation that they get a second opinion? What I am worried about is the correct diagnosis.

Dr. TARASOFF: That's a fair threshhold . . in almost all of these cases there's a concurrent medication that's working against the stimulant . . . stimulants increase the dopamine activity and if you look at these, there's a lot of medications that decrease dopamine activity. At the same time stimulants are stimulating in their very nature and a number of these patients are taking tranquilizers. So I think the combination of medications in clinical practice would raise some questions, and there may be a few exceptions but again, those should be so few that I don't think we need to go above current FDA guidelines . . . I think that most psychiatrists and child psychiatrists would consider reasonable before you start to say wait a minute, maybe something else is going on here, maybe this is the one in a thousand patient that I have that really does need an exception.

Dr. MCILVAIN: That particular prescriber seems to make a habit of that more than an exception. Prescriber C had his license suspended in the past for Medicaid fraud.

Dr. HOLLEN: Asked if we can fire a doctor?

Mr. FOGARTY: Absolutely.

Dr. KUHLS: Number one, I don't feel that P&T committee has the right or ability to make decisions concerning whether a doctor should be in a program or not. I don't think that's what the role of this committee should be. However you must have a QA committee and so I think what needs to be done is that Dr. Whitsett needs to write a letter to whoever the QA committee person is that we have a concern about these individuals. I don't think we should make the recommendation, but I think it should come from a different committee.
Dr. WHITSETT: Is the question whether it should be from the OHCA or with a state medical agency?
Dr. KUHLS: I don't think that we should be making recommendations to the licensure boards from a P&T committee. I think we should refer in-house to their doctor quality committee, let them look at it and make their decision as to what they're doing.
Dr. WHITSETT: Refer him to the medical licensing board, because they have a committee that is set up to evaluate certain situations?
Dr. KUHLS: Doesn't the OHCA usually have a committee that kind of looks at this, quality of care?
Mr. FOGARTY: Yes. Historically if they're licensed to practice we have a contract. We clearly would have the authority to go in on any of our contracted providers and look at those kinds of behaviors that constitute questionable quality and either act on it (as to contracting with them).
Dr. KUHLS: I'm not sure it's our responsibility to do that but it's our responsibility to let the other committee know that they need to look into that. Let them make the decision as to what they want to do with it . . .licensure board, etc. But as a P&T committee I don't think we should necessarily do that. My recommendation is that your recommendation for 2x the dose, I think that that's fair. I think that no matter what the situation is, I don't see how we can ever prescribe more than 2x the dose. Where it gets gray is when you get from the maximum FDA thing to 2x the dose. I think that there may be the rare patient and somebody might consider that. That's where I think in that situation we should do it like we said . . . put a PA process, make sure that that's looked at and that we have the right kind of specialist doing it. But I think if it's over 2x the dose I don't even care if it's a specialist or not, we shouldn't be paying for it.
Dr. CRENSHAW: You could look at it on the other side of the coin - we do have an obligation to the patients and a letter could be sent to this patient, we are aware that you are obtaining xxx amounts of medication and it might be in your best interests to contact another physician about your diagnosis and pointing out we're looking to their welfare and health.
Dr. HOLLEN: Have patients been referred to case management?
Dr. MCILVAIN: The only thing the OHCA can do is a lock-in to one pharmacy and this doctor has been very careful to make sure that they go to one pharmacy.
Dr. CRENSHAW: What concerns is we're only paying for 3 scripts per month and this one counted 27 prescribed meds.
Dr. MCILVAIN: He claims that she's using her Medicaid card for the more essential medications and getting all these other scripts other ways. But she's getting hydrocodone and generic Soma which are cheap but he claims that she's on Imitrex, (read list of meds) . . . brand name expensive meds so you would think that if she's really on all the other stuff she would be getting it through her Medicaid card and let the hydrocodone, pay cash or something. But he does say that she goes through manufacturer assistance programs. All she's getting from us are controlled drugs. On p. 42 she's had no weight loss or trouble sleeping. If she's taking 320 mg of Ritalin a day, it's hard to believe. He said on another patient (p. 45) patient taking 180 mg Adderall plus 90 mg methamphetamine, and patient has gained several pounds during treatment and is able to sleep appropriately. Patient L on 540 mg Adderall a day, must be DAW, patient has been calling us a lot because she's been having a hard time getting pharmacies to fill this for her and they're telling her they're out and I don't know if there's a nationwide shortage of Adderall 30 mg right or not. She also told our help desk today that she is or has been a pharmacy tech. The prescriber says she's got PTSD, depression & panic disorder, but she's not on any SSRI, really not on anything else except the Adderall and that's it. So if she has all the other comorbidities it just doesn't look like good therapy. In another letter, prescriber said he's tried 20 meds for patient's various problems in first 6 months of treatment to arrive at current dosing. He may not be giving meds much of a chance. Part of the reason these people have been getting these approved (by PA) . . . DUR subcommittee has looked at one of these already, another has been [checked out] informally. The prescribers send in letters and kind of hint patients may commit suicide if they don't get medications and you don't want to deny something that's going to kill somebody if they don't get it. Prescribers send in literature to justify dosing and seem to be using weight-based dosing to justify these doses but they never tell us how much the patients weigh so unless these people are really, really heavy even the weight-based dosing and I found several articles that say weight-based dosing is not the way to do it. One article did talk about giving patients as much as 230 mg of dextramphetamine/day, as much as 168 mg of methylphenidate/day, that's what one prescriber sent in to justify his dosing; but when you pull the actual article, it's not really a study, it was anecdotal and it said that anorexia and weight loss occurred in 90% of patients, insomnia in all patients, 90% had mild depression & weeping, 75% had hostility, verbal agressiveness and increased argumentativeness. I don't know how bad off the patients were before they started this treatment but it's questionable . . . the treatment may be worse than their original disease. They sent articles to justify dosing. We found other articles that argue the opposite. There are plenty of articles that state some type of maximum on the stimulant dosing.

Dr. WHITSETT: Clinical trials of these long acting once a day medications efficacy is not clearly superior. They were shown comparable to the other meds.
Dr. KUHLS: Everything was compared to placebo and very little data that shows superiority.
Dr. GRAHAM: Lot of states limit to one-a-day on time release Concerta and Adderall. Several states have that restriction and make them supplement with immediate release which is more practical.
Dr. MCILVAIN: If we had a level beyond which we're not going to approve it, it would be easier than this case-by-case, if you send in a letter we'll give you what you're asking for . . . a lot of these letters are sad but not really convincing that this is the only/best thing to do for them.
Dr. WHITSETT: Are majority of users using it once a day?
Dr. MCILVAIN: Concerta & Adderall XR are a problem . . . 13.8% of Adderall XR claims and 6.2% Concerta claims exceeded the max approved dose. I also did look at how many were more than one a day, but the majority of them are staying within one a day, but there was a larger percentage than you would think should be. But we have certain prescribers that just want to give high dose Concerta and they call us and complain and write letters until they get what they want. Unless we have a policy that just allows us to say no, it's going to continue to be a problem. It's hard to say no when they send in clinical justification for what they do.
Dr. SWAIM: So you need the clout of the Board to give you some teeth, right?
Dr. MCILVAIN: Something.
Dr. SWAIM: I'd make a motion you put that as an action item at the next meeting
Dr. KUHLS: I'd make a motion that like I said before, anytime we have a dosage that is 2x above the FDA that it's automatically"NO", and whenever we have something that is from the FDA, higher than the FDA limit but still less than 2, that it's still PA'd and looked at very cautiously and carefully.
Dr. WHITSETT: I think what we'll probably need to do is request this be an action item and then we'll come back and that's a suggested recommendation that the COP can put together and in the meantime if we need to convene a subcommittee I think that would be appropriate. It seems that we're vulnerable and not serving the best interest of our clients when we permit that to go on.
Dr. KUHLS: But at the same time what I would not make an action item is that I would make a motion that this Board send a letter to QA for OHCA demonstrating our concerns about these certain individuals - that they need to be evaluated more closely. I don't think we should wait for two months or whatever to do that.
Dr. WHITSETT: That we can do immediately.
Dr. MCILVAIN: That's kind of why we were wanting to do something - send out a letter - these people are already on these and they've been getting this for years now and they're up for renewal and they've been coming up for renewal, and as they've come up for renewal we've just been renewing them month by month and we will have to either keep doing this until we get a vote on it, we can do that rather than send out a letter and just cut them off now.
Dr. TARASOFF: Notifying a patient about a potential safety issue for them to discuss with their physician might be something that can be done in the next 2-3 months without . . . noting this is above FDA recommended maximums, however we recommend you discuss this with your doctor. At least that gets 2-3 months and we've made good faith effort to let them know this could be dangerous, and could be dangerous in combo with other meds you're taking. For next action item, think about maybe a threshhold, just 50% over, 1.5x the threshhold.
Dr. KUHLS: This 1.5, if you feel comfortable with that, that's fine, but I think it needs to be developed by the COP.
Dr. GRAHAM: We can bring a proposal back.
Dr. MCILVAIN: Another thing these prescribers are doing that's creating this problem, they're sending in petitions for a reasonable doses and the way PAs work is that they get it for a set length of time and for a set quantity, and we give them a whole year's worth of quantity and the PA is good for a whole year, so they're going in and filling it immediately for much larger quantities than they request on petitions so they're able to get the drug for their adult patient. In cases like that they get them stabilized on something and then they expect to get it renewed so that's another thing that will probably come up no matter what limits we set on PAs but when that happens then we'll just have to have a mechanism for dealing with it.
Dr. HOLLEN: We can't do quantity limitations per claim?
Dr. MCILVAIN: Could be. That could be . . .
Dr. GRAHAM: Quantity limits? It's not in effect yet.
Dr. KUHLS: The hope is that the QA committee will evaluate this and take care of the problem for certain individuals and what we need to do is set the standards for the future
Dr. WHITSETT: Doing that will go along ways in fixing the problem.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF SMOKING CESSATION PRODUCTS**
Materials included in agenda packet; presented by Dr. Browning. Dr. Whitsett suggested that an educational reminder to providers be sent out describing the new benefit of smoking cessation coverage without prior authorization. Dr. Whitsett stated that he would talk to Dr. McCaffrey for some guidance on future action. Several

suggestions were made by Board Members to possibly help support clients who want to quit smoking and to try and find ways to increase the number of clients who attempt to quit smoking.
ACTION: NONE REQUIRED.

AGENDA ITEM NO. 9: **OBRA 90 REVIEW**
Materials included in agenda packet; presented by Dr. Nesser. Information is included in the packet to provide new Board members policies and rules of the federal government and state mandated rules that apply to the DUR Board.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 10: **FDA & DEA INFORMATION UPDATES**
11A: FDA Updates
11B: DEA Updates
Updates included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED.

AGENDA ITEM No. 11: **FUTURE BUSINESS**
11A: Antiviral Utilization Review
11B: Anti-Cholesterol Medications
11C: Economic SMAC Report
11D: Annual PBPA Category Reviews
11E: Calcium Regulators Utilization Review
11F: Atypical Antipsychotic Utilization Review
11G: Synagis Utilization Review
Materials included in agenda packet; presented by Dr. Graham.
ACTION: NONE REQUIRED.

Mr. FOGARTY: Discussed the new benefit package that will go into effect January 1, 2004. He acknowledged Dr. Whitsett and the DUR Board for continually bringing up the need for more than 3 prescriptions per month limit at every DUR Board meeting.

AGENDA ITEM No. 13: **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: December 12, 2003

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 **November 18, 2003**.

Recommendation 1: Review and Vote on Quantity Limitation Additions.

ADDITIONAL QUANTITY LIMITATIONS
Oklahoma Medicaid
November 2003
The following additional medications were voted on by the DUR Board to be added to the previously approved quantity limitations for the Oklahoma Medicaid Fee-For-Service Program.
MOTION CARRIED.

Drug	Retail Pharmacy Limits	Comments
Dihydroergotamine (Migranal) 1 mL ampules for nasal spray	8 ampules per 28 days	4mg/week maximum dose
Eletriptan (Relpax)	8 tablets per 30 days	Maximum dose of 80mg / 24 hrs
Frovatriptan (Frova) 2.5 mg tablets	12 tablets per 30 days	Maximum dose of 7.5mg / 24 hrs
Palonosetron (Aloxi) 0.25mg / 5 ml vial	4 vials per 28 days	Maximum dose is 0.25 mg before chemotherapy every 7 days

APPENDIX B

Prospective Drug Utilization Review Quarterly Report

October 2003 through December 2003
Oklahoma Medicaid

Early Refill Activity Report

If a refill is attempted before 75% of the previous prescription has been exhausted, the refill attempt is rejected. In certain situations, a pharmacist with the Medicaid pharmacy helpdesk can override the ER reject with a "Super PA". The following table indicates the number of "hard edits" encountered by pharmacy providers, the number of "Super PAs" granted, and the reasons for these overrides.

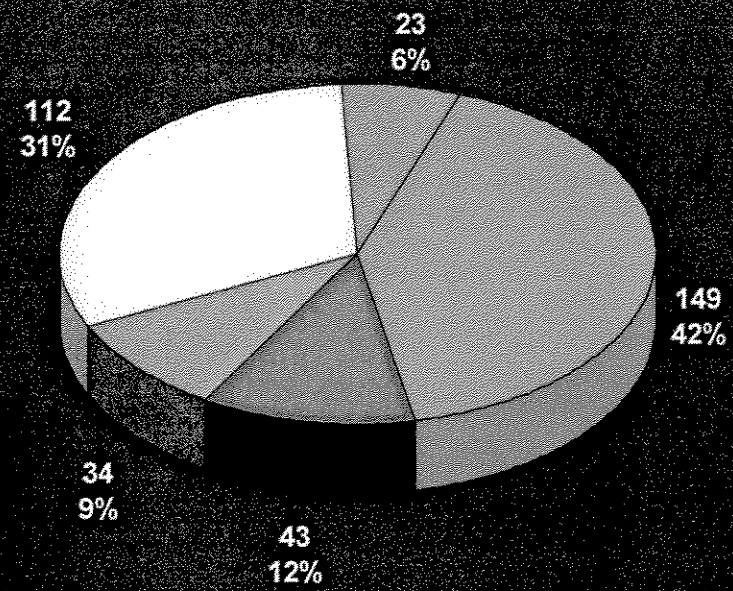
	Previous Qtr Average	Oct 2003	Nov 2003	Dec 2003	Current Qtr Average
Total ER edits	43,094	26,997	36,072	36,972	33,347
Total Super PA overrides (% total edits)	333 (0.77 %)	369 (1.37 %)	279 (0.77 %)	193 (0.52 %)	280 (0.84 %)
Override reason:					
• Dosage change	236	259	205	135	200
• Wrong D.S. on previous Rx	26	14	21	10	15
• Lost/Stolen/Broken Rx	34	35	20	15	23
• Other	37	61	33	33	42

Emergency PA Activity Report

In order to avoid a delay in treatment for Medications that require a prior authorization, a pharmacist with the Medicaid pharmacy helpdesk can override the reject with an "Emergency PA" for a 3-day supply. The following table indicates the types of Emergency PAs granted and the reasons for these overrides.

