Bill as Introduced

HB 1218 - AS INTRODUCED
2001 SESSION

01-2257
10/09

HOUSE BILL ***1218***

AN ACT relative to the regulation of pharmacists and prescription drug orders.

SPONSORS: Rep. Millham, Belk 4

COMMITTEE: Executive Departments and Administration

ANALYSIS

This bill allows the board of pharmacy to authorize and regulate the temporary absence of pharmacists from the pharmacy, the use of centralized prescription processing, the electronic transmission of prescriptions, and the filling of prescriptions by automated pharmacy systems.

This bill was requested by the board of pharmacy.

Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

01-2257
10/09

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand One

AN ACT relative to the regulation of pharmacists and prescription drug orders.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 Pharmacy; Definitions; Prescription; Electronic Order Included. Amend RSA 318:1, XVI to read as follows:

XVI. "Prescription" means a verbal, or written, or facsimile or electronically transmitted order for drugs, medicines and devices by a licensed practitioner, to be compounded and dispensed by licensed pharmacists in a duly registered pharmacy, and to be kept on file for a period of 4 years. ***A written order shall include an electronic transmission prescription received and retained in a form complying with rules adopted pursuant to RSA 318:5-a, XV.*** Prescriptions may also apply to the finished products dispensed by the licensed pharmacist in the registered pharmacy, on order of a licensed practitioner as defined in this section.

2 Pharmacy; Definitions; Supervision. Amend RSA 318:1, XIX to read as follows:

XIX. "Supervision" means under the direct charge or direction and does not contemplate [~~any~~] absence of the person responsible for providing such supervision***, except where permitted by rules of the board under RSA 318:5-a, XIV.***

3 New Paragraphs; Definitions. Amend RSA 318:1 by inserting after paragraph XXI the following new paragraphs:

XXII. "Automated pharmacy system" means mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collects, controls, and maintains all transaction information.

XXIII. "Central prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

XXIV. "Electronic transmission prescription" means both image transmissions of a prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber, and data transmissions of a prescription order, other than an electronic image transmission prescription, that is electronically transmitted by computer link, modem, or other computer communication device from a licensed prescriber to a pharmacy.

4 New Paragraphs; Board of Pharmacy; Rulemaking Authority. Amend RSA 318:5-a by inserting after paragraph XI the following new paragraphs:

XII. Procedures for the use, documentation, security, maintenance, and monitoring of

automated pharmacy systems.

XIII. Standards for contracting, implementation, and operation of central prescription processing.

XIV. The adoption of protocols and procedures for the temporary absence of a pharmacist from a pharmacy while on duty.

XV. The requirements for the use of electronic transmission prescriptions, including the contents of such order and the verification of electronic signatures.

5 Prescription Labels. Amend RSA 318:47-a to read as follows:

318:47-a Prescription Labels. Whenever a pharmacist dispenses a noncontrolled drug pursuant to a prescription, he or she shall affix to the container in which such drug is dispensed a label showing at least the name and address of the pharmacy and the name or initials of the dispensing pharmacist or pharmacist-in-charge; the prescription identification number assigned by the pharmacy; the date dispensed; any directions as may be stated on the prescription; the name of the prescribing practitioner; the name of the patient; all pertinent auxiliary labels; and, unless otherwise indicated by the prescribing physician, dentist, veterinarian, or advanced registered nurse practitioner, the name, strength, and quantity of the drug dispensed. ***All drugs dispensed to a patient that have been filled using a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities.*** No person shall alter, deface, or remove any label so affixed.

6 Controlled Drug Act; Prescription Labels. Amend RSA 318-B:13, II to read as follows:

II. Whenever a pharmacist dispenses any controlled drug on prescription issued by a practitioner, he ***or she*** shall affix to the container in which such drug is dispensed a label showing the name, address, and registry number of the pharmacy and name or the initials of the pharmacist; the name of the prescribing practitioner; the prescription identification number; the name of the patient; the date dispensed; any directions as may be stated on the prescription; and the name and strength and quantity of the drug dispensed. ***All drugs dispensed to a patient that have been filled using a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities.*** No person shall alter, deface, or remove any label so affixed.

7 Effective Date. This act shall take effect 60 days after its passage.

Amendments

Rep. Dyer, Hills. 8
February 5, 2002
2002-2433h
10/09

NOT ADOPTED

Amendment to HB 1218

Amend RSA 318:5-a, XII as inserted by section 4 of the bill by replacing it with the following:

XII. Procedures for the use, documentation, security, maintenance, and monitoring of automated pharmacy systems as prescribed in RSA 318:47-d.

Amend the bill by inserting after section 6 the following and renumbering the original section 7 to read as 8:

7 New Section; Automated Pharmacy Systems. Amend RSA 318 by inserting after section 47-c the following new section:

318:47-d Automated Pharmacy Systems.

I. An automated pharmacy system may be located in any pharmacy registered with the board. If an automated pharmacy system is located in a pharmacy, the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the locations where the automated pharmacy system is being used.

II. Drugs shall be removed from the automated pharmacy system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated pharmacy system shall be provided to the patient by a licensed healthcare professional.

III. The stocking of an automated pharmacy system shall be performed by a pharmacist.

IV. Review of the drugs contained within, and the operation and maintenance of, the automated pharmacy system shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated pharmacy system, an inspection of the automated pharmacy system for cleanliness, and review of all transaction records in order to verify the security and accountability of the automated pharmacy system.

V. The automated pharmacy system used at the clinic shall provide for patient consultation with a pharmacist via a telecommunication link that has 2 way audio and video.

VI. Drugs dispensed from the automated pharmacy system shall comply with the labeling

requirements of RSA 318:47-a.

2002-2433h

AMENDED ANALYSIS

This bill allows the board of pharmacy to authorize and regulate the temporary absence of pharmacists from the pharmacy, the use of centralized prescription processing, the electronic transmission of prescriptions. The bill also regulates the filling of prescriptions by automated pharmacy systems.

Speakers

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill # HB 1218 Date Feb 5, 2002

Committee EDTA

**** Please Print All Information ****

Name	Address	Phone	Representing	(check one) Pro	Con
Tina Balkus	Lebanon NH	624-1286	Dartmouth-Hitchcock	✓	
FRANK G CASE	44 BEACH RD Nott.	895-2718	NH Board of Pharmacy	✓	
Elizabeth Rygalas	470 Atlantic Ave, Boston MA		NACDS	✓	
DAVID Minnis	NH PHARMACISTS	224-2236		✓	
TOM BUNNER	3 SOUTH ST CONCORD, NH 03301	228-2830	NH STATE PHARMACY ASSN	WITH AMENDMENT	
Norm DeWolfe	BROOKS PHARMACY			✓	
Margaret Hayes	166 Seamans Dr Manchester 03103		NH Board of Pharmacy	✓	

Hearing Minutes

HOUSE COMMITTEE ON EXECUTIVE DEPARTMENTS AND ADMINISTRATION

PUBLIC HEARING ON HB 1218

BILL TITLE: relative to the regulation of pharmacists and prescription drug orders.

DATE: February 5, 2002

LOB ROOM: 100 SH **Time Public Hearing Called to Order:** 10:20 AM

Time Adjourned: 11:33 AM

(please circle if present)

Committee Members: Reps. Peterson, Dyer, Langer, Goulet, Hamel, Zolla, Allan, Cummings, Dexter, C. Hall, Robertson, O'Neil, Lent, Landers, Andosca, Clayton, Pawlek, Schulze and Drabinowicz.

Bill Sponsors: Rep. Millham, Belk 4

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

Rep. Millham, sponsor. Spoke briefly about bill.
* Paul Boisseau, Exec. Sec. Board of Pharmacy, 271-2350. Supports bill. Spoke as outlined in attached memo. Purpose of bill is to facilitate franchising of prescriptions. Permit pharmacists to take meal breaks and be absent from department while on duty. Number of pharmacists take into consideration both clerks and pharmacists? Ratios have not been established.
*Elizabeth Pujolas, representing National Assoc. of Chain Drug Stores. 470 Atlantic Ave., 4th fl., Boston, 02210. 617-273-8118. Supports bill.
*Lovell Landon, 7 Sprague Rd., Amherst, NH. 673-1097. Works for Dartmouth Hitchcock. Supports bill. Amendment #2433h. Spoke about the advantages being offered patients with prescription both in time and the elimination of problems by the benefits of a central pharmacy. This man talks about a high tech system to be used in the future for preparing a system at one end and the label is produced at the receiving location and then completed in the pharmacy at the receiving location. 40 states authorize this type of telecommunications.
Davis Minnis, representing NH Pharmacists. 224-2236. Should be very careful about how the conditions of the amendment are interpreted. Waiting is not the pharmacy's fault – some in the insurance company's delay in accepting a charge.

Respectfully submitted,

Ray F. Langer

Rep. Ray Langer Clerk

Testimony

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

TESTIMONY BEFORE THE NEW HAMPSHIRE HOUSE EXECUTIVE DEPARTMENTS AND AMINISTRATION COMMITTEE

February 5, 2002

On behalf of the National Association of Chain Drug Stores (NACDS) representing the 174 New Hampshire retail pharmacies, employing more than 12,600 employees throughout the state we would like to offer our support of HB 1218 relating to the regulation of the practice of pharmacy.

We applaud the introduction of legislation addressing technological advances in pharmacy practice such as electronic transmission of prescriptions, centralized prescription processing, and automated pharmacy systems, as well as legislation addressing the pharmacy practice environment such as meal breaks. Such advances are critical to enhancing pharmacists' worklife and workload but also patient satisfaction and convenience.

For most Americans, the community pharmacy is their community health resource center, offering easy, convenient access to a trusted health professional. Indeed, pharmacists are among America's most trusted professionals who, working in alliance with other health care providers, play a pivotal role monitoring and maintaining patient health.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

Today, four out of every five patients who visit a doctor leave with a prescription. As medical science advances and doctors rely more and more on drug therapy, outpatient prescription drug use is now at an all-time high.

The number of prescriptions needing to be filled is increasing dramatically. Prescription volume is expected to increase by an astounding 44% . . . from 2.78 billion prescriptions in 1998 to about 4 billion per year by 2004. However, at the same time the projected increase in pharmacists will only be about 6%. As of January 2000, chain pharmacies had more than 6,900 vacancies in their pharmacy departments. Every state but two now suffers a pharmacist shortage.

According to NACDS 2001 data, about 70% of New Hampshire's prescription drug benefits were provided through third party payors and about 10% through Medicaid. We believe that these percentages are even higher now and will continue to climb as they have each year. In enabling legislation like HB 1218 that allows pharmacy to utilize such technological and worklife advances is fundamentally important to the practice of pharmacy.

The entire pharmacy industry is coming together in an effort to address these challenges and improve public understanding of community pharmacy's critical role in patient health care. In 1999, NACDS joined with the American Pharmaceutical Association (APhA) and the National Community Pharmacists Association (NCPA) in writing a white paper "Implementing Effective Change in Meeting the Demands of Community Pharmacy Practice in the United States". This white paper evaluated the challenges facing the

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

pharmacy industry (i.e., increasing prescription utilization, decreasing personnel, and increasing third-party payors) and proposed solutions to many of these challenges.

Specifically, HB 1218 promotes:

- ***Centralized Prescription Processing and Filling***

  The National Association of Boards of Pharmacy (NABP) has endorsed the concept of central prescription processing and adopted model regulations which allow for centralization of prescription filling, refilling, DUR, claims adjudication and therapeutic interventions. The NABP Task Force recognized that centralized prescription processing is a growing activity in pharmacy practice arising out of the increased prescription volume and shortage of pharmacists.

  The pressing need for pharmacists to be available for and involved with pharmaceutical care demands that the regulatory environment allow for technological advancements that increase efficiency and offer advantages over existing systems. Central processing allows many advantages and increased flexibility for pharmacies to outsource such functions as third party claims processing and prescription filling on an individualized basis as appropriate for that pharmacy.

- ***Electronic Transmission of Prescriptions***

Electronic transmission of prescription from a doctor's office to the pharmacy should be allowed for a number of sound public policy reasons.

- It is an efficient and safe method to transmit prescription to the pharmacy.
- It can reduce problems associated with translating handwriting and eliminates the need for phone calls of clarification.
- It can reduce the likelihood of prescriptions being lost between the doctor's office and the pharmacy.

- ***Temporary Absence of Pharmacists from the Pharmacy for Meal breaks***

We support allowing pharmacists to take a break while the pharmacy remains open during the pharmacist's temporary absence. Such rules are critical as one of the means to improve pharmacists' worklife and workload issues, to enhance patient satisfaction and convenience, and to address growing prescription volumes.

Increasingly, Boards of Pharmacy allow pharmacists to take breaks on the premises while allowing the pharmacy to remain open. These states include Alabama, California, Florida, Massachusetts, Mississippi, New Hampshire, New Jersey, North Carolina, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Wyoming. Boards of Pharmacy have recognized that allowing pharmacists to take breaks at their discretion while the pharmacy remains open enhances pharmacists' worklife, and allows the pharmacy to continue to provide appropriate and necessary pharmacy services.

NACDS supports HB 1218 in an effort by the Board of Pharmacy to assist pharmacy not only in today's operating environment, but also in preparation for the future of community pharmacy.

TESTIMONY
submitted by

THE NEW HAMPSHIRE STATE BOARD OF PHARMACY
regarding

HB 1218

"An act relative to the regulation of pharmacists and prescription drug orders."

before the
EXECUTIVE DEPARTMENTS AND ADMINISTRATION
COMMITTEE OF THE HOUSE

presented by

Paul G. Boisseau, R.Ph.
Executive Secretary for the Board of Pharmacy
on
February 5, 2002

HB 1218 is a request of the Board of Pharmacy and has four objectives:

1. To provide for the temporary absence of the pharmacist (from the prescription department) for rest/meal breaks according to Board established protocol;
2. Recognizes and establishes guidelines for centralized prescription filling;
3. It provides for the implementation of electronic prescribing technology to allow physician connectivity directly with the pharmacy provider for purposes of transmitting prescription information;
4. It recognizes, defines and provides for the implementation of certain automated pharmacy systems.

I will explain all of these in greater detail in a few minutes but first, the Board believes that applied separately or collectively, the areas addressed by this bill will provide for greater patient safety by significantly reducing errors in the dispensing function of the practice of pharmacy.

As a bit of background:

- 55,000 community pharmacies in U.S.
  218 community pharmacies in NH

- 200,000 active pharmacists in U.S.
  1,000 practicing pharmacists in NH
- 2.8 billion prescriptions dispensed in the U.S. in 2000
  3.15 billion prescriptions dispensed in the U.S. in 2001
  4+ billion prescriptions per year in the U.S. by 2005
- 100-125 prescriptions/day per pharmacist (on average, 22,900 prescriptions/year per pharmacist)
- The average over-65 year old patient gets about 20 prescriptions (new and refills) per year compared to about 3 for a person in his/her 20's.