	Prev Qtr Total	HTN	NSAID	Anti-ulcer	Stimulant	Anti-histamine	Hypnotic	Current Qtr Totals
Override reason:								
Dr. paperwork pending	4				2			2
Emergency situation	0							0
Released from hospital	0							0
Other	0						1	1
Totals:	4	0	0	0	2	0	1	3

Oklahoma Medicaid RetroDUR Activity Report - Reviewed September 2003



Top 200 RPS

- Duration
- Overutilization
- Drug-Disease
- Duplication
- Drug Interactions

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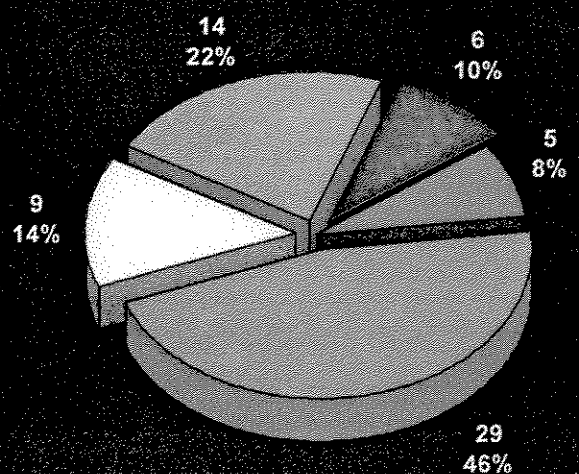
Oklahoma Medicaid RetroDUR Activity Report - Follow Up September 2003



Top 200 RPS

Drug Interactions
- Drug-Disease
- Duplication
- Duration
- Overutilization

32 total conflicts
32 cases followed up

Total Responses		
Pharmacy =	36/67	54%
Physician =	44/76	58%

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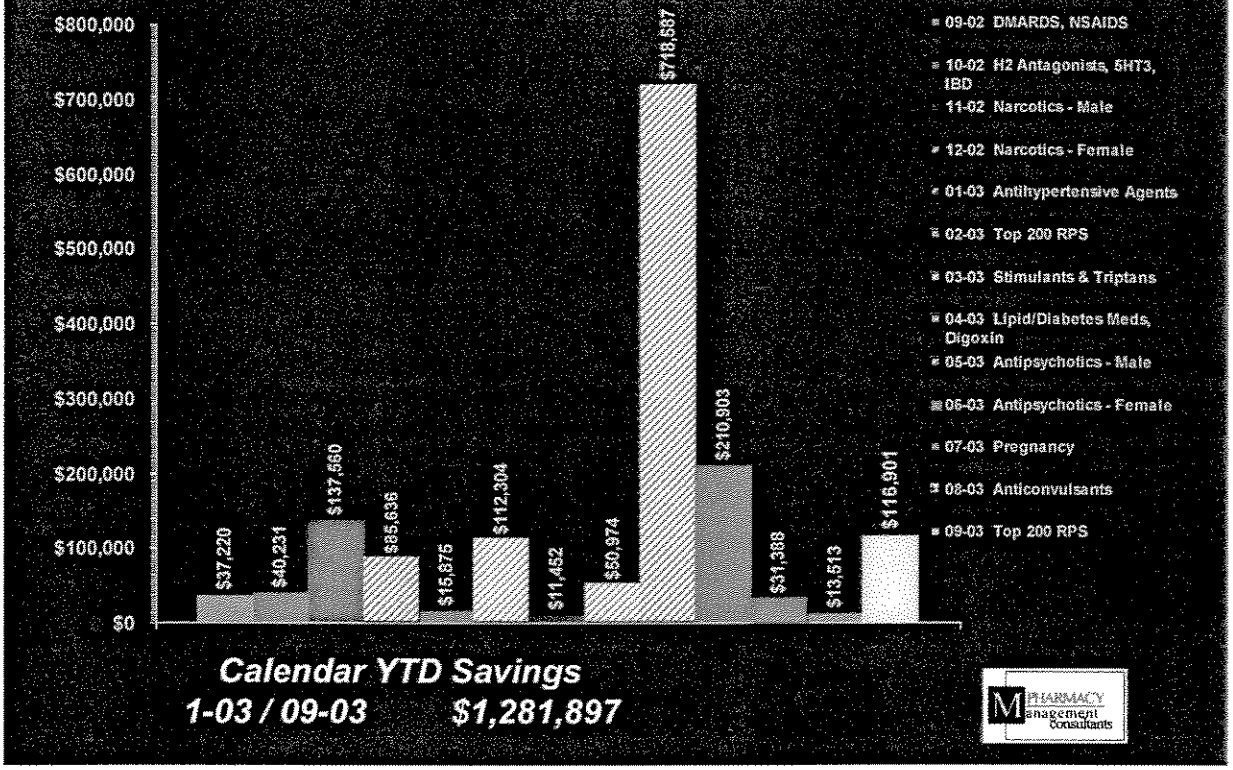
Oklahoma Medicaid RetroDUR Savings Report
September 2002 – September 2003



Calendar YTD Savings
1-03 / 09-03 $1,281,897

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Activity Audit for

November 01 2003 Through November 30 2003

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	8	10	29	6	8	6	0	0	15	2	0	0	3	3	1	4	0	2	1	3	3	4	0	0	0	1	109
2	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
3	18	21	95	6	20	14	0	0	40	11	0	0	17	18	0	8	0	1	2	7	20	1	1	0	0	0	300
4	17	16	79	13	19	22	2	0	51	14	1	1	8	17	4	3	1	3	2	7	11	3	1	0	0	0	295
5	19	21	114	8	24	26	0	0	68	17	3	0	13	26	2	8	2	6	0	14	21	5	2	0	0	0	399
6	20	22	74	11	29	19	2	0	64	16	3	0	5	27	4	9	2	4	4	9	16	8	1	0	0	0	349
7	19	11	79	8	20	14	0	0	51	21	1	0	10	20	3	8	1	1	1	14	13	2	1	0	0	0	298
8	8	4	35	2	8	3	0	0	27	12	0	0	4	14	1	4	1	3	2	2	6	5	0	0	0	0	141
9	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
10	11	7	38	7	17	9	0	0	36	16	0	0	3	9	0	4	0	0	1	7	8	4	0	0	0	0	177
11	15	24	102	7	28	19	0	0	65	16	1	0	10	22	1	4	2	2	9	11	25	2	5	0	0	0	370
12	17	22	60	7	24	12	0	0	32	29	2	0	2	16	2	3	3	2	7	8	17	7	1	0	0	1	274
13	13	17	73	5	33	17	0	0	67	10	0	0	21	24	5	8	1	2	8	7	9	2	4	0	0	0	326
14	11	27	68	6	12	7	7	0	54	22	2	2	15	14	3	10	0	3	3	8	14	3	1	0	0	0	292
15	5	5	23	4	9	5	0	0	14	4	0	0	2	5	2	0	0	0	1	3	6	1	0	0	0	2	91
16	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
17	6	10	69	4	15	3	3	0	39	7	0	0	6	9	2	2	1	0	1	3	5	2	2	0	0	0	189
18	21	11	99	6	27	17	0	0	48	23	1	0	9	20	4	6	2	3	3	9	19	11	1	0	0	0	340
19	17	18	86	7	20	14	0	0	52	12	0	1	9	10	2	5	5	2	4	5	19	5	3	0	0	0	296
20	10	19	56	7	21	14	0	0	40	23	0	0	6	18	1	5	4	1	5	6	10	6	1	0	0	1	254
21	9	20	76	17	16	9	0	0	47	13	0	1	6	18	2	2	0	0	3	3	8	8	2	0	0	0	260
22	9	11	20	5	6	5	0	0	22	6	1	0	3	11	1	10	1	1	3	7	4	7	0	0	0	0	133
23	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
24	15	12	45	5	17	11	0	0	25	10	0	0	3	11	4	1	0	0	1	4	10	6	0	0	0	0	180
25	18	37	84	5	27	15	0	0	64	21	0	1	10	31	1	17	3	1	4	17	10	15	6	0	0	1	388
26	13	10	61	7	22	16	0	0	73	18	0	1	11	13	0	2	0	1	4	6	17	3	3	0	0	1	282
27	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
28	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
29	6	7	19	0	8	1	0	0	5	2	0	0	3	2	1	0	0	0	0	2	4	1	2	0	0	0	63
30	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

Activity Audit for

November 01 2003 Through November 30 2003

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.	305		1484		430		14		999		15		179		46		29		69		275		37		0		
Den		362		153		278		0		325		7		358		123		38		162		111		0		7	
Average Length of Approvals in Days	104		93		96		151		277		82		352		366		366		349		279		4		0		

Smoking Cessation	5 PA's for Zyban	15 Total PA's Approved
	10 PA's for Nicotine Patch	15 Unique RID's

Changes to existing PA's	384
Total (Previous Year)	7921

Monthly Totals

	Number	Percent of Total
Approved	3887	53.98%
Additional PA's	3	0.04%
SUPER PA's	279	3.87%
Emergency PA's	1	0.01%
Duplicates	397	5.51%
Incompletes	699	9.71%
Denied *	1935	26.87%
Total	7201	100.00%

Daily Average of 288.04 for 25 Days

*** Denial Codes**

762 = Lack of clinical informatio	40.67%
763 = Medication not eligible	1.76%
764 = Existing PA	16.69%
772 = Not qualified for requested Tier	15.25%

SUPER PA's

Early Refill Attempts	36072
Dosing Change	205
lost/stolen/broke	20
Other	33
wrong DS	21

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.)

Activity Audit for

December 01 2003 Through December 31 2003

ate	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	12	10	82	7	23	10	0	0	45	13	1	0	9	14	1	5	2	2	2	4	13	2	0	0	0	0	257
2	11	33	101	14	30	17	1	0	35	15	1	1	19	20	2	9	2	6	7	12	14	4	1	0	0	1	356
3	12	12	107	8	20	14	0	0	44	17	0	0	12	16	4	7	1	0	2	8	23	8	4	0	0	0	319
4	11	34	113	7	22	18	0	0	63	19	0	0	14	31	1	8	2	3	2	12	21	3	1	0	0	2	387
5	12	19	80	10	15	21	2	0	36	25	1	0	12	18	5	7	4	4	0	6	14	15	1	0	0	1	308
6	5	6	25	2	12	7	0	0	22	5	0	0	4	9	0	4	0	0	1	4	10	3	1	0	0	1	121
7	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
8	15	10	39	3	14	6	2	0	36	11	0	0	5	11	0	4	0	0	2	7	3	8	0	0	0	3	179
9	18	35	128	9	44	23	1	0	68	19	3	1	17	25	2	14	3	3	5	11	16	17	4	0	0	4	470
0	18	35	90	13	22	22	0	0	52	20	1	0	10	25	3	18	3	4	4	8	22	8	1	0	0	0	379
1	14	41	83	12	17	7	2	0	43	12	0	0	8	14	5	16	2	2	2	9	16	5	1	0	0	1	312
2	17	22	62	1	15	15	0	0	35	21	0	0	11	12	2	6	0	2	0	7	9	4	0	0	1	1	243
3	11	9	30	2	11	9	0	0	29	12	0	0	5	8	3	4	0	0	0	1	11	5	0	0	2	1	153
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	2	4	9	2	6	7	0	0	8	4	0	0	4	4	0	0	0	0	0	0	1	3	0	0	0	0	54
6	13	18	38	9	9	13	0	0	23	14	0	0	8	6	0	4	2	1	2	7	11	3	2	0	0	0	183
7	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
8	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
9	0	0	1	0	0	0	0	0	1	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	2	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
1	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
2	6	11	54	2	16	5	0	0	20	8	1	1	4	4	0	1	1	1	0	9	8	4	0	0	0	0	156
3	12	20	99	14	22	21	1	0	66	22	1	0	17	24	2	5	2	1	4	15	14	2	3	1	0	2	370
4	9	18	47	3	6	6	1	0	38	17	0	0	6	11	0	6	2	0	0	6	5	4	1	0	0	0	186
5	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
6	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
7	0	0	4	0	1	1	0	0	0	1	0	0	3	0	0	0	0	1	0	0	1	0	0	0	0	0	12
8	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
9	10	16	45	6	13	3	5	1	25	9	0	0	4	9	1	3	1	1	3	1	13	1	2	0	0	1	173
0	21	22	74	4	33	21	0	1	54	17	1	0	7	18	5	2	0	0	4	6	8	4	2	0	0	2	306
1	16	21	92	13	23	15	14	0	39	18	1	0	16	14	0	6	2	0	1	8	19	5	1	0	0	0	324

Activity Audit for

December 01 2003 Through December 31 2003

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.	245		1404		375		29		783		11		195		36		29		41		252		25		3		
Den.		398		141		261		2		302		3		293		129		31		141		108		1		20	
Average Length of Approvals in Days	100		92		95		151		283		98		356		358		366		366		270		15		70		

Smoking Cessation	1 PA's for Zyban	11 Total PA's Approved
	10 PA's for Nicotine Patch	11 Unique RID's

Changes to existing PA's	276
Total (Previous Year)	4867

Monthly Totals

	Number	Percent of Total
Approved	3429	46.39%
Manual PA Approvals**	675	9.13%
Additional PA's	5	0.07%
SUPER PA's	193	2.61%
Emergency PA's	0	0.00%
Duplicates	349	4.72%
Incompletes	470	6.36%
Denied *	1834	24.81%
Manual PA Denials**	436	5.90%
Total	7391	100.00%

Daily Average of 295.64 for 25 Days

*** Denial Codes**

762 = Lack of clinical information	30.97%
763 = Medication not eligible	1.47%
764 = Existing PA	13.47%
772 = Not qualified for requested Tier	9.27%

SUPER PA's

Early Refill Attempts	36972
Dosing Change	135
lost/stolen/broke	15
Other	33
wrong DS	10

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)

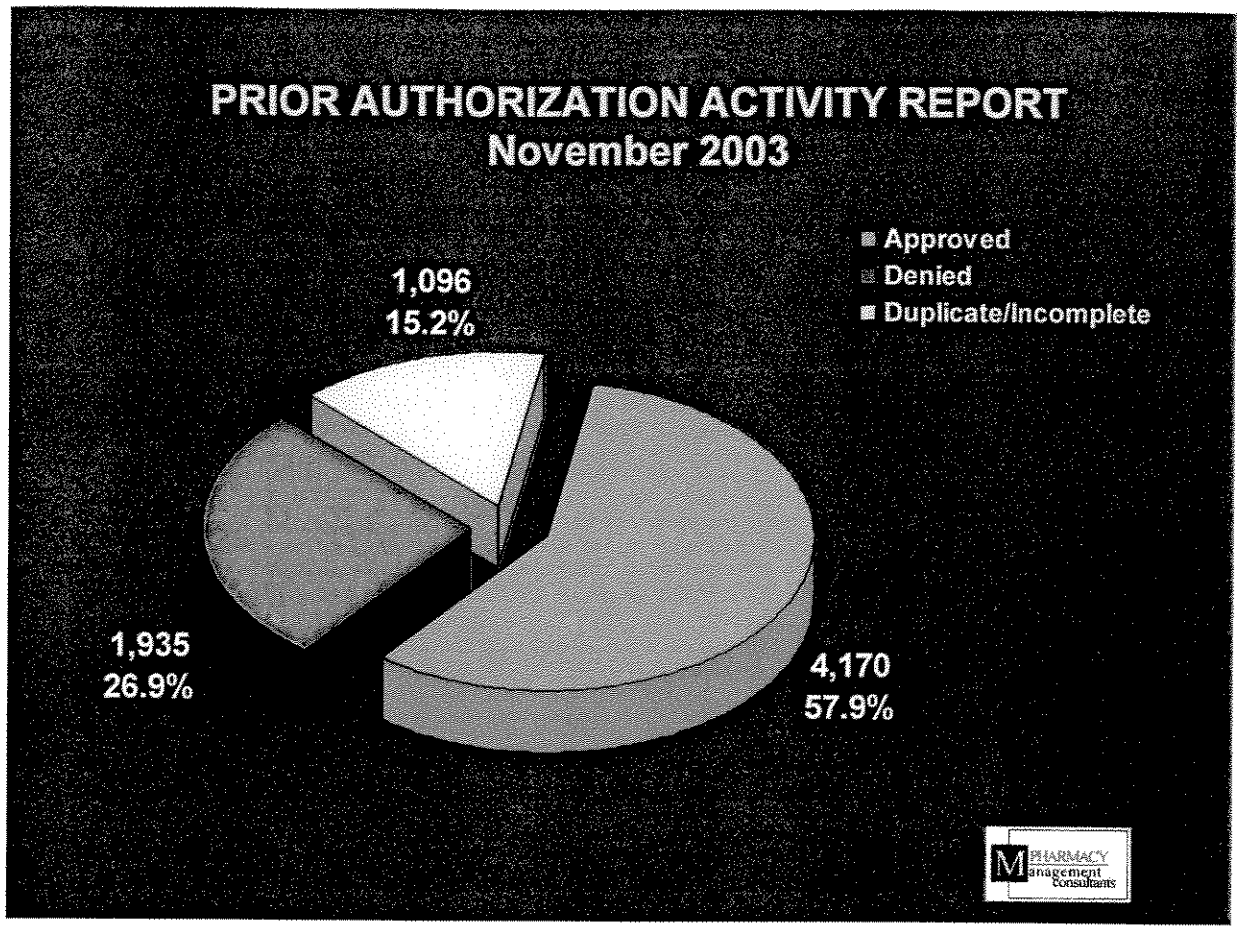
Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)