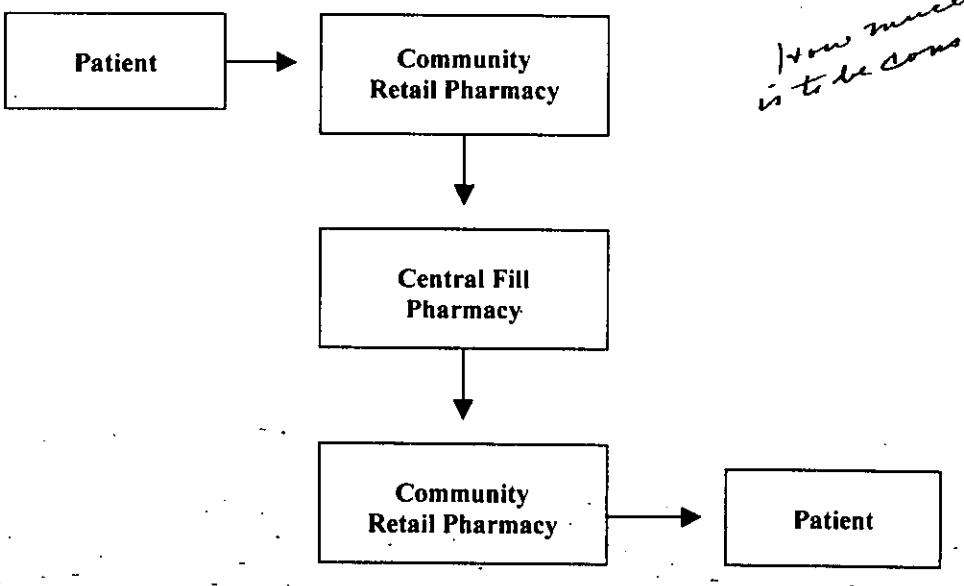
Turning to HB 1218:

- **Page 1, line 11 "Supervision"** is amended to provide for the temporary absence of a pharmacist from the pharmacy department while he/she is on duty. This would allow the Board, under rulemaking, to formally adopt protocols and procedures which will allow a pharmacist to take up to a 30-minute meal/rest break during any work shift that is 8-hours or longer.

  Although the Board encourages this respite it is totally voluntary and at the discretion of the pharmacist. The protocol also requires that the pharmacist remains on the premises and available to quickly return to the prescription department in the event of an emergency as may be defined by a patient's immediate need.

  This type of protocol is now in effect in many states and is welcomed by pharmacists. The Board is convinced that this short break, especially in a busy pharmacy, helps to relieve stress and contributes to patient safety.

- **Page 1, line 19 "Central prescription processing".**



How much time is to be considered

As in the illustration, the patient drops off/calls in a refill prescription order to his/her local community pharmacy. The pharmacy justifies the refill and transmits the refill information and request to another licensed location (known as the central fill pharmacy) which fills the prescription and returns it to the original community pharmacy where it is picked up or delivered by/to the patient.

Since the process requires several hours (perhaps even overnight) it works best for refills of maintenance drugs (medication taken over time to control asthma, diabetes, blood pressure, depression, arthritis, cholesterol or any number of other chronic conditions). Of note, 48% of all prescriptions filled are for maintenance medication. note

However, new prescriptions or refills needing immediate attention would continue to be filled at the pharmacy in the customary fashion. Although no controlled substances are allowed to be processed using the central fill concept, DEA is currently in the process of amending its regulations to allow this practice.

Again turning to statistics, between 1999 and 2004, the volume of prescriptions dispensed in retail pharmacies is expected to increase at least 35% while during the same period the number of available pharmacists is projected to increase by only 6%. Obviously; we need to increase efficiencies while at the same time maintaining quality patient care.

- **Page 1, line 23 "Electronic transmission prescription".** Here, the Board intends to clarify, recognize and facilitate the use of electronic transmission technology to reduce the amount of medication errors.

  First the bill differentiates between a facsimile (faxed) prescription order and one that is electronically transmitted by the prescriber to a pharmacy using a computer link or modem. And, secondly, the bill would enable the Board to develop rules that would assure the integrity of the transmitted prescription data.

  According to the U.S. Department of Health and Human Services, drug errors resulting from mis-prescribing and the administration of drugs injure or kill 50,000 to 100,000 patients a year – the majority of which are due to adverse drug reactions. However, prescription medication errors alone contributed to some 7,000 deaths in Y2000.

  Electronic prescriptions accomplish several things. First they reduce the amount of handwritten prescriptions which, too often, are difficult to read and are a major source of dispensing errors, especially today with the wide variety of drugs – many with sound-alike names. For example, an FDA safety alert recently issued, advises

pharmacists to be especially cautious when filling handwritten prescriptions for either SEROQUEL® (used for the treatment of schizophrenia) or SERZONE® (used in the treatment of depression). Because both names look alike, especially when handwritten, FDA reports that 23 medication errors have been reported as of November 2001. Of those events, four patients required emergency room visits, three were hospitalized and one died.

There are over 750 confusingly similar drug names (both brand and generic names). Confusion in drug names and poor handwriting account for 15% of medication dispensing errors.

Facilitating and encouraging the use of electronically generated prescription information will eliminate a good number of dispensing errors caused by handwritten prescriptions.

Secondly, using electronic pathways to obtain prescription refill authorizations will save telephone time (and frustration) for not only the pharmacist and prescriber but for the patient as well.

- **Page 1, line 16 "Automated pharmacy system".** This new definition formally recognizes mechanical systems that assist in the dispensing of prescription drugs. The use of robotic technology has been shown to significantly enhance the efficiency and accuracy of prescription processing and distribution. Properly designed and supervised, automation is yet another tool that can be effectively used to reduce medication errors.

  Automated pharmacy systems can be utilized in licensed pharmacies, remote areas of a licensed location (such as in the ER or OR), in clinics and perhaps even adapted for health care facilities (such as a nursing home for emergency drugs).

  HB 1218 attempts to recognize and facilitate the use of technologies to improve pharmacy operations and ultimately to provide better patient care and safety by minimizing medication errors.

State of New Hampshire

HOUSE OF REPRESENTATIVES

CONCORD

January 1, 2003

The Honorable Craig Benson
Governor of New Hampshire
State House, Room 208
Concord, NH 03301

The Honorable Thomas Eaton
President of the Senate
State House, Room 302
Concord, NH 03301

The Honorable Gene Chandler
Speaker of the House
State House, Room 308
Concord, NH 03301

Dear Governor Benson, Senate President Eaton and Speaker Chandler:

Re: HB 1218, Chapter 281, Laws of 2002 Relative to the regulation of pharmacists and prescription drug orders, relative to the use of non-original containers to organize prescription and nonprescription drugs, and relative to the management of certain plan benefits under Medicaid by the department of health and human services.

Pursuant to HB 1218, Chapter 281, Laws of 2002, enclosed please find the annual report of the oversight committee. Should you have any question or comments regarding the report, please do not hesitate to contact me.

Sincerely,

Representative Janeen Dalrymple
Chair

Enclosures
cc: Steve Winter, Senate Clerk
Karen O. Wadsworth, Clerk of the House
Michael York, State Librarian

Committee Members:
Senator Sylvia Larsen, Vice-Chair
Senator Russell Prescott
Senator Theodore Gatsas
Representative Rogers Johnson
Representative Judson Dexter

ANNUAL REPORT

relative to the regulation of pharmacists and prescription drug orders, relative to the use of non-original containers to organize prescription and nonprescription drugs, and relative to the management of certain plan benefits under Medicaid by the department of health and human services.

HB 1218 (Chapter 281 of 2002)

January 1, 2003

HB 1218 (Chapter 281 of 2002), Established a legislative oversight committee consisting of three members of the House of Representatives and three members of the Senate. The committee is charged with reviewing the Commissioner of Health and Human Services annual report to the legislative oversight commission. This report shall include:

- The cost savings to the state realized during the current budget biennium from the institution of a prior authorization program;

- Any unintended costs in other Medicaid healthcare services programs, including long-term care admissions, hospital admissions, emergency room visits, and physician visits during the current budget biennium from the institution of a prior authorization program;

- A report on the volume of prior authorizations as a percentage of total claims, average call waiting time, and other issues that the state's pharmacy benefits administrator is required to comply with under the terms of the pharmacy benefits management contract;

- A report of the effectiveness of the department of health and human services' pharmacy lock-in program; and

- Recommendations for other opportunities to improve the management of pharmacy services or to expand pharmacy benefits to additional populations.

- A report of actions taken by the pharmacy and therapeutics committee since the last meeting of the oversight committee, including a list of any medications made subject

to prior authorization, the criteria for approving such prior authorization, and minutes of the pharmacy and therapeutics committee meetings.