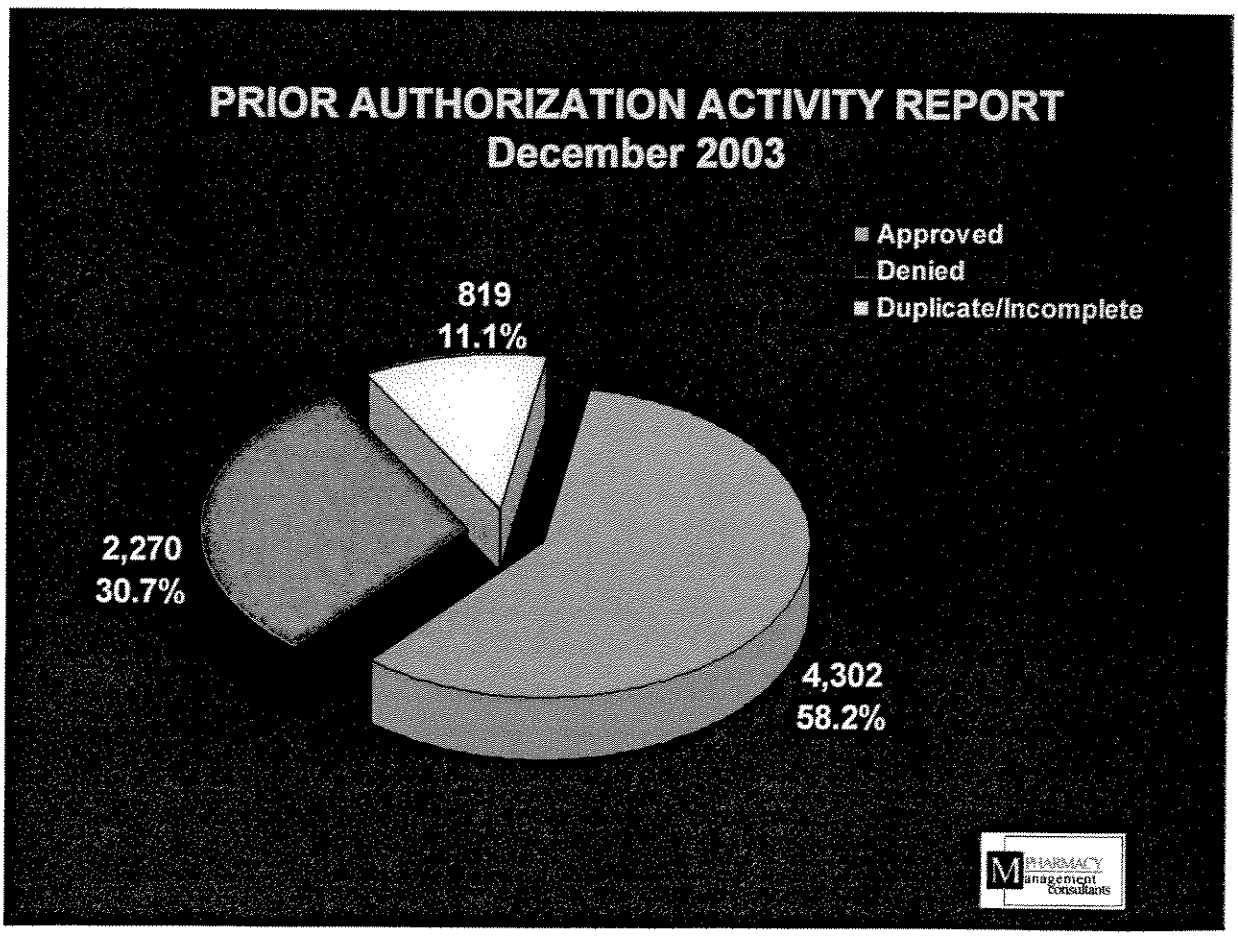
***The manual PA's were done during the week of December 15-19 during which time we were experiencing computer technical prob*

PRIOR AUTHORIZATION ACTIVITY AUDIT

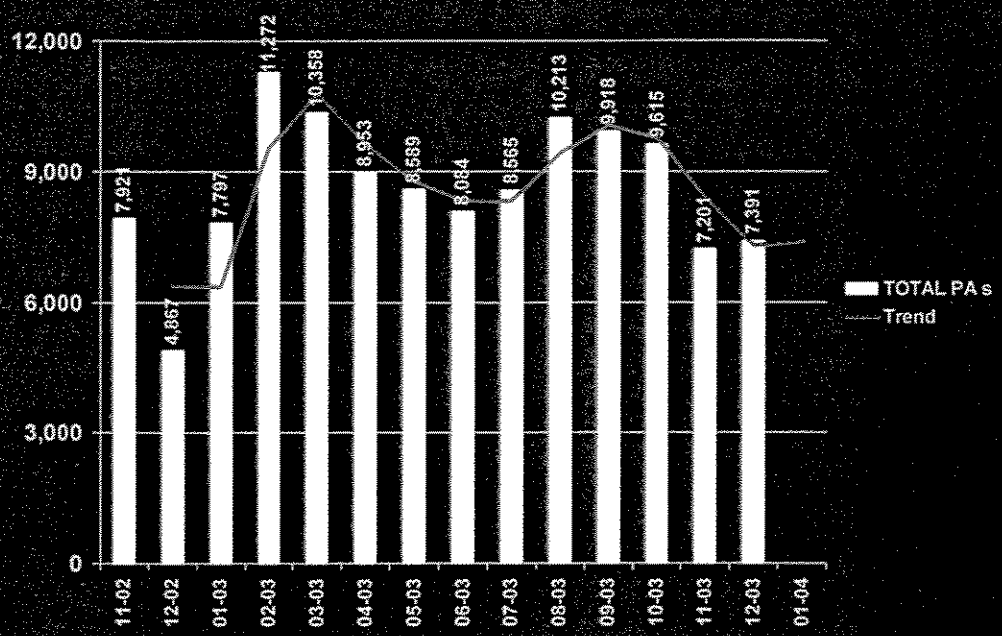
Monthly Totals

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)*
January	4,124	8,669	9,296	8,427	7,797
February	3,542	8,077	7,194	6,095	11,272
March	3,856	7,588	7,748	6,833	10,358
April	3,867	6,390	7,676	13,381	8,953
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**


PRIOR AUTHORIZATION ACTIVITY REPORT
November 2003
Approved
Denied
Duplicate/Incomplete
1,096
15.2%
1,935
26.9%
4,170
57.9%
PHARMACY Management Consultants

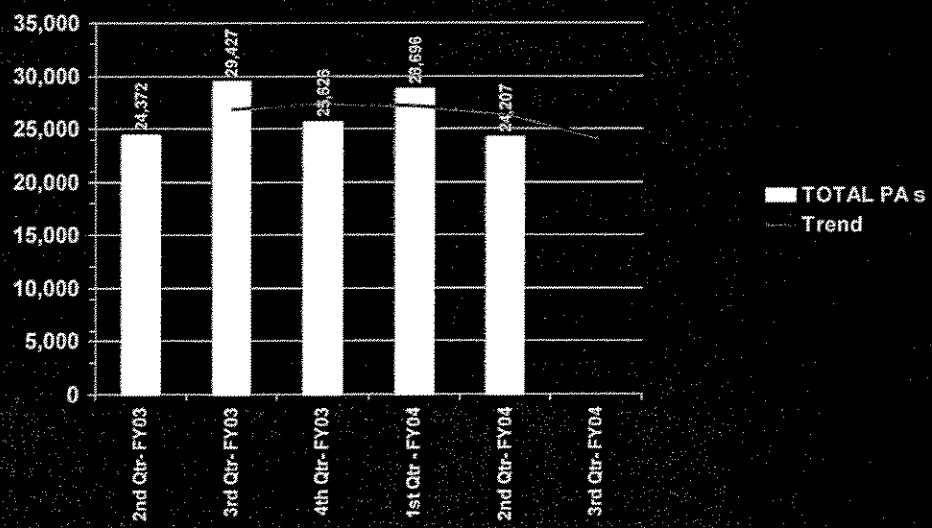

PRIOR AUTHORIZATION ACTIVITY REPORT
December 2003
Approved
Denied
Duplicate/Incomplete
819
11.1%
2,270
30.7%
4,302
58.2%
PHARMACY Management Consultants

PRIOR AUTHORIZATION REPORT
November 2002 – December 2003

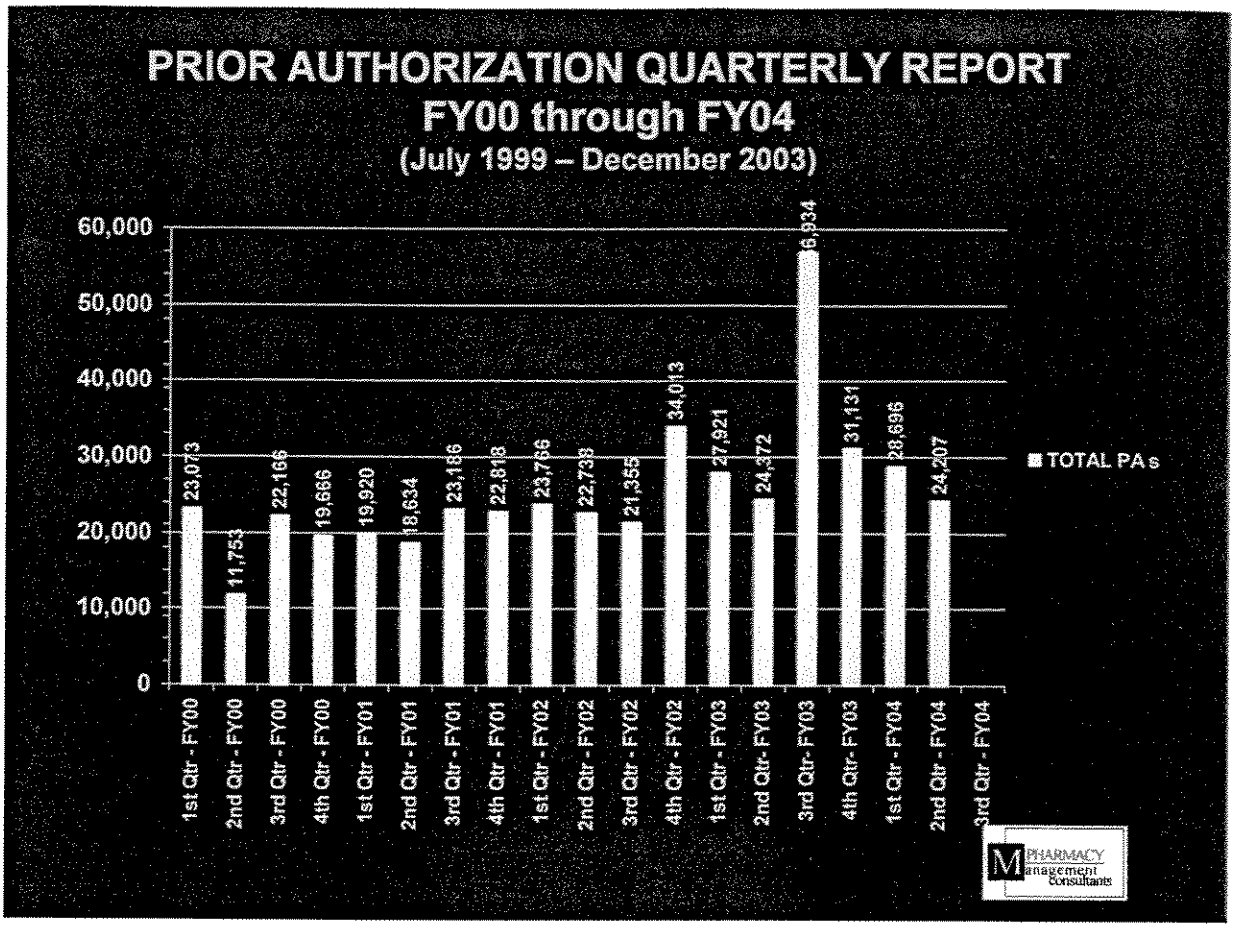


PHARMACY Management Consultants

PRIOR AUTHORIZATION QUARTERLY REPORT
2nd Quarter SFY03 thru 2nd Quarter SFY04

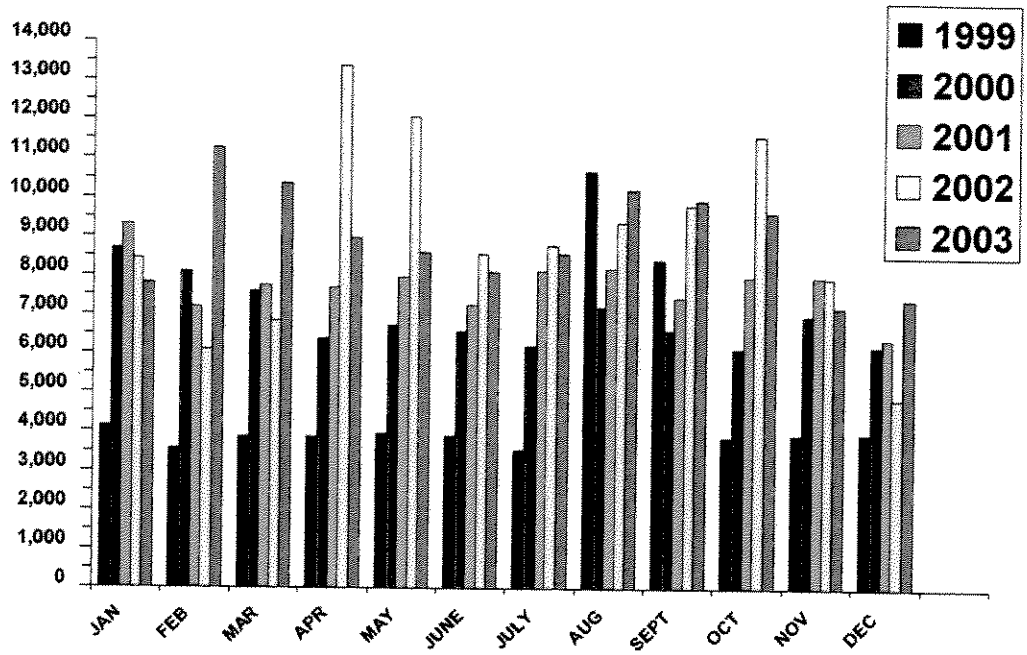


PHARMACY Management Consultants


PRIOR AUTHORIZATION QUARTERLY REPORT
FY00 through FY04
(July 1999 – December 2003)
60,000
50,000
40,000
30,000
20,000
10,000
0
23,073
11,753
22,166
19,666
19,920
18,634
23,186
22,818
23,766
22,739
21,355
34,013
27,921
24,372
56,934
31,131
28,696
24,207
1st Qtr - FY00
2nd Qtr - FY00
3rd Qtr - FY00
4th Qtr - FY00
1st Qtr - FY01
2nd Qtr - FY01
3rd Qtr - FY01
4th Qtr - FY01
1st Qtr - FY02
2nd Qtr - FY02
3rd Qtr - FY02
4th Qtr - FY02
1st Qtr - FY03
2nd Qtr- FY03
3rd Qtr- FY03
4th Qtr- FY03
1st Qtr - FY04
2nd Qtr - FY04
3rd Qtr - FY04
TOTAL PAs
PHARMACY Management Consultants

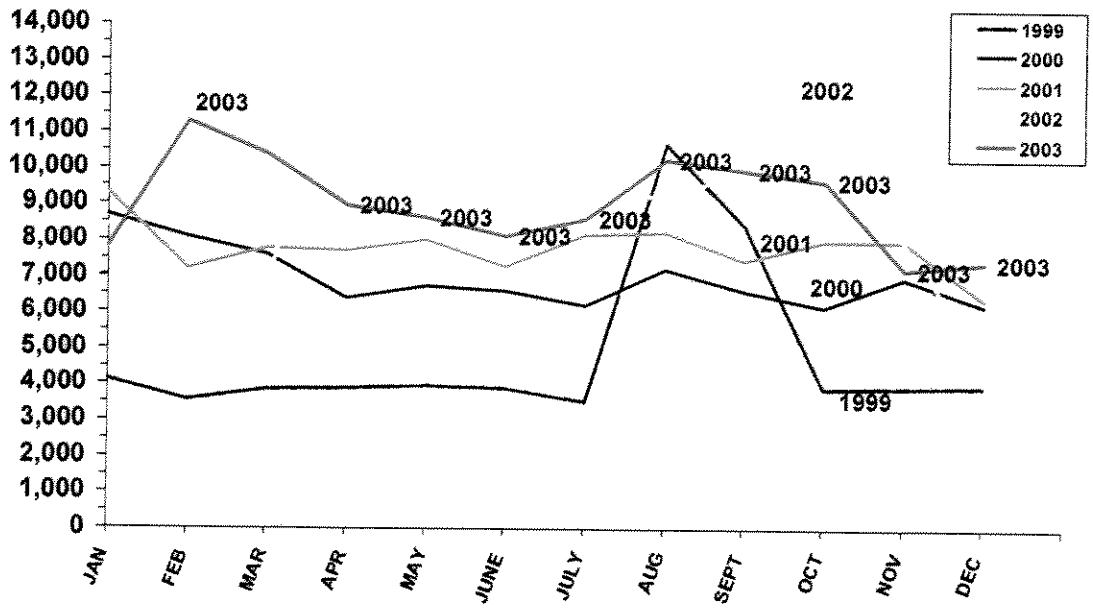
Monthly PA Activity

Calendar Years 2000-2003



Monthly PA Activity

Calendar Years 2000-2003



CALL VOLUME - NOVEMBER 2003

OV 2003	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	170	0	163	1	6	64	60	23	0	23	164	4	0	0	1	0	1	169	0	0	1	0	0	0
2	24	0	24	0	0	18	4	1	0	1	23	0	0	0	0	1	0	24	0	0	0	0	0	0
3	513	7	463	28	15	152	311	25	0	25	483	12	1	0	0	12	5	508	3	0	1	0	1	0
4	543	11	481	32	19	180	233	74	0	56	502	15	1	0	3	9	13	537	0	0	2	0	4	0
5	509	13	380	38	78	159	187	127	0	36	423	76	0	0	1	2	7	501	3	0	4	0	1	0
6	462	14	407	29	12	151	222	55	0	34	436	5	0	1	5	13	2	457	2	0	2	0	1	0
7	487	8	416	34	29	149	237	73	0	28	448	27	0	0	1	6	5	486	1	0	0	0	0	0
8	81	0	80	0	1	35	33	2	0	11	77	0	0	0	0	3	1	80	1	0	0	0	0	0
9	23	0	22	0	1	12	6	1	0	4	22	0	0	0	0	0	1	23	0	0	0	0	0	0
10	457	6	415	26	10	145	205	49	0	58	429	4	1	0	3	3	17	451	0	0	2	0	4	0
11	472	14	405	16	37	166	203	73	0	30	423	32	1	0	1	5	10	467	1	0	1	0	3	0
12	500	9	413	34	44	138	218	91	0	53	454	33	0	0	0	2	11	496	1	0	1	0	2	0
13	424	13	364	32	15	143	175	62	0	44	397	15	1	0	2	7	2	415	3	0	2	0	3	1
14	402	9	341	40	12	146	167	53	0	36	382	7	1	0	0	5	7	388	3	0	3	1	6	1
15	68	0	66	0	2	24	24	7	0	13	65	0	0	0	2	0	1	68	0	0	0	0	0	0
16	36	0	32	2	2	26	5	0	0	5	34	0	0	0	0	0	2	36	0	0	0	0	0	0
17	506	7	415	40	44	186	235	65	0	20	451	40	0	1	0	7	7	491	2	0	4	1	8	0
18	531	9	464	32	26	162	277	57	0	35	497	18	0	0	2	8	6	515	4	0	4	0	8	0
19	473	11	399	21	42	171	182	70	0	50	425	39	0	0	0	4	5	468	0	0	2	0	3	0
20	493	11	402	38	42	146	226	74	0	47	433	32	0	0	0	9	19	475	8	1	1	1	7	0
21	449	17	367	39	26	133	201	76	1	38	414	18	0	0	2	7	8	440	2	0	2	0	4	1
22	118	0	111	6	1	70	31	11	0	6	116	1	0	0	0	1	0	117	1	0	0	0	0	0
23	36	0	34	1	1	11	11	2	0	12	34	1	0	0	0	0	1	36	0	0	0	0	0	0
24	456	8	384	45	19	163	216	38	0	39	427	9	0	0	0	8	12	444	3	2	2	1	4	0
25	416	10	345	48	13	135	205	50	0	26	396	7	0	0	3	4	6	406	5	0	1	0	4	0
26	396	6	356	24	10	126	169	37	0	64	382	5	0	0	0	5	4	394	0	1	1	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	98	0	96	2	0	53	22	6	0	64	98	0	0	0	0	0	0	97	0	0	1	0	0	0
30	35	0	33	1	0	22	4	2	0	7	33	1	0	0	0	0	1	35	0	0	0	0	0	0
Total	9,178	183	7,878	609	507	3,086	4,069	1,204	1	865	8,468	401	6	2	26	121	154	9,024	43	4	37	4	63	3
rcentage	100.00%	1.99%	85.84%	6.64%	5.52%	33.62%	44.33%	13.12%	0.01%	9.42%	92.26%	4.37%	0.07%	0.02%	0.28%	1.32%	1.68%	98.32%	0.47%	0.04%	0.40%	0.04%	0.69%	0.03%

CALL VOLUME - DECEMBER 2003

DEC 2003	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	628	7	548	43	30	205	350	51	0	22	576	27	1	0	1	21	2	612	4	2	3	0	6	1
2	561	8	466	45	42	202	267	70	0	22	515	32	0	0	1	8	5	556	0	2	2	0	1	0
3	601	10	479	45	67	198	259	102	1	41	533	55	0	0	3	6	4	587	7	1	5	0	1	0
4	529	15	439	33	42	171	205	94	1	58	473	28	1	0	5	7	15	522	2	2	3	0	0	0
5	461	8	401	38	14	144	208	69	0	40	436	12	1	0	0	6	6	454	1	1	4	0	1	0
6	134	0	128	4	2	66	40	7	0	21	132	1	0	0	0	0	1	134	0	0	0	0	0	0
7	24	0	20	1	3	9	6	3	0	6	22	0	0	0	0	0	2	23	0	0	0	0	1	0
8	581	11	462	59	49	131	298	107	2	43	508	37	2	0	3	12	19	573	3	2	1	0	2	0
9	510	8	406	29	67	150	194	79	1	86	439	49	0	0	0	9	13	503	1	0	4	1	1	0
10	563	9	460	54	40	157	266	85	0	55	514	28	0	0	1	5	15	561	0	1	1	0	0	0
11	469	7	385	38	39	142	198	80	0	49	415	31	1	2	0	14	6	456	7	3	1	0	2	0
12	404	8	364	23	9	191	149	29	0	35	382	4	1	2	0	7	9	396	1	5	1	0	1	0
13	87	0	78	4	5	48	18	1	0	20	81	0	0	0	5	1	0	87	0	0	0	0	0	0
14	22	0	21	1	0	10	7	2	0	3	22	0	0	0	0	0	0	22	0	0	0	0	0	0
15	556	19	450	33	54	149	251	105	0	51	476	50	1	0	1	16	12	549	3	2	1	0	1	0
16	536	11	470	44	11	260	160	63	0	53	513	5	0	0	0	10	8	534	0	1	1	0	0	0
17	554	10	534	10	0	277	177	50	0	50	554	0	0	0	0	0	0	554	0	0	0	0	0	0
18	653	10	633	10	0	500	100	53	0	0	643	10	0	0	0	0	0	653	0	0	0	0	0	0
19	530	5	520	5	0	430	80	20	0	0	520	10	0	0	0	0	0	530	0	0	0	0	0	0
20	98	0	98	0	0	78	20	0	0	0	98	0	0	0	0	0	0	98	0	0	0	0	0	0
21	33	0	33	0	0	28	5	0	0	0	33	0	0	0	0	0	0	33	0	0	0	0	0	0
22	521	2	498	16	5	78	376	39	0	28	510	4	0	0	0	5	2	518	1	0	2	0	0	0
23	530	12	475	36	7	271	141	75	0	43	513	2	0	0	0	5	10	530	0	0	0	0	0	0
24	286	9	247	13	17	31	177	66	0	12	238	41	0	0	2	3	2	284	0	0	2	0	0	0
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
26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	71	0	69	1	1	31	16	6	0	18	70	1	0	0	0	0	0	71	0	0	0	0	0	0
28	20	0	19	0	1	9	4	3	0	4	19	1	0	0	0	0	0	20	0	0	0	0	0	0
29	538	15	450	58	15	123	295	78	0	42	508	6	0	1	4	7	12	536	0	2	0	0	0	0
30	518	21	432	51	14	122	281	86	0	29	491	10	0	0	2	6	9	508	1	3	5	0	1	0
31	443	10	422	11	0	219	200	24	0	0	433	10	0	0	0	0	0	443	0	0	0	0	0	0
Total	**11,461**	**215**	**10,007**	**705**	**534**	**4,430**	**4,748**	**1,447**	**5**	**831**	**10,667**	**454**	**8**	**5**	**28**	**148**	**152**	**11,347**	**31**	**27**	**36**	**1**	**18**	**1**
ercentage	**100.00%**	**1.88%**	**87.31%**	**6.15%**	**4.66%**	**38.65%**	**41.43%**	**12.63%**	**0.04%**	**7.25%**	**93.07%**	**3.96%**	**0.07%**	**0.04%**	**0.24%**	**1.29%**	**1.33%**	**99.01%**	**0.27%**	**0.24%**	**0.31%**	**0.01%**	**0.16%**	**0.01%**

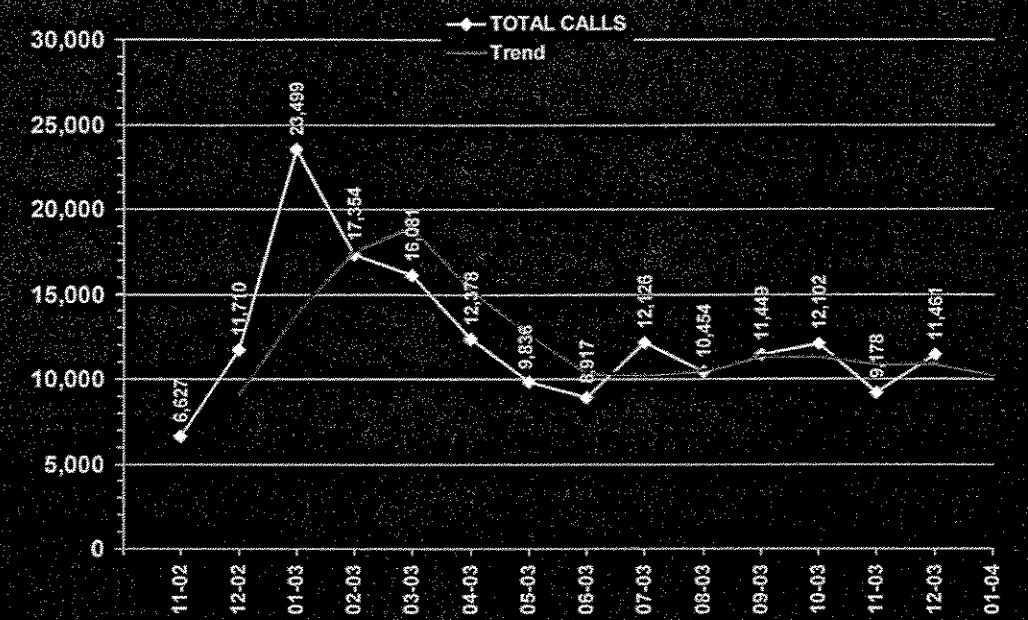
CALL VOLUME

Monthly Totals

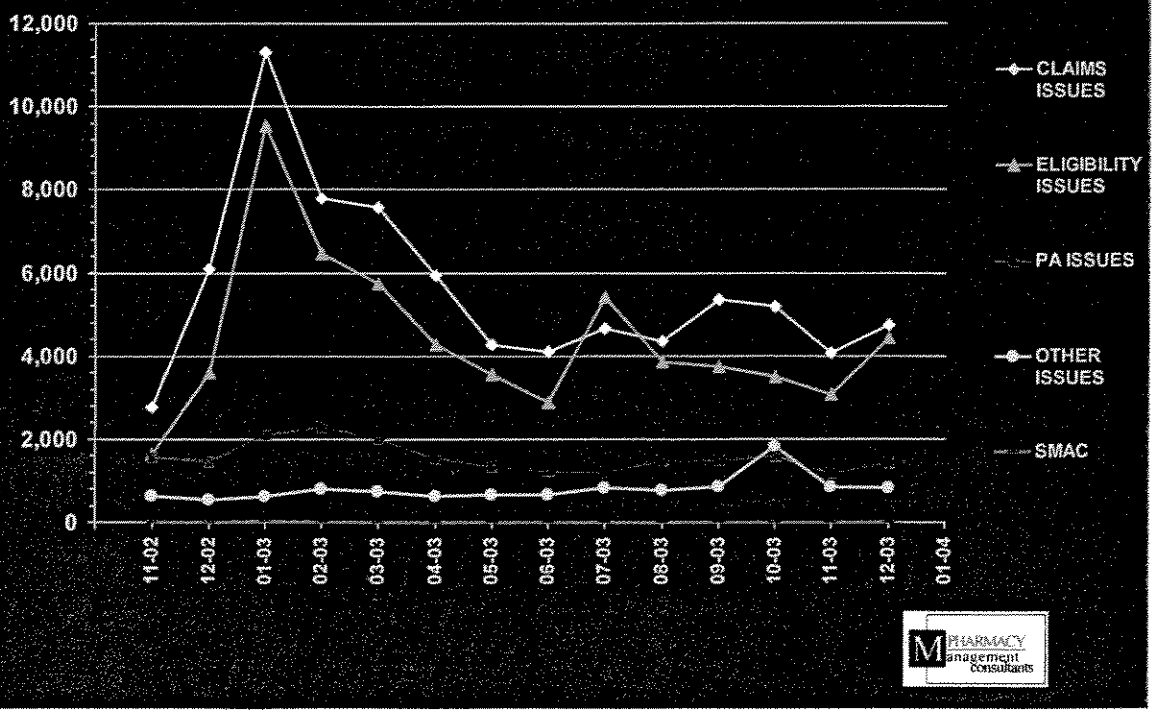
MONTH	1999 Total	2000 Total	2001 Total	2002 Total	2003 Total
January	* 0	3,697	4,905	6,295	23,499
February	* 0	3,335	4,393	5,049	17,354
March	* 0	4,157	4,668	5,858	16,081
April	* 0	3,337	4,556	8,047	12,378
May	* 0	3,804	5,540	7,586	9,836
June	* 0	2,820	4,982	6,368	8,917
July	* 0	3,242	5,465	7,651	12,126
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**

* Help Desk Call Center implemented in August 1999.