REVIEW:

August 13, 2002

Lori Real of the Department of Health and Human Services (H/HS) gave a brief overview of the legislation and requirements regarding the purpose of the committee. The discussion next focused on the Pharmaceutical and Therapeutics Advisory Committee (PTAC) scheduled to meet on August 27th. A decision was made that the legislative oversight committee should meet after each PTAC meeting. The committee also discussed the offer of Representative Johnson's participation in the auditing of PBM (FirstHealth).

September 19, 2002

Discussion was held regarding the Co-Chairmanship decision from the first meeting and the final vote was Representative Dalrymple, Chairman and Senator Larsen, Vice-Chairman.

Lori Real of H/HS introduced Roland Lamy and Dr. William Kassler of H/HS. Mr. Lamy discussed cost inequities with drug company expenditures which are as high as four times the amount in revenues for marketing, advertising and compensation than they spend in and research and development (R&D) of new drugs. He also stated that H/HS has saved the state money since the program began.

Rep. Johnson inquired about the source of the data and found that the material came from a Families USA report entitled Profiting from Pain: Where Prescription Drug Dollars Go. Rep. Johnson was concerned that the data may be biased.

Dr. Kassler presented a general overview of the PTAC committee meetings but was not able to respond to specifics because he did not have time to review the PTAC minutes.

The committee raised concerns about the prior authorization process established by FirstHealth, the prescription drug management firm. Dr. Kassler stated that there would be changed made to this based on the PTAC recommendations.

November 13, 2002

Lisa Swanson, a new employee of H/HS presented how the department arrived at the cost estimates for the program. These savings were based upon the EDS contract changes from November 2001 as well as the establishment of of the program in 2001. H/HS could not identify the specific savings attributable to the FirstHealth contract. The department primary focus is on the effect of the program on prescription drug in the Medicaid population. The following are drug trends:

- 2000 - 25%
- 2001 - 19%
- 2002 - 9%

The department stated that they reviewed all prior authorizations and identified those that had subsequent issues based upon health interactions. They found that there were no adverse effects prior to authorization and that prior authorization only accounted for.3% of all drugs in the program.

The department also mentioned that FirstHealth had reported that they had met all performance goals to date. This information has not been confirmed through an audit process.

H/HS at this time was still engaged in the rulemaking process regarding:

- Compete the PBM Rule making
- Implement auditing, effective January 1, 2003
- Implement clinical detailing
- Implement disease state management for Asthma
- Implement pharmacy lock-in

Findings

The committee met following each PTAC meeting to review their work. The committee raised concerns about the following:

- The legislative oversight committee should conduct a financial audit to track the funding and find where the money goes.

- Rebates to the Department of Health and Human Services should go to the Department of Revenue Administration and then back to H/HS through a transfer.

- A quarterly basis report (by PTAC) should be instituted to ensure that the system is functioning and that the money is not following a broken program to recommend continuation.

- PTAC should be forthcoming with leadership and come forward with answers regarding questions.

- Identify the net positive gains

ATTACHMENT LISTING

Attachment A:	August 13, 2002 Meeting Minutes and Attachments Appointed list of PTAC members Summary of Public Comments (PTAC meeting 8/26/03) Notice of NH Pharmacy and Therapeutics Committee Hearing Managing Risks Costs - September 2002 Proposed Criteria recommendations - 8/27/03
Attachment B:	September 19, 2002 MeetingMinutes and Attachments
Attachment C	November 13, 2002 Meeting Minutes and Attachments Medicaid Pharmacy Benefit Management SFY 02 Annual Report

COMMITTEES MEETING TIMELINE

PTAC	Oversight
August 27	September 17
October	November
December	January
February	March
April	May
June	

* Pharmaceutical and Therapeutics Advisory Committee (PTAC)

ATTACHMENT A

8.13.02 MIN

Minutes of the Meeting
HB 1218
Legislative Oversight of the Medicaid
Prescription Drug Benefits Management Program
August 13, 2002

10:00- Meeting called to order by Rep. Dalrymple. Only Reps. Dalrymple and Johnson present, hence no quorum and no official votes can take place.

Reps. Dalymple and Johnson named co-chair of the committee, again unofficial as no quorum present.

Discussion as to the purpose of the committee.

Lori Real of DHHS gave a brief overview of the bill and our obligation to it, including the report to be submitted.

Sen. Larsen arrived at 10:30.

Discussion turned to the Pharmaceutical and Therapeutics Advisory Committee (PTAC), which is due to meet on August 27 at DHHS. A public hearing is scheduled for the previous day. It was decided that this committee should meet after the PTAC committee meeting in Sept., Nov., Jan., March, and May.

Additional discussion on when or if the PBM (FirstHealth) can and should be audited by the committee. It was noted that it was in our preview to conduct such audits. Rep.Johnson suggested that he participate in the audit as he is specifically trained to conduct them. Sen. Larsen objected, stating that she thought it would be a conflict of interest. Rep. Johnson replied that this was not so as he would work on behalf of the State with no personal recompense to him or any other charge. Lori Real stated that Rep. Johnson would have to sign a confidentiality statement. Rep. Johnson responded that it would not be a problem, as he has signed them routinely as part of his normal work activities.

There being no other business to come before the committee, the meeting ajourned at 11:25.

Respectfully submitted by Rep. Johnson.

State of New Hampshire

HOUSE OF REPRESENTATIVES

CONCORD

MEMORANDUM

DATE: August 22, 2002

TO: **Members of the Study Committee on HB 1218 (Chapter 281:9, Laws of 2002), relative to the regulation of pharmacists and prescription drug orders, relative to the use of non-original containers to organize prescription and nonprescription drugs, and relative to the management of certain plan benefits under Medicaid by the Department of Health and Human Services:**

Rep. Rogers Johnson	Sen. Sylvia Larsen
Rep. Judson Dexter	Sen. Russell Prescott
	Sen. Theodore Gatsas

FROM: **Rep. Janeen Dalrymple, Co-Chair** (603) 898-4527
Rep. Rogers Johnson, Co-Chair (603) 778-8666

SUBJECT: **Next Meeting**

Please mark your calendars and plan to attend the next meeting of the study committee, scheduled for:

Thursday, September 19 at
10:00 a.m. in LOB Room 205

Also please note that there will be a Public Hearing held on Monday, August 26, from 10:00 a.m. to 12:00 noon at the Department of Health and Human Services PTAC Auditorium at 6 Hazen Drive in Concord regarding the Pharmacy Therapeutic Advisory Committee report.

JD:co

Attachment: Minutes of Meeting held August 13

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

129 PLEASANT STREET, CONCORD, NH 03301-3857
603-271-5254/5256 TDD Access: 1-800-735-2964

Kathleen G. Sgambati
Acting Commissioner

Lori H. Real
Director

September 13, 2002

The Honorable Janeen Dalrymple
7 Penobscott Avenue
Salem, NH 03079

Dear Representative Dalrymple:

As requested, the purpose of this letter is to provide meeting materials in preparation for the September 19th meeting of the Legislative Oversight Committee on Prescription Benefit Management (PBM). This package contains the following information:

- PBM overview – a presentation outlining: 1) purpose of the Legislative Oversight Committee, 2) why pharmaceutical costs are rising, 3) how the Department of Health and Human Services is managing rising pharmaceutical costs.
- A summary of the Public Hearing held on August 26, 2002.
- Pharmacy and Therapeutics Advisory Committee (PTAC) – this information contains the agenda and criteria provided to the members of the Pharmacy and Therapeutics Advisory Committee for review prior to their meeting on August 27, 2002. A listing of the PTAC members is also enclosed.
- The minutes of the Pharmacy and Therapeutics Advisory Committee meeting on August 27, 2002 are being finalized and will be distributed to you at the meeting.

If you have any questions regarding the contents of this package please feel free to contact me at your convenience at 271-3676. The Department looks forward to meeting with you on September 19th to review this information.