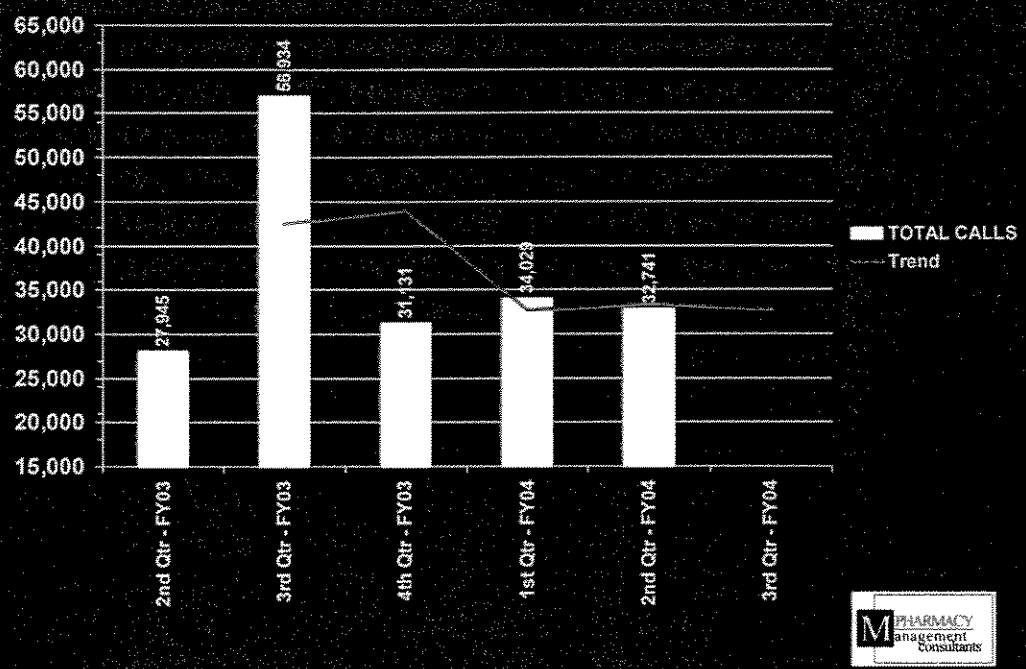
CALL VOLUME MONTHLY REPORT
November 2002 – December 2003



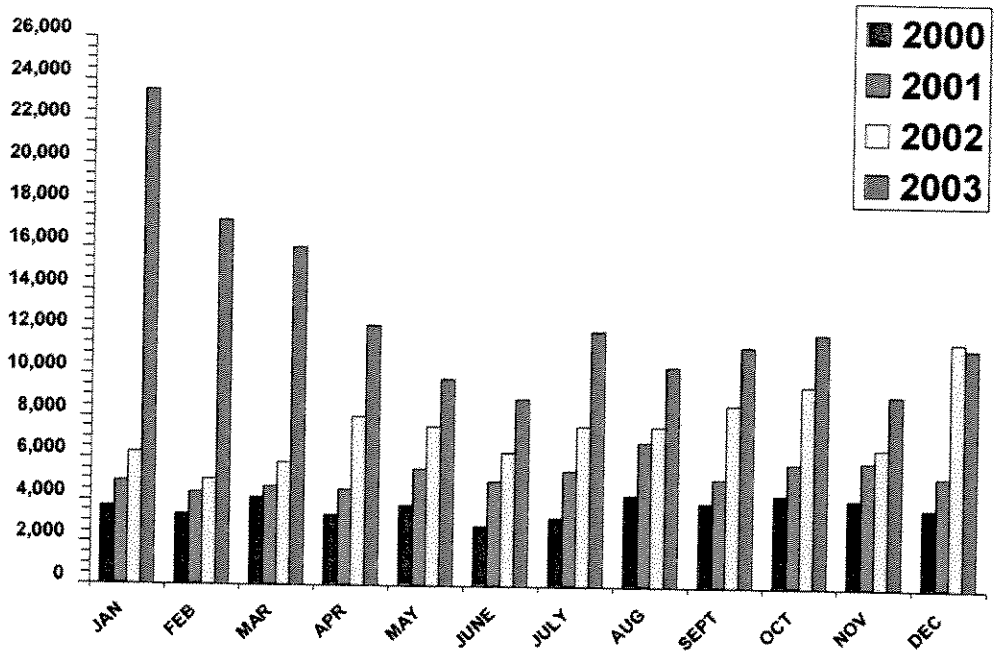
CALL VOLUME ISSUES
November 2002 - December 2003



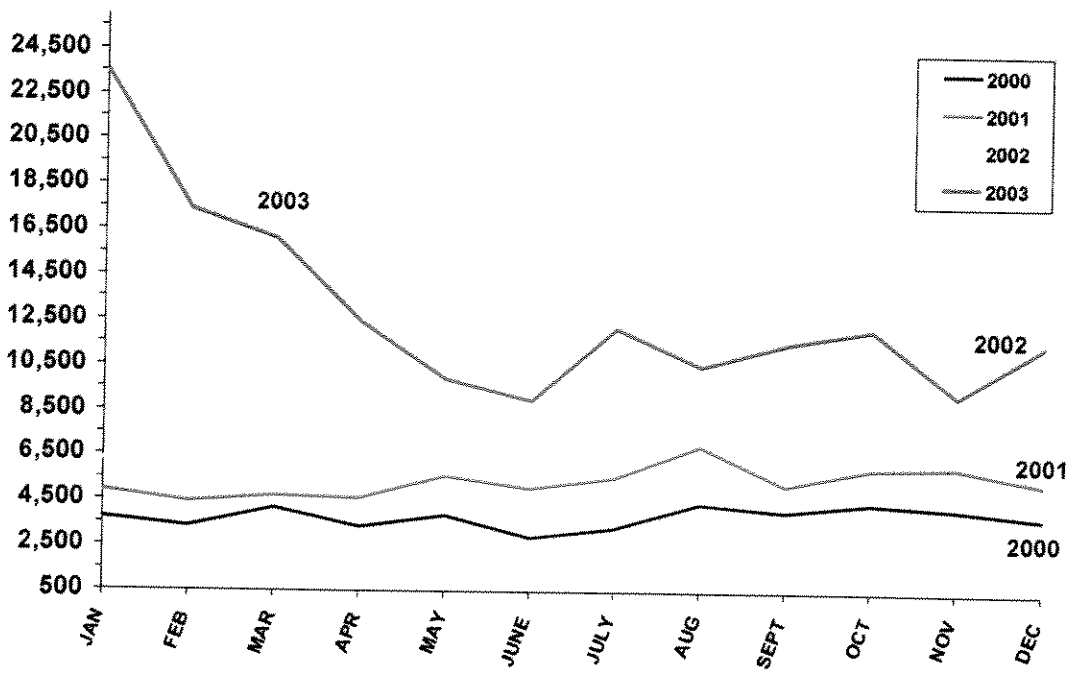
CALL VOLUME
QUARTERLY REPORT
2nd Quarter SFY03 thru 2nd Quarter SFY04



Monthly Call Volume
Calendar Years 2000-2003



Monthly Call Volume
Calendar Years 2000-2003



APPENDIX C

Prior Authorization Annual Review - Fiscal Year 2003

ADHD/Narcolepsy Drugs

Oklahoma Medicaid
January 2004

Product Based Prior Authorization

With respect to the ADHD/narcolepsy medications, there are two tiers of medications in the therapeutic category. A failed trial with a tier-1 ADHD medication or a clinical exception to a tier-1 trial is required before a tier-2 ADHD medication can be approved.

Medication	Age Groups	PA Requirements
Ritalin, Ritalin SR, Dexedrine, Dexedrine Spansule, Adderall	Children up to 21 years old	No PA required
	Adults	PA required – Diagnosis of ADHD or narcolepsy.
Ritalin LA, Concerta, Metadate CD, Focalin, Adderall XR, Strattera	Children and Adults	PA Required – Requires failed trial with Ritalin, Dexedrine or Adderall. Diagnosis of ADHD or narcolepsy.
Desoxyn and Cylert	Children and Adults	PA Required – Requires failed trial with Ritalin and Dexedrine. Diagnosis of ADHD or narcolepsy.

Fiscal Year '03 Changes

Product added to tier-2: Strattera

Utilization

For the period of July 2002 through June 2003, a total of 11,575 clients received ADHD medications through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	Per Diem
Tier 1	35,200	2,236,880	1,082,488	2.066	$1,910,549.26	8,169	$1.825
Tier 2	26,574	949,070	798,392	1.189	$2,192,335.50	6,037	$2.821
Total	**61,774**	**3,185,950**	**1,880,880**	**1.694**	**$4,102,884.76**	**11,575***	**$2.250**

*Total unduplicated clients for FY03

Total Cost FY '03 **$4,102,884.76**
Total Cost FY '02 *$2,984,815.91*
Total Claims FY '03 **61,774**
Total Claims FY '02 *53,001*
Per Diem FY '03 **$2.250**
Per Diem FY '02 *$1.988*

Total petitions submitted in for this category during specified time period: 10,525

Approved *6,714*
Denied 2,478
Incomplete 1,333

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

Age	Female	Male	Totals
0 to 9	1,443	3,804	5,247
10 to 19	1,495	4,419	5,914
20 to 34	74	83	157
35 to 49	81	46	127
50 to 64	39	22	61
65 to 79	23	11	34
80 to 94	27	5	32
95 and Over	3	0	3
Totals	**3,185**	**8,390**	**11,575**

Recommendations

The college of pharmacy has the following recommendations for Fiscal Year 2004:

- Stimulant doses over 1.5 times the FDA approved maximum should not be covered.

- When the prescriber requests stimulant doses over 1 but not more than 1.5 times the FDA approved maximum, the following additional information will be requested before the prior authorization is approved:

  "For dosing in excess of the FDA approved maximum please provide information about patient's titration up to and, if available, progress on this high dose stimulant therapy. We request that prescriber send information about: patient's level of appetite suppression, sleep loss, and hallucinations; whether patient is receiving any psychosocial treatment along with drug therapy; and whether any testing via objective rating scales has been done on patient recently to assess patient's response to treatment. Thank you."
- More than one dosage unit of Concerta or Adderall XR should not be covered.

APPENDIX D

Prior Authorization Annual Review – Fiscal Year 2003
Non-Steroidal, Anti-Inflammatory Drugs (NSAIDs)
Oklahoma Medicaid
January 2004

Product Based Prior Authorization – NSAIDs

With respect to the non-steroidal, anti-inflammatory drugs (NSAIDs), there are two tiers of drugs in this therapeutic classification. A trial of two tier-1 medications within 120 consecutive days is required before the approval of a tier-2 medication.

(A) The clinical exceptions for the non-steroidal, anti-inflammatory drugs in tier-2 are demonstrated by the following conditions:
- (i) history of upper GI bleeding, or
- (ii) history of NSAID-induced ulcer, or
- (iii) active peptic ulcer disease, or
- (iv) concurrent use of warfarin, or
- (v) concurrent chronic use of oral corticosteroids, or
- (vi) chronic NSAID therapy in elderly or debilitated patients, or
- (vii) indomethacin for management of gout.

(B) These clinical conditions are demonstrated by documentation sent by the prescribing physician and pharmacist.

NSAIDs	
(Arthritis Medications or Non-Steroidal, Anti-Inflammatory Drugs)	
Tier 1	**Tier 2**
diclofenac ER (Voltaren XR®)	diclofenac sodium/misoprostol (Arthrotec®)
diclofenac potassium (Cataflam®)	celecoxib (Celebrex®)
diclofenac sodium (Voltaren®)	indomethacin (Indocin®)
etodolac ER (Lodine XL®)	meloxicam (Mobic®)
fenoprofen (Nalfon®)	naproxen sodium (Naprelan®)
flurbiprofen (Ansaid®)	piroxicam (Feldene®)
ibuprofen (Motrin®)	rofecoxib (Vioxx®)
ketoprofen (Orudis®)	valdecoxib (Bextra®)
ketoprofen ER (Oruvail®)	
meclofenamate (Meclomen®)	
mefanamic acid (Ponstel®)	
nabumetone (Relafen®)	
naproxen (Naprosyn®)	
naproxen sodium (Anaprox®)	
naproxen EC (Naprosyn EC®)	
oxaprozin (Daypro®)	
sulindac (Clinoril®)	
tolmetin (Tolectin®)	

Changes for Fiscal Year 2003

No changes occurred.

Utilization – Fiscal Year 2003

For the period of July 2002 through June 2003, a total of 41,349 clients received non-steroidal, anti-inflammatory drugs through the Oklahoma Medicaid fee-for-service program.