Sincerely,

Lori H. Real, M.H.A.
Director

Enclosures
cc: Senator Sylvia Larsen
Senator Theodore Gatsas
Senator Russell Prescott
Representative Rogers Johnson
Representative Judson Dexter

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

6 HAZEN DRIVE, CONCORD, NH 03301-6527
603-271-4796 800-852-3345, Ext. 8946 TDD Access: 1-800-735-2964

Kathleen G. Sgambati
Acting Commissioner

Lori H. Real
Director

NEW HAMPSHIRE PHARMACY & THERAPEUTICS ADVISORY COMMITTEE
New Hampshire Department of Health and Human Services

APPOINTED LIST OF MEMBERS
August 2002

Commissioner Appointments

William Kassler, MD, MPH
Department of Health & Human Services
State Medical Director
6 Hazen Drive
Concord, New Hampshire 03301

Stephen Bartels, MD
Medical Director
Dartmouth Psychiatric Research Center
105 Pleasant Street
Concord, New Hampshire 03301

Doris Lotz, MD
Medicaid Medical Director
Office of Health Planning and Medicaid
129 Pleasant Street
Concord, New Hampshire 03301

Robert Lenza, R.Ph.
Pharmacy Director
Anthem Blue Cross and Blue Shield
3000 Goffs Falls Road
Manchester, New Hampshire 03111

Lenny Parker, R.Ph.
Executive Director
Unicare Health Services, Inc.
23 Parameter Road
Londonderry, New Hampshire 03053

Margaret Clifford, R.Ph.
Office of Health Planning & Medicaid
Medicaid Administrative Services
6 Hazen Drive
Concord, New Hampshire 03301

NH Medical Society Nominees Appointed by the Commissioner

Richard Lafleur, MD — Internal Medicine
Southern NH Internal Medicine Associates
44 Birch Street, Suite 300
Derry, New Hampshire 03038

Steven Paris, MD — Pediatrics
Dartmouth Hitchcock Medical Center
100 Hitchcock Way
Manchester, New Hampshire 03104

Eric Pollak, MD, MPH — Family Practice
Concord Family Medicine
141 East Side Drive
Concord, New Hampshire 03301

Bryan King, MD — Psychiatry
Department of Child & Adolescent Psychiatry
Dartmouth Hitchcock Medical Center
One Medical Center Drive
Hanover, New Hampshire 03855

NH Pharmacy Association Nominees Appointed by the Commissioner

Roger Hebert, R.Ph.
Rice's Pharmacy
59 Main Street
Nashua, New Hampshire 03060

Paul Santos, Pharm. D. — Pharm. D.
Lakes Region General Hospital
80 Highland Street
Laconia, New Hampshire 03246

SUMMARY OF PUBLIC COMMENTS

PTAC PUBLIC HEARING, AUGUST 26, 2002

Purpose of Hearing: To solicit public comment regarding prior authorization criteria and drugs and classes of drugs subject to prior authorization

Testimony was presented by 17 individuals, including: Ann Blair, NH Hospice & Palliative Care Organization; Dr. Joe Miller, SCOA; Cherylnn Griffin, Purdue Pharma; Shannon Benedetto, PharmD, Pfizer; David Anderson, Astra-Zeneca; Tina Cowgill, Astra-Zeneca; Mary Kaysen, Purdue Pharma; Paul Arnstein, RN, PhD, Family Nurse Practitioner; Client (name protected for confidentiality purposes); Anne Marie Durant, nurse and citizen; Cinde Warmington, Atty, Shaheen & Gordon, representing Purdue; Valerie Acres, Sheehan Phinney Capitol Group; Dr. Sedan Savage, NH Medical Society; Rep Rogers Johnson, PBM Legislative Oversight Committee; Nancy Galli, concerned citizen; Robert Howes, long term care pharmacist, Neighbor Care; Judith Griffin, long term care ombudsman.

PTAC Members Present: Dr. Doris Lotz, Dr. Bryan King, Peg Clifford, R.Ph., Paul Santos, PharmD, Dr. William Kassler, Lenny Parker, R.Ph., Robert Lenza, R.Ph.

General Prior Authorization Comments:

- One drug company testified that PA limits access, imposes a clerical burden, and adds cost.
- Dr. Miller noted that there is a real financial problem in this country, people are underinsured, uninsured, etc. It was suggested that, rather than fighting for coverage of drugs, that the drug companies show some benevolence to the needy.
- A concerned citizen expressed her opinion that illegal aliens get better treatment than we do.
- The long-term care ombudsman stated that PA places a bureaucratic red tape burden on physicians; such further barriers may drive more physicians away from participating.
- PA program creates a two-tiered system with the neediest being denied care.

Specialists
Long-term care

General Process Comments:

- Committee was encouraged to hear comments directly and give adequate time to hear/review written testimony.
- A letter was sent by Sheehan Phinney and entered into the record suggesting that the hearing be held in conjunction with the PTAC meeting so all can directly hear the testimony.
- Dr. Miller suggested, with all the emphasis on pain management, that an anesthesiologist with great experience in pain be added to the PTAC committee.
- Member of legislative oversight committee expressed disappointment that hearing was Monday with PTAC being the next day. He would have expected a 2 week time period between the two meetings. He hopes that ALL the information will be available to the PTAC and to the Legislative Committee.
- Dr. Miller noted that when he was practicing, he always gave the drug rep "detail men" an audience, but when it came to considering the appropriate medications for his patients, he always went to the peer review journals. He noted that PTAC is made up of very well qualified medical professionals in whom he has a lot of faith.

NH Medical Society Task Force on Pain Comments:

- Dr. Sedan Savage testified that this group has reactivated their task force. Data gathering is ongoing. Report completion is expected for October, 2002. They welcome input.

Client Experience:

- Testimony was provided by a client, age 53, insulin dependent, with diabetic neuropathy. She noted that the doctors fought for her oxycontin. If she is in pain, she can't sleep, can't eat, etc. If she can't eat, she can't take her insulin. She has tried other meds. She experiences great anxiety over the wait for approval, which has happened several times over the past nine months.

Oxycontin Related Comments:

- Multiple comments were presented by drug companies and patient advocates regarding pain being an individual factor, people respond differently to pain and to different opiods in differing ways.
- Limiting access to certain opiod meds lowers the quality of life and may reduce life expectancy; also promotes the expansion of health disparities.
- An exception was requested by NH Hospice and Palliative Care for life threatening illness.
- Above organization also requested that PTAC reconsider the oxycontin exception of "hospice" to be reworded to "palliative care," as there is no hospice benefit in NH Medicaid.
- It was suggested by some drug companies and by a family nurse practitioner at Dartmouth-Hitchcock Clinic that oxycontin should be tied to level of pain—not disease state. Recommend using the criteria of pain.

- Recommend by drug company that there be more education of physicians and young people.
- Recommend by drug company that PA be required only if dosing interval is more frequently than every 12 hours or daily dose is greater than 320 mg.
- Nurse practitioner requested we please distinguish between the medical and criminal issues at hand. Overturn policy that excuses pharmacies and payors from their obligation to facilitate access to all drugs that are necessary to meet the medical needs of the communities that they serve.
- Nurse practitioner posed the question of "why is it OK to treat cancer pain, but not other pain?" All deserve humane, compassionate care. Criteria should not be diagnosis based.
- Criteria of "failure on 3 other narcotics" received several comments from drug companies, practitioners, and client. There was noted the concern about proper patient care; it is clinically inappropriate to switch and then return to one that works. Cycling on and off is not appropriate for constant pain. Alternatives such as the fentanyl patch and methadone, may remain in system when switching and/or may accumulate in system w/ resultant side effects. Alternatives such as morphine may not be appropriate for renal impaired, diabetics, elderly, etc. Should not have to endure multiple treatment failures.

Cox II Inhibitor Related Comments:

- Recommend by drug company that concomitant oral corticosteroid factor should be a 2 point value to be consistent with private health plans.
- Recommend by drug company the addition of Bextra to cox II inhibitors requiring PA and updating the PA request form as there are now 3 Cox II's on the market.
- Recommend by long term care pharmacist continuing with current elderly exemption.
- Recommend by drug company adding cardiovascular disease to the criteria.