Tier	# of Claims	Total Units	Total Days	Units/Day	Total Costs	Per Diem	Total Clients
Tier-1	80,698	4,825,858	2,032,910	2.37	$ 1,703,191.58	$ 0.84	32,424
Liquids	4,665	1,735,001	46,631	37.21	$ 100,333.39	$ 2.15	2,351
Tier-2	43,211	2,023,203	1,529,681	1.32	$ 4,655,882.33	$ 3.04	8,281
Liquids	50	7,180	1,446	4.97	$ 5,313.01	$ 3.67	13
Total	**128,624**	**8,591,242**	**3,610,668**	**2.38**	**$ 6,464,720.31**	**$ 1.79**	**41,349***

*Unduplicated clients for FY03

Total Cost FY '03	**$6,464,720.31**
Total Cost FY '02	*$6,355,352.07*
Total Claims FY '03	**128,624**
Total Claims FY '02	*133,376*
Total Clients FY '03	**41,349**
Total Clients FY '02	*38,932*
Per Diem FY '03	**$1.79**
Per Diem FY '02	*$1.75*

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

Age	Female	Male	Totals
0 to 9	1,123	1,234	2,357
10 to 19	5,626	3,790	9,416
20 to 34	5,403	759	6,162
35 to 49	3,544	1,743	5,287
50 to 64	3,785	1,767	5,552
65 to 79	5,543	1,719	7,262
80 to 94	4,213	762	4,975
95 and Over	300	38	338
Totals	**29,537**	**11,812**	**41,349**

Claims were also divided into the two available tiers and reviewed by age and gender.

Tier-1 Claims

Age	Female	Male	Totals
0 to 9	1,116	1,233	2,349
10 to 19	5,594	3,771	9,365
20 to 34	5,326	718	6,044
35 to 49	3,208	1,566	4,774
50 to 64	2,843	1,486	4,329
65 to 79	3,578	1,319	4,897
80 to 94	2,211	492	2,703
> 94	185	28	213
Totals	**24,061**	**10,613**	**34,674**

Tier-2 Claims

Age	Female	Male	Totals
0 to 9	8	1	9
10 to 19	65	38	103
20 to 34	133	61	194
35 to 49	491	254	745
50 to 64	1,248	390	1,638
65 to 79	2,352	501	2,853
80 to 94	2,275	329	2,604
> 94	130	14	144
Totals	**6,702**	**1,588**	**8,290**

Total petitions submitted for this category during reviewed period: 9,066.

Approved *4,037*
Denied* 3,731
Incomplete* 652
*646 additional petitions were originally denied but subsequently approved.

Review of Cox-2 Inhibitor Utilization

Market Share for Cox-2 Inhibitors July 2002 through June 2003.

Brand Name	Total Cost/ Brand FY '02	% Share/ Brand FY '02	Total Cost/ Brand FY '03	% Share/ Brand FY '03
Celebrex®	$ 2,694,604.13	62.65%	$ 2,674,577.76	61.97%
Vioxx®	$ 1,571,754.78	36.54%	$ 1,314,738.18	30.46%
Bextra®	$ 35,009.51	0.81%	$ 326,361.69	7.56%

A total of 7,420 clients received cox-2 inhibitors. Of these, 69 % were 65 years of age or greater.

Recommendations

The college of pharmacy recommends continuation of the current criteria and tier structure.

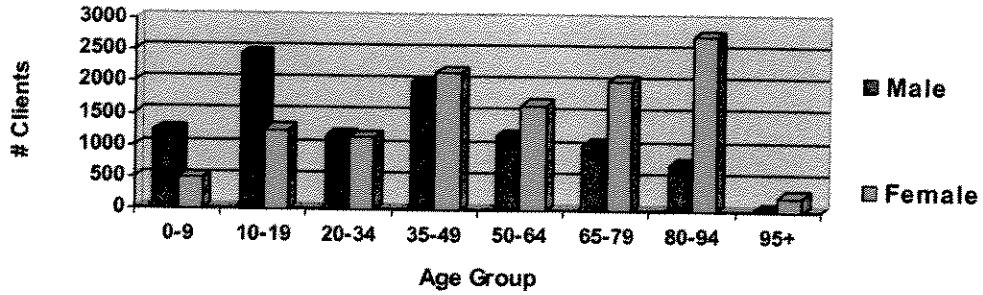
APPENDIX E

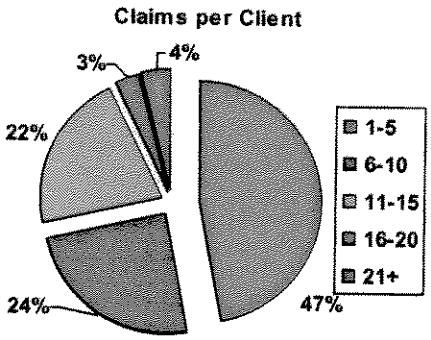
ATYPICAL ANTIPSYCHOTICS: Utilization Review
Oklahoma Medicaid
June 1, 2002 – May 31, 2003

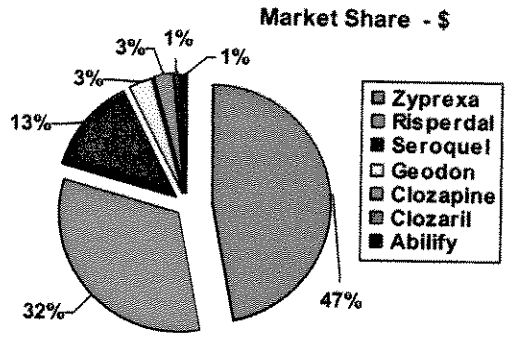
Drug	*How Supplied*	*Dosing Schedule*	*Max Dose/Day*	*FDA Approved Indication(s)*
Aripiprazole - **Abilify**	10, 15, 20, & 30 mg tablets	QD	30 mg	***Schizophrenia:*** Treatment of schizophrenia.
Clozapine – **Clozaril** & generics	25 & 100 mg tablets	QD - BID	900 mg	***Schizophrenia:*** Management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia. Reduction in risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders.
Olanzapine - **Zyprexa**	2.5, 5, 7.5, 10, 15, 20 mg tablets (Zyprexa); 5, 10, 15, 20 mg orally disintegrating tablets (Zyprexa Zydis)	QD	20 mg	***Schizophrenia:*** Treatment of schizophrenia. ***Bipolar mania:*** Short-term treatment of acute manic episodes associated with Bipolar I disorder.
Quetiapine - **Seroquel**	25, 100, 200, 300 mg tablets	BID - TID	800 mg	***Schizophrenia:*** Treatment of schizophrenia.
Risperidone - **Risperdal**	0.25, 0.5, 1, 2, 3, 4 mg tablets; 0.5, 1, 2 mg orally disintegrating tablets (M-Tabs); 1 mg/mL oral solution; 25, 37.5, 50 mg microspheres for injection (Risperdal Consta)	QD - BID	8 mg	***Schizophrenia:*** Treatment of schizophrenia. ***Bipolar mania:*** Short-term treatment of acute manic or mixed episodes associated with Bipolar I disorder.
Ziprasidone - **Geodon**	20, 40, 60, 80 mg capsules, 20 mg powder for injection	BID (oral)	200 mg (oral), 40mg (IM)	***Schizophrenia:*** Treatment of schizophrenia. ***Acute agitation*** *(injection only):* Treatment of acute agitation in schizophrenic patients for whom treatment with ziprasidone is appropriate and who need IM antipsychotic medication for rapid control of the agitation

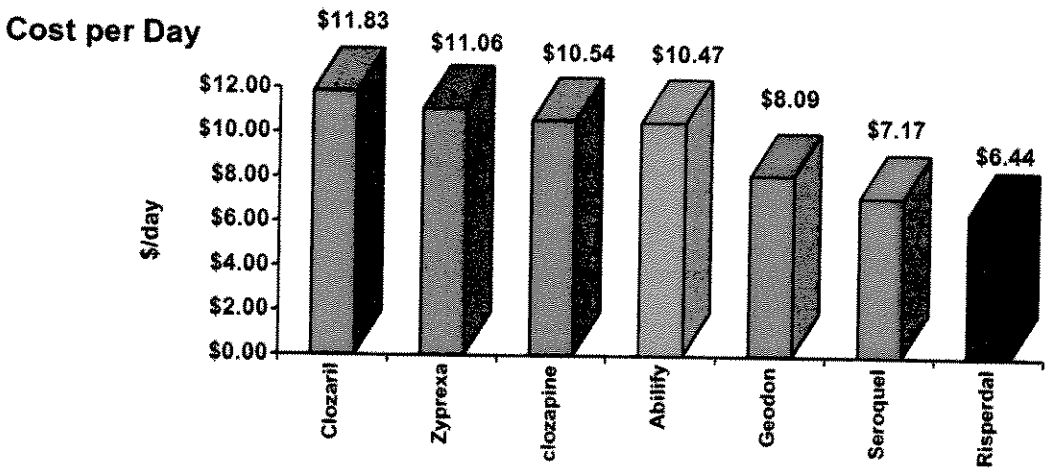
Drug & Strength	*Total # of Clients*	*Total # of Claims*	*Total # of Units*	*Total # of Days*	*Total $ Paid*	*$/Unit**	*$/Day**	*Mean Units/ Day*	*Mean Mg/Day*
Aripiprazole **Abilify**	391	762	59,223	26,994	$282,272.94	$4.77	$10.47	2.45	37.24
Clozapine **Clozaril**	135	1747	113,425	28,564	$327,529.91	$2.98	$11.83	4.04	366.18
Clozapine **generic**	375	6677	490,008	104,794	$1,072,434.47	$2.26	$10.54	5.07	458.02
Olanzapine **Zyprexa**	8,950	53,318	2,337,625	1,702,162	$18,418,246.37	$8.05	$11.06	1.45	12.14
Quetiapine **Seroquel**	4,474	24,714	1,907,191	753,974	$5,268,806.14	$2.83	$7.17	2.73	271.95
Risperidone **Risperdal**	10,504	66,112	3,647,973	2,037,324	$12,792,984.97	$3.59	$6.44	1.88	2.38
Ziprasidone **Geodon**	1,257	5381	360,789	165,163	$1,293,329.96	$3.70	$8.09	2.38	104.78
TOTAL 6/1/02-5/31/03	**21,488**	**158,711**	**8,916,234**	**4,818,975**	**$39,455,604.76**	**$4.43**	**$8.19**	n/a	n/a
Total 6/1/01 – 5/31/02	*18,452*	*140,889*	*7,753,194*	*4,105,165*	*$30,576,747.93*	*$3.94*	*$7.45*	n/a	n/a
Change vs. Previous Year	3,036↑	17,822↑	1,163,040↑	713,810↑	$8,878,856.83↑	$0.49↑	$0.74↑	n/a	n/a
% Change vs. Previous Year	16.5%↑	12.6%↑	15.0%↑	17.4%↑	29.0%↑	12.4%↑	9.9%↑	n/a	n/a

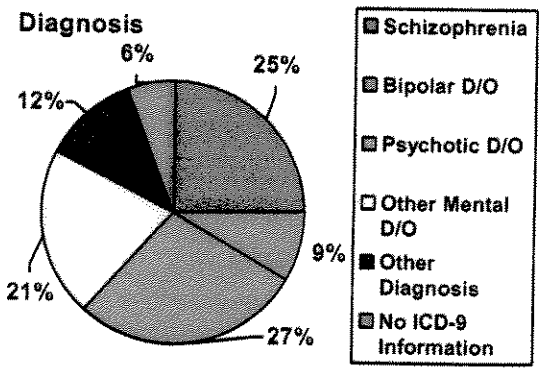
*Based on pharmacy reimbursement including ingredient cost and dispensing fee of pharmacy claims without recoupment charges.

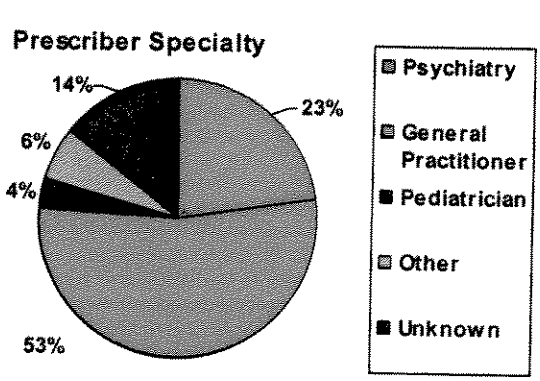

Clients
3000
2500
2000
1500
1000
500
0
0-9
10-19
20-34
35-49
50-64
65-79
80-94
95+
Age Group
Male
Female


Claims per Client
3%
4%
22%
24%
47%
1-5
6-10
11-15
16-20
21+


Market Share - $
3%
1%
3%
1%
13%
32%
47%
Zyprexa
Risperdal
Seroquel
Geodon
Clozapine
Clozaril
Abilify


Cost per Day
$/day
$12.00
$10.00
$8.00
$6.00
$4.00
$2.00
$0.00
$11.83
$11.06
$10.54
$10.47
$8.09
$7.17
$6.44
Clozaril
Zyprexa
clozapine
Abilify
Geodon
Seroquel
Risperdal


Diagnosis
6%
25%
12%
9%
21%
27%
Schizophrenia
Bipolar D/O
Psychotic D/O
Other Mental D/O
Other Diagnosis
No ICD-9 Information


Prescriber Specialty
14%
23%
6%
4%
53%
Psychiatry
General Practitioner
Pediatrician
Other
Unknown

Prescriber Specialty:

7,662 (35.7%) of the patients filled an atypical antipsychotic prescription written by a prescriber whose primary or secondary specialty was psychiatry or psychology during the year studied.
11,002 (51.2%) of the patients received a prescription for any drug from a psychiatrist in the last four years.

Use in the Pediatric Population:

The atypical antipsychotics are not FDA approved for use in pediatric and adolescent patients. Despite the lack of data on their safety and efficacy in this population, these drugs are frequently used on patients in this age group. Of the 21,488 patients using atypical antipsychotics during the period studied, 5,409 (25.2%) were under age 20. Since schizophrenia is rare among children, much of the use in this age group is likely to be for off-label uses such as aggression, mood disorders, conduct disorder and other pervasive developmental disorders, autism, movement disorders, and Tourette's syndrome.

Of the 5,409 patients under age 20 in the year studied, when ICD-9 codes on medical claims for the last four years were examined,

- 400 (7.4%) had schizophrenia
- 803 (14.8%) had bipolar disorder
- 1,683 (31.1%) had a psychotic disorder

The following chart shows the growth in the usage of atypical antipsychotics by pediatric Oklahoma Medicaid patients from one year to the next. The percentages in the chart are atypical antipsychotic claims as a percentage of all mental health medication claims. This shows that atypical antipsychotics are increasingly being used instead of other mental health medications in this population.

Age Group	0-5 years	6-10 years	11-14 years	15-18 years
Jan-June **2000**	5%	8%	9%	13%
Jan-June **2001**	7%	12%	13%	15%

*This chart is adapted from a report produced by OU COP PhD candidate Tara Jenkins.

Use in Nursing Home Patients:

Of the 21,488 patients using atypical antipsychotics during the period studied, 7,629 (35.5%) resided in nursing homes. Much of the use in nursing home patients is likely to be for off-label uses such as Alzheimer's and Parkinson's dementia, aggression, and agitation. Many of these patients may not have psychosis, and these drugs are sometimes inappropriately used for their sedating properties.

Of the 7,269 nursing home patients in the year studied, when ICD-9 codes on medical claims for the last four years were examined,

- 1,380 (19.0%) had schizophrenia
- 212 (2.9%) had bipolar disorder
- 2,868 (39.5%) had a psychotic disorder

Atypical Antipsychotic Polypharmacy:

Of the 21,488 patients using atypical antipsychotics during the period studied, 1,475 (6.9%) used more than one atypical antipsychotic concomitantly for more than 30 days. Of these, 559 (37.9%) were nursing home patients.

Dosing:

High dose claims: 6,674 (4.2%) of the atypical antipsychotic claims were for doses exceeding the maximum FDA approved dosing.
Low dose claims: 60,578 (38%) of the atypical antipsychotic claims were for doses less than the minimum starting or target dose recommended in the package labeling.

Limitations in Other States:

Upon review of other states' Medicaid program websites, it was found that several states have placed some restrictions on the use of atypical antipsychotics.

State	Intervention
California	Educational programs for physicians and pharmacies after identifying atypical antipsychotic prescribing and dispensing that falls outside accepted standards, such as polypharmacy, use in young children, excessively high doses, etc.
Kentucky	PA required for **Zyprexa** (olanzapine). (If there has been a claim for Zyprexa, Seroquel, Risperdal, Geodon, Clozaril, Depakote, or lithium within the past 24 months, Zyprexa is approved without the need for a PA). Patients stabilized on Zyprexa during an inpatient hospital admission are allowed to continue upon completion of a PA. For other patients, PA for Zyprexa is subject to documentation of failure with Seroquel, Risperdal, Geodon, or Clozaril.
Maine	PA required for **Abilify**, **Zyprexa**, and brand name **Clozaril** (generic clozapine is a preferred drug). **Geodon** quantity limit of 2 per day; **Abilify** limited to 1 per day. There are limitations on off-label uses; for example, Zyprexa is not covered for Alzheimer's disease.
Massachusetts	PA required for **Risperdal M-Tab**, **Zyprexa Zydis**, brand name **Clozaril**, overlapping therapy of 2 or more atypical antipsychotics for more than 60 days (clozapine excluded), and for any atypical antipsychotic when the dosing exceeds the following: **Abilify** (Aripiprazole) 15 mg/day Clozapine 900 mg/day **Zyprexa** (Olanzapine) 20 mg/day **Seroquel** (Quetiapine) 800 mg/day (or if dose < 200 mg/day for more than 60 days unless patient is >65 years old) **Risperdal** (Risperidone) 6 mg/day **Geodon** (Ziprasidone) 160 mg/day
Missouri	PA required for brand-name **Clozaril**; must explain why can't use generic. Educational program (letters and possibly peer-to-peer interventions) when prescribing problems are identified through retrospective DUR.

Texas	Retrospective DUR program looks at high-dose prescribing, drug interactions, and multiple concurrent atypical antipsychotics for more than 4 weeks.
Washington	PA required for patients exceeding the following ages: **Abilify** (Aripiprazole) 18 years & older **Clozapine** 17 years & older **Zyprexa** (Olanzapine) 6 years & older **Seroquel** (Quetiapine) 6 years & older **Risperdal** (Risperidone) 6 years & older **Geodon** (Ziprasidone) 6 years & older
West Virginia	PA required for **Abilify** and **Zyprexa**. Patients already on these agents will receive authorization to continue them. New patients are required to try one of the other atypical antipsychotics for 2 weeks, unless they meet a clinical exception listed on the PA form.

New Combination Product:

Symbyax™ = Olanzapine/Fluoxetine combined in one capsule.
Available strengths:
6 mg olazapine / 25 mg fluoxetine
6 mg olazapine / 50 mg fluoxetine
12 mg olazapine / 25 mg fluoxetine
12 mg olazapine / 50 mg fluoxetine
Indication: treatment of depressive episodes associated with bipolar disorder.

Recommendations:

1. Refer clients using more than 2 atypical antipsychotics concurrently to the Therapy Management Program. Consider requiring such clients to be referred to a psychiatrist or have a new evaluation.
2. Refer nursing home clients using more than 1 atypical antipsychotic concurrently to the Therapy Management Program.

APPENDIX F

Forteo, Calcium Regulators, and Evista Utilization Comparison Fiscal Year 2003 to 1st quarter Fiscal Year 2004

Oklahoma Medicaid
November 2003

Forteo - approved December 2002 and available since January 2003.

- Is the first agent approved for the treatment of osteoporosis that stimulates new bone formation.
- Administered 20mcg/dose SQ once per day.
- Increases BMD, reconstructs bone architecture and has the same effects on the bone and kidney as endogenous parathyroid hormone.
- FDA labeled indications are for men with primary or hypogonadal osteoporosis, postmenopausal women with osteoporosis both men and women who are at high risk for fractures, have a history of fractures, multiple risk factors for the development of fractures, cannot tolerate other therapies, or have failed other therapies.
- Adverse effects similar to other osteoporosis medications.

Utilization

For the period of July 2002 through June 2003, a total of 7,496 clients received Forteo, calcium regulators or Evista through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	Per Diem
Fosamax 5mg	257	9,416	9,534	0.99	$20,499.23	78	$2.15
Fosamax 10mg	2,186	86,080	85,687	1.00	$185,673.73	722	$2.17
Fosamax 35mg	344	2,018	13,313	0.15	$30,384.38	120	$2.28
Fosamax 40mg	1	30	30	1.00	$147.91	1	$4.93
Fosamax 70mg	12,778	66,981	451,730	0.15	$1,017,965.18	4,102	$2.25
Didronel 200mg	24	1,146	528	2.17	$3,075.76	10	$5.83
Didronel 400mg	66	1,766	1,518	1.16	$9,736.25	28	$6.41
Actonel 5mg	1,302	48,925	48,791	1.00	$101,462.27	403	$2.08
Actonel 30mg	661	4,945	24,314	0.20	$72,646.16	240	$2.99
Actonel 35mg	5,187	22,997	157,022	0.15	$347,765.03	1,095	$2.21
Calcimar 200	1	2	30	0.07	$51.14	1	$1.70
Calcitonin 200	1	10	30	0.33	$91.72	1	$3.06
Miacalcin 200 inj	328	1,850	6,488	0.29	$33,784.58	89	$5.21
Miacalcin 200spry	10,831	37,078	217,299	0.17	$632,191.26	3,245	$2.91
Forteo 750 sol	32	120	981	0.12	$20,479.75	16	$20.88
Evista 60mg	7,791	310,511	304,801	1.02	$686,895.85	2,343	$2.25
Total	**41,790**	**593,785**	**1,322,096**		**$3,162,850.20**	**7,496***	

*Total unduplicated clients for FY03

For the period of July 2003 through September 2003, a total of 4,882 clients received Forteo, calcium regulators or Evista through the Medicaid fee-for-service program.

Product	# of Claims	Total Units	Total Days	Units/ Day	Total Cost	Total Clients	Per Diem
Fosamax 5mg	41	1,785	1,902	0.94	$3,968.82	22	2.09
Fosamax 10mg	308	13,462	13,428	1.00	$31,184.13	178	2.32
Fosamax 35mg	97	521	3,656	0.14	$8,515.95	52	2.33
Fosamax 40mg	2	60	60	1.00	$309.82	1	5.16
Fosamax 70mg	2,877	15,923	109,871	0.14	$259,693.87	1,536	2.36
Didronel 200mg	9	511	215	2.38	$1,492.93	6	6.94
Didronel 400mg	8	286	216	1.32	$1,639.18	6	7.59
Actonel 5mg	186	7,700	7,667	1.00	$16,962.41	105	2.21
Actonel 30mg	95	977	4,155	0.24	$14,829.76	56	3.57
Actonel 35mg	1,876	8,547	58,606	0.15	$133,816.69	860	2.28
Miacalcin 200 inj	70	376	1,437	0.26	$7,187.15	29	5.00
Miacalcin 200spry	2,678	9,188	56,444	0.16	$166,868.08	1,321	2.96
Forteo 750 sol	37	153	1,374	0.11	$26,874.87	23	19.56
Evista 60mg	1,802	76,052	75,318	1.01	$184,970.72	943	2.46
Total	**10,086**	**135,541**	**334,349**		**$858,314.38**	**4882***	

*Total unduplicated clients for FY04

Total Cost FY '03 **$3,162,850.20**

Total Cost 1st quarter of FY04 *$858,314.38*

Total Claims FY '03 **41,790**

Total Claims 1st quarter of FY04 *10,086*

Total Clients FY 03 ***7,496***

Total Clients 1st quarter of FY04 *4,882*

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

FY03

Age	Female	Male	Totals
0 to 9	5	4	9
10 to 19	6	8	14
20 to 34	37	18	55
35 to 49	257	61	318
50 to 64	993	132	1,125
65 to 79	2,684	153	2,837
80 to 94	2,781	128	2,909
95 and Over	225	4	229
Totals	**6,988**	**508**	**7,496**

1st quarter FY04

Age	Female	Male	Totals
0 to 9	1	1	2
10 to 19	7	7	14
20 to 34	19	14	33
35 to 49	152	51	203
50 to 64	598	94	692
65 to 79	1,744	94	1,838
80 to 94	1,862	69	1,931
95 and Over	166	3	169
Totals	**4,549**	**333**	**4,882**

Recommendations:

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

Prior authorization for Forteo.

Restricted use to:

- Postmenopausal women at high risk for fracture, or that cannot tolerate, are allergic to, or have failed to improve while on other agents.
- Men with primary or hypogonadal osteoporosis.
- Appropriate ICD-9 code.
- No concurrent use of Forteo with other agents until/when more information is available.
- Minimum 3 month trial with one other agent (Fosamax, Evista, Estrogen, Calcimar or Miacalcin unless contraindicated, intolerant, or allergic) within the last month.
- PA approval for one month's supply per fill for duration of 1 year. With a maximum duration of 2 years.

APPENDIX G

FDA Talk Paper

T03-79
November 21, 2003

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Approves Third Drug To Treat Erectile Dysfunction

The Food and Drug Administration (FDA) today approved Cialis® (tadalafil), an oral medication to treat erectile dysfunction (ED, or impotence) in men. This is the third oral product approved for this condition. This drug is different than currently approved products for ED in that it stays in the body longer.

Erectile dysfunction (ED) affects millions of men in the United States. Cialis acts by relaxing muscles in the penis and blood vessels, allowing increased blood flow into the penis, which produces an erection.

Cialis was evaluated in randomized, placebo-controlled trials involving more than 4,000 men with erectile dysfunction. In two of these trials, men had ED associated with diabetes mellitus or following radical prostatectomy for prostate cancer.

The drug's effectiveness was assessed using a sexual function questionnaire. In addition, patients were asked to report if they were able to achieve an erection adequate for intercourse and whether that erection was maintained to allow completion of intercourse. In all of these trials, Cialis improved patients' ability to achieve and maintain a penile erection. In other studies, sexual activity was improved in some patients at 30 minutes after taking a dose; additional studies demonstrated improvements for up to 36 hours after taking Cialis when compared to placebo.

The recommended starting dose for most patients is 10 mg taken prior to anticipated sexual activity. A higher dose of 20mg is available for patients whose response to the 10mg dose is not adequate. A lower dose (5 mg) is also available and may be necessary for patients taking other medicines or having medical conditions that may decrease the body's ability to metabolize tadalafil. Cialis should not be used more than once per day.

Cialis should not be used with nitrates (such as nitroglycerin tablets or patches) or with an alpha blocker other than FLOMAX 0.4mg daily (alpha blockers are medicines used to treat benign prostatic hyperplasia and high blood pressure) because the combination may significantly lower blood pressure and lead to fainting or even death in some men.

Because some drugs affect the metabolism of Cialis, patients should inform their doctors that they are taking Cialis. For example, patients taking ketoconazole or ritonoavir should not take more than a 10mg dose of Cialis once every 72 hours.

Also, in patients with moderately or severely decreased kidney function, the starting dose is 5mg taken once daily. In this group, the dose may be increased to 10mg taken once every 48 hours. In patients with mild or moderate liver impairment, the maximum dose of Cialis is 10mg.

In most patients, after taking a single dose of Cialis, some of the drug will remain in the

body for more than 2 days. In those with decreased kidney function, impairment of the liver, or those taking certain medications (e.g. ketoconazole or ritonavir) tadalafil can remain in the body longer.

Cialis should not be taken by men in whom sexual activity is inadvisable because of their underlying cardiovascular status (heart condition). Patients should inform their doctor about any heart problems that they have experienced before taking Cialis.

Cialis is not recommended in patients who have suffered a heart attack or stroke within the last six months, or patients who have significantly low blood pressure, uncontrolled high blood pressure, unstable angina, severe liver impairment, or retinitis pigmentosa (an eye disorder).

The most common side effects reported in clinical trials included headache, indigestion, back pain, muscle aches, flushing, and stuffy or runny nose. Patients who get back pain and muscle aches usually get it 12 to 24 hours after taking Cialis and these usually go away by themselves within 48 hours. A small number of patients taking Cialis also reported abnormal vision.

Before taking Cialis, patients are advised to undergo a thorough medical history and physical examination to attempt to diagnose the underlying cause of the erectile dysfunction and to identify appropriate treatment.

Cialis confers no resistance to AIDS or other sexually transmitted diseases.

Cialis is manufactured for Lilly ICOS LLC by Eli Lilly and Company.

Additonal information on Cialis

####

Roche Pharmaceuticals

53

December 2003

Dear Health Care Professional:

Roche Laboratories Inc. is writing to inform you of new preclinical safety data that have implications for the use of Tamiflu® (oseltamivir phosphate) in very young children. Tamiflu is indicated for the treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older who have been symptomatic for no more than 2 days. Tamiflu is also indicated for the prophylaxis of influenza in adult patients and adolescents 13 years and older. **Tamiflu is not indicated for either treatment or prophylaxis of influenza in patients less than 1 year of age.**

The early start of the 2003-04 influenza season, together with early reports of increased hospitalizations and deaths in children, has raised concern among parents and physicians about influenza this year. CDC estimates that the serious complications of influenza, including pneumonia, hospitalize about 114,000 people annually in the United States in an unremarkable season. Some health experts estimate that the death toll from this year's outbreak will exceed the annual average of 36,000 people. Of particular concern is that at least 42 children under age 18 have died so far this season from illness attributed to influenza and its complications.

While Tamiflu has been demonstrated to be effective and well tolerated in treating patients as young as 1-year-old, preclinical findings in juvenile rats have raised possible concerns regarding the use of Tamiflu in infants less than 1 year of age. A single dose of 1000 mg/kg oseltamivir phosphate (about 250 times the recommended dose in children) in 7-day-old rats resulted in deaths associated with unusually high exposure to both oseltamivir and oseltamivir phosphate. Further studies showed levels of oseltamivir phosphate in the brain to be approximately 1500 times those seen in adult animals. It is likely that these high exposures are related to an immature blood-brain barrier. Studies showed no deaths or other significant effects in older juvenile rats given the same or higher doses of Tamiflu. The exposures to oseltamivir phosphate associated with no adverse effects in the brain of juvenile rats correspond to approximately 800-fold the exposure expected in a 1-year-old child. The clinical significance of these preclinical data to human infants is uncertain. However, given the uncertainty in predicting the exposures in infants with immature blood-brain barriers, it is recommended that Tamiflu not be administered to children younger than 1 year, the age at which the human blood-brain barrier is generally recognized to be fully developed.

Details of these preclinical findings have been discussed with the Food and Drug Administration, and we are in the process of incorporating the information into the Tamiflu package insert. Given the possible desire to treat very young children with Tamiflu during this active influenza season, **we wish at this time to emphasize the importance of using Tamiflu only for labeled indications and only in patients 1 year and older.**

These data do not affect the use of Tamiflu in older children or in adults. In clinical trials, patients 1 year and older who were treated with Tamiflu within 2 days of symptom onset experienced a reduction in the duration of flu of about 1.5 days. Tamiflu is also effective in preventing the spread of influenza in close contacts in adolescents aged 13 years and older and in adults. The enclosed complete product information includes details on dosing and duration of treatment and prophylaxis for patients within labeled indications.