Viagra Related Comments:

- A cost model was presented by a drug company with the conclusion drawn that PA'ing Viagra may cost more in administrative costs ($15/prescription) than is saved. It was also stated that standard practice is to re-evaluate the need to PA if the approval rate is greater than 90-95%.
- If PTAC continues with the PA requirement, above drug company suggests that SSRI (selective serotonin reuptake inhibitor) induced sexual dysfunction be added to the list of approved criteria [disease states]. (would result in improved compliance and reduction in relapse of depression)

Proton Pump Inhibitor Comments:

- Prior authorization was opposed.
- If continue with PA, drug company states that process and criteria should be applied equally and consistently across all PPI's. Commend the Department for such.
- Recommend by one drug company that gastroenterologists be exempt from having to request PA's. At the point at which a patient is under gastroenterology care, appropriate diagnoses, testing, and alternative therapies have likely occurred.
- Recommended by above drug company that PTAC solicit input on PA criteria by specialists.
- Above drug company also disagrees with new 8 week lifetime therapy limit before PA is required. It should remain at 12 weeks. Twelve weeks is consistent with package insert, limit is lifetime, conditions are often chronic with relapse common.

NOTICE OF NEW HAMPSHIRE PHARMACY AND THERAPEUTICS COMMITTEE PUBLIC HEARING AUGUST 26, 2002

The New Hampshire Pharmacy and Therapeutics Committee invites you to attend a public hearing on August 26, 2002 at 10 a.m. until 12 noon in the auditorium of the Health and Human Services Building, 6 Hazen Drive, Concord, New Hampshire. The purpose of the hearing is to solicit information and provide an opportunity for the public to present its views for the Committee regarding the following agenda for the New Hampshire Pharmacy and Therapeutic Committee meeting on August 27, 2002:

AGENDA FOR PHARMACY AND THERAPEUTICS COMMITTEE MEETING AUGUST 27, 2002

1. Introductions and welcome to Committee members.
2. Review of the prior authorization criteria for the following drugs and classes of drugs:

Therapeutic Class	Products Requiring Prior Authorization
Gastrointestinal Medications	• All brand name products that have an approved generic equivalent such as **Zantac®, Tagamet® and Pepcid®** • All Proton Pump Inhibitors such as **Prilosec®, Nexium®, Aciphex®, Protonix® and Prevacid®** will be allowed for **twelve (12)** weeks within a lifetime before a prior authorization is required
Controlled Substances	• All brand name products that have an approved generic equivalent such as Percocet®, Darvocet®, Tylenol® #3, Fiorinal®, MS Contin®, Vicodin®, Demerol® • All **Oxycontin®** products
Arthritis Medication/Non-Steroidal Anti-Inflammatory (NSAIDs):	• All brand name products that have an approved generic equivalent such as **Motrin®, Naprosyn®, Ansaid®, Anaprox®, Relafen®, Daypro®** • All Cyclooxygenase II (COX II) Inhibitors such as **Celebrex® and Vioxx®** for patients under the age of 60; patients 60 years or older will not need prior authorization
Erectile Dysfunction Treatment Medications:	• All drugs for erectile dysfunction treatment require a prior authorization
Anti-obesity Medications:	• All anti-obesity medications require a prior authorization

3. Discussion of prescription quantity limits.
4. Adjourn.

If you need further information concerning this public hearing, please contact Janice C. Paterson, Esq., Office of Health Planning and Medicaid, Legal Services Unit, at 1-800-852-3345, ext. 8946 (in state only) or (603) 271-8946.

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

6 HAZEN DRIVE, CONCORD, NH 03301-6527
603-271-4796 800-852-3345, Ext. 8946 TDD Access: 1-800-735-2964

Kathleen G. Sgambati
Acting Commissioner

Lori H. Real
Director

September 16, 2002

The Honorable Rogers Johnson
PO Box 565
Stratham, NH 03885

Dear Representative Johnson:

This letter is in response to your offer of assistance at the organizational meeting of the Pharmacy Benefit Management Legislative Oversight Committee (Committee) held on August 13, 2002. During that meeting, you expressed an interest in personally conducting a claims audit of the Department of Health and Human Services (Department) pharmacy claims to determine any unintended consequences of the prior authorization requirements. You stated that your professional qualifications include conducting pharmacy claims auditing, and that you would be willing to conduct such an audit for no charge. You expressed that, in your opinion, your current professional affiliation would not present a problem with your undertaking a review of the pharmacy benefit management claims.

While your offer of assistance is appreciated, the Department is unable to accept that offer. The Department has significant concerns regarding an actual or potential conflict with your public duties that might exist, should you personally undertake such an audit. The Department also notes that the law that created the Committee also expressly authorizes the Legislative Budget Assistant to undertake an audit if one is requested by the Committee. To explain further, were you to undertake to conduct such an audit your function would be that of consultant to the legislature and the Department. The work might require that you provide recommendations and conclusions to the legislative body. It is our belief that this role inherently conflicts with your role as a member of the legislative oversight committee. As a member of the Committee you must monitor, review and oversee the Medicaid prescription drug benefit management program administered by the Department, not provide an auditing or consulting function. In our view, the dual role that you have proposed would not be in accordance with the legislative intent. Moreover, the Department would not be comfortable in the position of dealing with you as both a consultant to the Department and a legislator exercising oversight of Departmental activities.

The Department acknowledges the obligations and requirements of Chapter 281, Laws of 2002, particularly the reporting requirements outlined in paragraph 281:9 IV, and assures that it will provide the Committee with a report, on November 1, 2002, that contains the elements of cost savings, unintended costs in other Medicaid healthcare services programs, volume of prior authorizations as a percentage of total claims, average call waiting time, and other issues that the pharmacy benefit administrator is required to comply with under the terms of the contract.

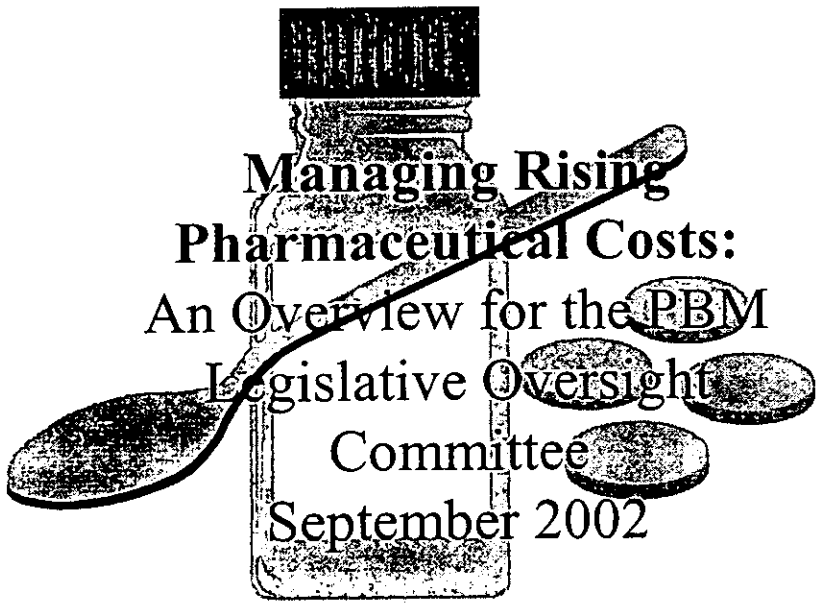
Again, thank you for your offer of assistance to provide a personal audit of the pharmacy claims. If you have any questions concerning this information, please contact me at (603) 271-8946.

Sincerely,

Janice C. Paterson

Janice Paterson, Esq.

cc: Lori H. Real



Managing Rising Pharmaceutical Costs:

An Overview for the PBM Legislative Oversight Committee

September 2002

Purpose

- Review Purpose of Legislative Oversight Committee;
- Review Why Pharmaceutical Costs are Rising?
- Review How the Department of Health and Human Services is Managing Rising Pharmaceutical Costs.

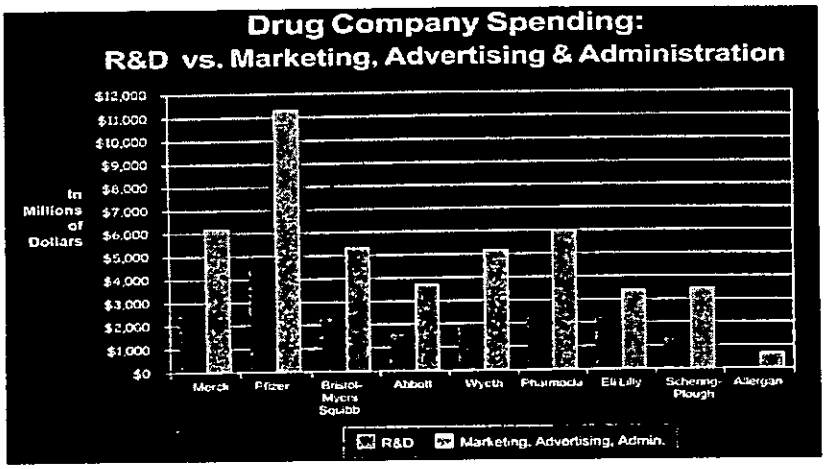
Pharmacy Benefit Management Legislative Oversight Committee

1. Review Department of Health and Human Services Annual Report (due November 1st);
2. Review report of actions taken by the Pharmacy and Therapeutics Advisory Committee;
3. May request assistance of legislative budget assistant in auditing the program; and
4. May make recommendations for proposed legislation, report findings and make recommendations to the speaker, president, governor and JLCAR by January 1 each year.

Why are pharmaceutical costs rising?

Drug Company Marketing & Advertising

Source: Families USA

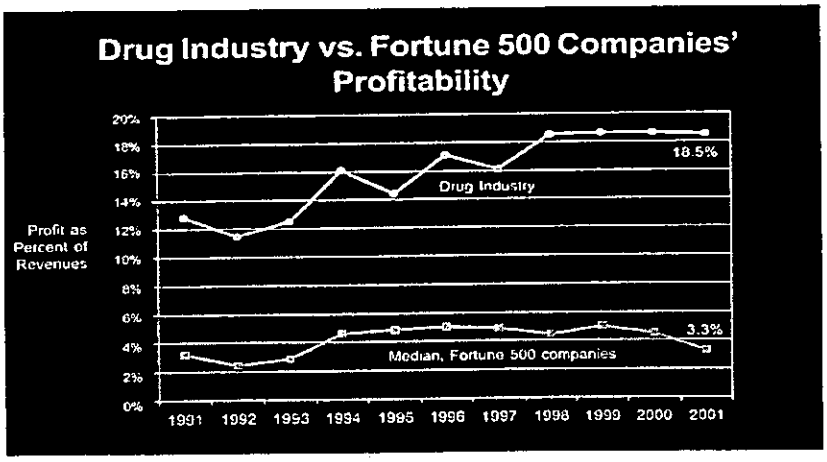


R+D
- ? percentage

- Advertising -

Drug Industry Profits

Source: Families USA



Profits -

18.5% profits

Fortune 500 3.3%

Prescription Drugs have become the primary driver of medical care costs

- Availability of home infusions (IV drug) therapy has decreased hospitalizations
- Direct to consumer advertising
- Newer drugs to market are capable of doing more than ever before, often replacing surgery or other invasive treatments

How is the Department of Health and Human Services (DHHS) managing rising pharmaceutical costs?

Pharmacy Benefit Management
Components Implemented

- Prior Authorization - for medications that require prior authorization, recipients must meet approved criteria before a drug will be authorized.
- Prospective Drug Utilization Review Edits - Such as Early Refill, Therapeutic Duplication, Drug to Drug Interaction
- Maximum Allowable Cost Pricing for multi-source products. Adjustment to average wholesale price (AWP) to reflect true cost of the drug
- Third Party Liability Cost Avoidance –Medicaid is the payer of last resort

1ST Health Services — who are they what do we pay for — Administrat

Pharmacy and Therapeutics Advisory Committee (PTAC) Responsibilities

- Advise DHHS on:
  - Medications subject to prior authorization;
  - Criteria for approving prior authorization; and
  - Criteria for a pharmacy lock-in program.
- PTAC shall hold a public hearing to seek input on medications to be prior authorized and criteria. Notice shall be given 30 days in advance of the public hearing.

— What is Lock in.

State office publish → DCBS PTC 9:00 pm. DCBS Public Hearing 5:30 PM

Pharmacy and Therapeutics Advisory Committee (PTAC) Membership

- Medical Director of the DHHS;
- Five persons appointed by DHHS Commissioner;
- Four physicians nominated by the NH Medical Society from 1) Internal Medicine, 2) Pediatric, 3) Family Practice and 4) Psychiatry specialties.
- Two pharmacists (1 a Pharm.D.) nominated by the NH Pharmacists Association.

Medications Requiring Prior Authorization

- Less than 1% of all pharmaceutical claims require prior authorization:
  - Gastrointestinal Meds
  - Controlled Substances
  - Arthritis Meds/Non-Steroidal Anti-Inflammatory Drugs
  - Erectile Dysfunction Treatment Meds
  - Anti-obesity Meds

Improving the Quality of Care

- **Prospective Drug Utilization Review** – prevents potentially harmful drug interactions/contraindications
- **Retrospective Drug Utilization Review** – post payment utilization review. Providers are notified of potentially harmful drug interactions/ contraindications
- **Prior Authorization** - assures clinically appropriate drug therapy
- **Provider Education** – targeted to providers and issues identified in the retro-Drug Utilization Review

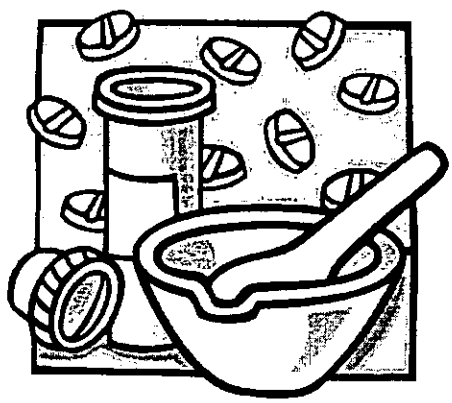
Summary

- Pharmacy Cost Drivers: Drug Industry Marketing, Advertising and Profits
- Pharmacy Benefit Cost Management Quality Initiatives implemented in SFY 02
  - Prospective Drug Utilization Review Edits
  - Maximum Allowable Cost Pricing for Generics
  - Prior Authorization
  - Third Party Liability Cost Avoidance

Questions?

- Call NH Department of Health and Human Services:
  - Roland Lamy, Assistant Director, Office of Health Planning and Medicaid 271-5254 or email at rlamy@dhhs.state.nh.us

PROPOSED CRITERIA RECOMMENDATIONS



P&T Committee
August 27th 2002

CRITERIA FOR PRIOR AUTHORIZATION

TABLE OF CONTENTS

ERECTILE DYSFUNCTION MEDICATIONS CRITERIA

Pharmacology:

Sildenafil: A selective competitive inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5) that involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation.

Alprostadil: Alprostadil induces erection by relaxation of trabecular smooth muscle and by dilation of cavernosal arteries.

Medications:

Brand Name	Generic Names	Dosage Strengths	Quantity Limits/month
Viagra®	Sildenafil citrate	25mg, 50mg, 100mg	6
Edex®	Alprostadil (Prostaglandin E1; PGE1)	12.45mcg, 24.9mcg, 49.8mcg	6
Caverject®	Alprostadil (Prostaglandin E1; PGE1)	6.15mcg, 11.9mcg, 23.2mcg	6
Muse®	Alprostadil (Prostaglandin E1; PGE1)	125mcg, 250mcg, 500mcg, 1000mcg	6

Criteria for Authorization:

- Patient must be male and 21 years of age or older.
- Diagnosis of erectile dysfunction must result from one of the following disease states:

CORONARY ARTERY DISEASE	MULTIPLE SCLEROSIS
HYPERTENSION OR OTHER CARDIAC DISEASE	RADICAL PROSTATECTOMY
PERIPHERAL VASCULAR DISEASE	TRANS-URETHRAL RESECTION OF PROSTATE*
DIABETES MELLITUS	SURGERY FOR THE COLON
CORONARY BYPASS	SPINAL CORD INJURY
CHEMOTHERAPY	

* not an indication for Viagra® use.