We would also like to remind you about FluSTAR™, a state-of-the-art surveillance network for tracking and reporting flu. Information about FluSTAR™ can be accessed by visiting www.flustar.com.

If you have any questions or require additional information concerning Tamiflu, please contact the Roche Pharmaceuticals Service Center at 1-800-526-6367.

Roche Laboratories is committed to providing you with the most current product information for Tamiflu. You can assist us in monitoring the safety of Tamiflu by reporting adverse reactions to Roche Laboratories at 1-800-526-6367, by FAX at 1-800-532-3931, via www.fda.gov/medwatch, or by mail to MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely,
Dominick Iacuzio, PhD
Medical Director, Roche Laboratories Inc.
Enclosure: Complete Product Information for Tamiflu® (oseltamivir phosphate) Capsules and for Oral Suspension

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

December 15, 2003

IMPORTANT DRUG WARNING – New Prescribing Information

Dear Health Care Professional,

This letter is to advise you of the possibility of patients falling asleep while performing daily activities, including operation of motor vehicles, while receiving treatment with Permax® (pergolide mesylate), a dopamine agonist, indicated as adjunctive treatment to levodopa/carbidopa in the management of the signs and symptoms of Parkinson's disease. While somnolence is a common occurrence in patients receiving Permax and many clinical experts believe that falling asleep while engaged in activities of daily living only occurs in the context of pre-existing somnolence, many patients who have fallen asleep have perceived no warning. Health Care Professionals should be alerted to the potentially serious risks associated with the events and should carefully evaluate their patients for the presence of somnolence, and should have a discussion with them.

To communicate this important safety information, the Warnings section in the US Package Insert for Permax has been updated to include the following:

> ***Falling Asleep During Activities of Daily Living*** **— Patients treated with Permax have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles which sometimes resulted in accidents. Although many of these patients reported somnolence while on Permax, some perceived that they had no warning signs such as excessive drowsiness, and believed that they were alert immediately prior to the event. Some of these events had been reported as late as 1 year after the initiation of treatment.**
>
> **Somnolence is a common occurrence in patients receiving Permax. Many clinical experts believe that falling asleep while engaged in activities of daily living always occurs in a setting of preexisting somnolence, although patients may not give such a history. For this reason, prescribers should continually reassess patients for drowsiness or sleepiness, especially since some of the events occur well after the start of treatment. Prescribers should also be aware that patients may not acknowledge drowsiness or sleepiness until directly questioned about drowsiness or sleepiness during specific activities.**
>
> **Before initiating treatment with Permax, patients should be advised of the potential to develop drowsiness and specifically asked about factors that may increase the risk with Permax such as concomitant sedating medications or the presence of sleep disorders. If a patient develops significant daytime sleepiness or episodes of falling asleep during activities that require participation (e.g., conversations, eating, etc.), Permax should ordinarily be discontinued. If a decision is made to continue Permax, patients should be advised to not drive and to avoid other potentially dangerous activities.**
>
> **While dose reduction may reduce the degree of somnolence, there is insufficient information to establish that dose reduction will eliminate episodes of falling asleep while engaged in activities of daily living.**

The somnolence statement in the Information for Patients subsection of the Precautions section in the US Package Insert for Permax has been updated to include the following (new wording underlined):

> Because pergolide mesylate may cause somnolence and the possibility of falling asleep during activities of daily living, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that pergolide mesylate therapy does not affect them adversely. Patients should be advised that if increased somnolence or new episodes of falling asleep during activities of daily living (e.g., watching television, passenger in a car, etc.) are experienced at any time during treatment, they should not

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

drive or participate in potentially dangerous activities until they have contacted their physician. Due to the possible additive sedative effects, caution should also be used when patients are taking other CNS depressants in combination with pergolide mesylate.

Our primary concern is the safety and well–being of patients who use Permax. If you become aware of any case(s) of the event described above in patients treated with Permax or other dopaminergic agents, please report the event promptly. You may contact Amarin Pharmaceuticals, Inc., our US licensee for Permax, regarding events associated with Permax at 1-800-969-4877, or you may contact the FDA MedWatch program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857.

If you have any additional questions regarding Permax, you may contact Amarin Pharmaceuticals, Inc. at 1-800-969-4877.

Sincerely,

Patrizia A. Cavazzoni, MD
Director, Global Product Safety – Neuroscience
Eli Lilly and Company

Permax is a registered trademark of Eli Lilly and Company, and is licensed exclusively in the United States to Amarin Pharmaceuticals, Inc. Please see accompanying Prescribing Information.

News Release
FOR IMMEDIATE RELEASE
October 30, 2003

56

The Myth of the "Chilling Effect"

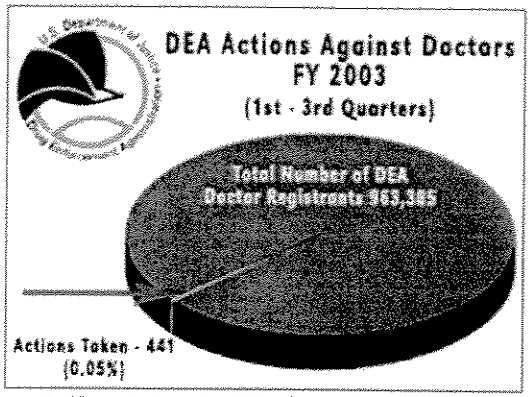
Doctors Operating Within Bounds of Accepted Medical Practice Have Nothing to Fear From DEA

Drug Enforcement Administration (DEA) statistics show that the vast majority of practitioners registered with DEA comply with the requirements of the Controlled Substances Act (CSA) and prescribe controlled substances in a responsible manner in treating their patients' medical needs.

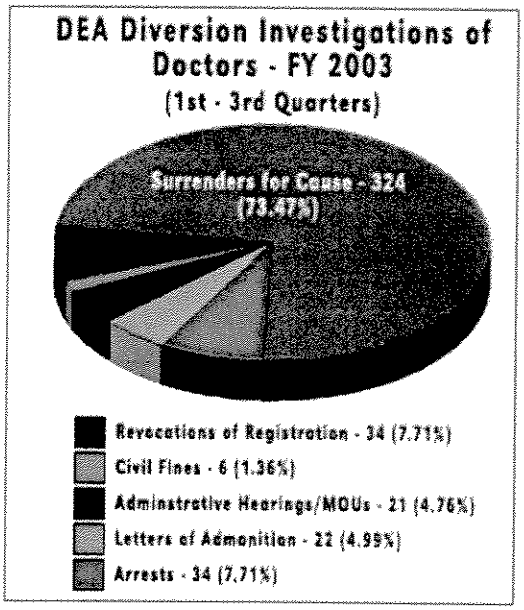
One of the the missions of the Drug Enforcement Administration (DEA), Diversion Control Program (DCP), is to prevent, detect and investigate the diversion of legitimately manufactured controlled substances. The Controlled Substances Act (CSA) requires doctors to become registered with DEA in order to prescribe, dispense or administer controlled drugs to their patients for legitimate medical reasons.

The DEA may initiate an investigation of a practitioner upon receipt of information of an alleged violation of the provisions of the CSA and may pursue sanctions against the practitioner based upon the facts determined from that investigation.

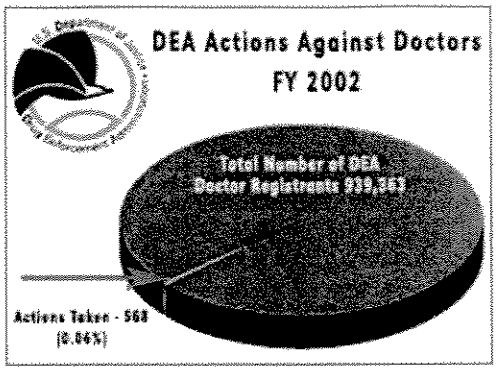
Since FY 1999 the DEA registrant population has continually increased reaching almost 1 million doctors (as of June 30, 2003). During this same time, DEA has pursued sanctions on less than one tenth of one percent of the registered doctors. The pie charts pictured put this in graphic perspective.

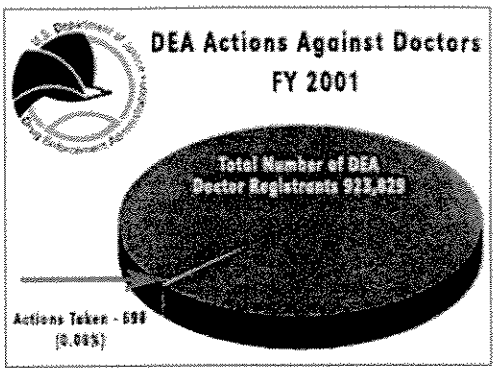


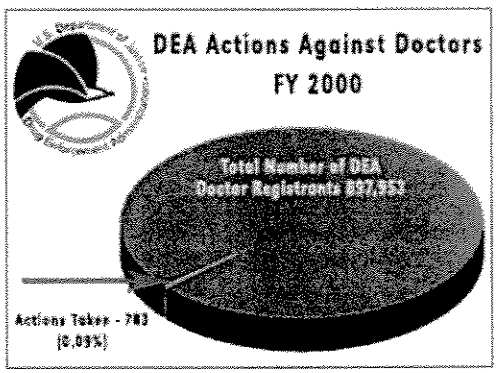
Actions taken by DEA include: letters of admonition, informal hearings, civil penalties, voluntary surrenders of registration for cause, revocations of registrations, and arrests.

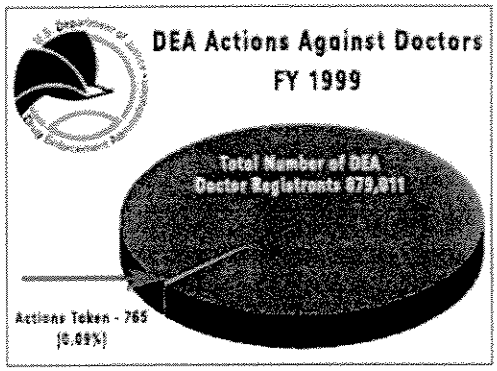


Total Number of Doctor Registrants	963,385	Percent of Doctor Registrants
Investigations of Doctors Initiated in FY 2003*	557	0.06%
Actions Taken Against Doctors in FY 2003*	441	0.05%
Arrests of Doctors in FY 2003*	34	0.01%
*partial year data		


DEA Actions Against Doctors
FY 2002
Total Number of DEA Doctor Registrants 939,363
Actions Taken - 568
(0.06%)


DEA Actions Against Doctors
FY 2001
Total Number of DEA Doctor Registrants 923,829
Actions Taken - 698
(0.08%)


DEA Actions Against Doctors
FY 2000
Total Number of DEA Doctor Registrants 897,953
Actions Taken - 783
(0.09%)


DEA Actions Against Doctors
FY 1999
Total Number of DEA Doctor Registrants 879,811
Actions Taken - 765
(0.09%)

57

58

United States Department of Health & Human Services

News Release

FOR IMMEDIATE RELEASE
Friday, Nov. 21, 2003

Contact: HHS Press Office
(202) 690-6343

21st Century Medicare: More Choices - Better Benefits

Prescription Drug Coverage for Medicare Beneficiaries

A recently developed bipartisan agreement will give all Medicare beneficiaries access to prescription drug coverage and the buying power to reduce the prices they pay for drugs. The proposal provides enhanced coverage for the lowest income beneficiaries and an immediate prescription drug discount card for all beneficiaries until the full plan is available nationwide. Additionally, the proposal includes savings for many state governments; increased coverage for preventive services; and provisions for modernizing the drug delivery infrastructure.

Medicare Drug Benefit

Beginning in 2006, Medicare beneficiaries will have access to the standard drug benefit described below. Although drug plan sponsors may change some of the specifications below, the benefit offered must at least be equal in value to the standard benefit. Standard coverage includes:

- A monthly premium of about $35
- A deductible of $250
- Coinsurance of 25 percent up to an initial coverage limit of $2250
- Protection against high out-of-pocket prescription drug costs, with copays of $2 for generics and preferred multiple source drugs and $5 for all other drugs, or 5 percent of the price, once an enrollee's out-of-pocket spending reaches a limit of $3,600

Those beneficiaries with limited savings and low incomes will receive a more generous benefit package, as described below:

Beneficiaries with limited savings and incomes below 135 percent of the federal poverty line ($12,123 for individuals, $16,362 for couples) will receive:

- A $0 deductible
- A $0 premium
- No gap in coverage
- Copays of $2 for generics and preferred multiple source drugs and $5 for all other drugs, up to the out-of-pocket limit [NOTE: For full dual eligibles under 100% of poverty, the copayment is reduced to $1 and $3 and for those full dual eligibles who are residents of nursing homes there is no copay.]

- $0 copay for all prescriptions once the out-of-pocket limit is reached.

Beneficiaries with limited savings and incomes below 150 percent of the federal poverty level ($13,470 for individuals; $18,180 for couples) will receive:

- A sliding scale monthly premium that would be about $35 for beneficiaries with incomes of 150 percent of the federal poverty level
- A $50 deductible
- No gap in coverage
- Coinsurance of 15 percent up to the out-of-pocket limit
- Copays of $2 or $5 once the out-of-pocket limit is reached

The Medicare-Endorsed Prescription Drug Discount Card

Medicare beneficiaries without drug coverage will be eligible for the Medicare-endorsed Prescription Drug Discount Card, which will begin operation six months after enactment and continue until the full benefit is implemented. The card program is estimated to save beneficiaries between 10 and 25 percent on most drugs. Those with incomes below 135 percent of poverty will be given immediate assistance through a Medicare-endorsed prescription drug discount card with $600 annually to apply toward purchasing their medicines.

Savings for State Governments and Employers

In addition to providing help to beneficiaries, the bipartisan agreement would help states by paying an increasing percentage of current state costs for prescription drugs for those who are enrolled in both the Medicare and Medicaid programs. The percentage increases from 10 percent initially to 25 percent in ten years. In 2002, states spent nearly $7 billion on prescription drugs for dual eligibles.[1] States would continue to share in the responsibility of providing this coverage to these low-income beneficiaries.

In addition, states already operating drug assistance programs for seniors who do not qualify for Medicaid-including Pennsylvania, New York, New Jersey, Connecticut and Massachusetts-could see their spending on drugs reduced by coordinating with the new Medicare drug benefit.

For employers that offer their Medicare-eligible retirees prescription drug coverage, the bipartisan agreement also provides a 28 percent subsidy for each enrollee's annual drug spending between $250 and $5000.

New Preventive Benefits

Beginning in 2005, all newly enrolled Medicare beneficiaries will be covered for an initial physical examination, and all beneficiaries will be covered for cardiovascular screening blood tests, and those at risk will be covered for a diabetes screen. These new benefits can be used to screen Medicare beneficiaries for many illnesses and conditions that, if caught early, can be treated, managed, and can result in far fewer serious health consequences.

Modernizing Drug Delivery Systems

The bipartisan agreement also calls for the use of electronic prescribing in the delivery systems that will bring prescription drugs to Medicare beneficiaries. Such systems should sharply reduce the substantial number of prescribing errors that occur each year, by helping to better identify and thus prevent potentially adverse drug interactions. In addition, such changes can foster further use of data-driven disease management programs.

[1]Dale, S.B. and J.M. Verdier. "State Medicaid Prescription Drug Expenditures for Medicare-Medicaid Dual Eligibles." Commonwealth Fund. April 2003.

60

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Note: All HHS press releases, fact sheets and other press materials are available at *http://www.hhs.gov/news*.

Last Revised: November 24, 2003