- Patient's current medication history must NOT have nitrates present, unless they are being used for a non-cardiac reason. No other exceptions are to be made.

Length of Authorization: **12 Months**

References:

1. Urology Forum. Prostate BPH. Urology Channel. www.urologychannel.com. October 2001.
2. Understanding Cancer of the Prostate. Cancer BACUP booklet series. www.cancerbacup.com. October 2001.
3. AACE Clinical Practice Guidelines for the Evaluation and Treatment of Male Sexual Dysfunction. Endocrine Practice. 1998 Jul-Aug;4(4):219-35.
4. Efacts: Copyright © 2001 by Facts and Comparisons.
5. Drugdex, 1974 – 2001. MICROMEDEX, INC.
6. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

PROTON PUMP INHIBITORS CRITERIA

Pharmacology:

Proton pump inhibitors belong to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the H^+/K^+ ATPase enzyme system at the secretory surface of the gastric parietal cell. This enzyme system is the "acid (proton) pump" within the gastric mucosa; therefore, these agents have been characterized as gastric acid pump inhibitors. They block the final step of acid production.

Medications:

Brand Names	Generic Names	Dosage Strengths
Aciphex®	Rabeprazole	20 mg
Nexium®	Esomeprazole	20 mg , 40 mg
Prevacid®	Lansoprazole	15 mg , 30 mg
Prilosec®	Omeprazole	10 mg , 20 mg , 40 mg
Protonix®	Pantoprazole	20 mg , 40 mg , 40 mg/vial (IV)

ALL DOSES REQUIRE AUTHORIZATION AFTER 8 WEEKS[1] PER LIFETIME OF THERAPY

Criteria for Authorization:

1. **Erosive Esophagitis Grade 2 or greater:**
   - Diagnosed by endoscopy.
   - Authorize for 6 months and can be renewed for up to 2 years from the date of endoscopy.
2. **Barrett's Esophagus:**
   - Diagnosed by endoscopy.
   - Authorize for up to one year and can be renewed for up to 2 years from the date of endoscopy.
3. **Pathological Hypersecretory Condition (Zollinger-Ellison Syndrome):**
   - Diagnosed by serum gastrin (while patient was not on a PPI for 1-2 weeks) and serum secretin stimulation test.
   - Authorize for up to one year.
4. **GERD:**
   - The prescriber must document that one of the following conditions has been met:
     - An upper GI series, barium swallow or endoscopy with positive results within the past 2 years. **OR**
     - A failure on an acute dose of a H2RA within the past 2 years.
   - If the patient has had an EGD, authorize for 6 months and can be renewed for up to two years from the date of endoscopy.
   - Otherwise, authorize for up to 6 months.

5. **Positive H. pylori diagnosis:**
   - Authorize BID dosing for one month.
   - H2RAs are used for maintenance therapy after the H. pylori regimen.
6. **Active GI Bleed:**
   - Authorize QD dosing for one month.
   - H2RAs are used for maintenance therapy.
7. **Hyperacidity in Cystic Fibrosis Patients:**
   - An upper GI procedure is not required, but the prescriber must document a failure on an acute dose of an H2RA within the past 2 years.
   - Authorize for up to 6 months.

Length of Authorization: **As indicated above**

PPI Dosage Chart

Conditions	Omeprazole Prilosec®	Esomeprazole Nexium®	Lansoprazole Prevacid®	Rabeprazole Aciphex®	Pantoprazole Protonix®
GERD	20 mg qd	20 mg qd	15 mg qd	20 mg qd	40 mg qd
Erosive Esophagitis	20 mg qd	20-40 mg qd (healing) 20 mg qd (maintenance)	30 mg qd (healing) 15 mg qd (maintenance)	20 mg qd	40 mg qd
Barrett's Esophagus	20-40 mg qd	-	30-60 mg qd	-	-
Pathological Hypersecretory Conditions (Zollinger-Ellison Syndrome)	Up to 360 mg/d (in divided doses)	-	Up to 180 mg/d (in divided doses)	Up to 120 mg/d (in divided doses)	-
H. pylori	Triple therapy: 20 mg bid X 10 days Dual therapy: 40 mg qd X 14 days	Triple therapy: 40 mg qd X 10 days	Triple therapy: 30 mg bid X 10-14 d Dual therapy: 30 mg qd X 14 days	-	-

References:

1. American Journal of Gastroenterology 2000:95 (Supplement 8):54-8. Kathy P. Castello
2. Kenneth R. DeVault, M.D., F.A.C.G., Donald O. Castell, M.D., F.A.C.G., and The Practice Parameters Committee of the American College of Gastroenterology. Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. American Journal of Gastroenterology. June 1999, Volume 94, Number 6: Pages 1434-1442.
3. University of Michigan Health System Guidelines for Clinical Care. Peptic Ulcer Disease.
4. Samir Malhotra, M.D., DM. Regimens for the Eradication of Helicobacter Pylori: A " Meta-Analysis" of Meta-Analyses. Medscape Pharmacotherapy, 2001.
5. Storr M, Meining A, Allescher HD. Pharmacoeconomic Issues of the Treatment of Gastroesophageal Reflux Disease. Expert Opin Pharmacother 2001 Jul;2(7):1099-1108.
6. Colin W. Howden, M.D., F.A.C.G., and Richard H. Hunt, F.R.C.P., F.A.C.G. Guidelines for the Management of Helicobacter Pylori Infection. American Journal of Gastroenterology. December 1998 Volume 93, Number 12: Pages 2330-2338.
7. American Gastroenterological Association Medical Position Statement. Evaluation of Dyspepsia. Gastroenterology. 1998;114:579-581.
8. Bonnie B. Dean, Reshmi M. Siddique, Beverly D. Yamashita, Ashoke S. Bhattacharjya, and Joshua J. Ofman. Cost-Effectiveness of Proton-Pump Inhibitors for Maintenance Therapy of Erosive Reflux Esophagitis. Am J Health-Syst Pharm 58(14): 1338-1346, 2001.
9. Gastroenterology Treatment Updates. Management Issues in Acid Peptic Disorders: GERD and Erosive Esophagitis. Medscape 2000.
10. Fennerty B, M.D. Update on Barrett's Esophagus. Digestive Disease Week 2001. May 22nd 2001.
11. Efacts: Copyright © 2001 by Facts and Comparisons.
12. Drugdex, 1974 – 2001. MICROMEDEX, INC.
13. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

OXYCONTIN® CRITERIA

Pharmacology:

Oxycontin® is a semisynthetic analog classified as a narcotic analgesic agonist.

Medications:

Brand Name	Generic Name	Dosage Strengths
Oxycontin®	Oxycodone	10 mg, 20 mg, 40 mg, 80 mg

Criteria for Authorization:

All requests for Oxycontin® will reject at the pharmacy EXCEPT for requests for hospice patients.

There are 3 circumstances allowing approval:

- Pain associated with cancer
- Pain associated with acute sickle cell disease. There is a 10-day supply limit
- Failure on three other narcotics

The following guidelines should be used:

- A maximum quantity of 6 tablets per day or 480 mg per day.
  - ➢ If the prescriber is using more than 480 mg per day for an approved indication, and indicates that the dose is medically necessary, the higher dose may be approved.
  - ➢ If the number of tablets is over 6 per day, suggestions on how to reduce the number of tablets should be made when appropriate (a smaller number of larger doses).
- If the prescriber wants to use Oxycontin® in a circumstance other than one of the above allowed circumstances, inform him/her that there are other analgesic products available.
- If the prescriber is adamant about not switching, tell him/her that First Health will need to contact the State for permission to approve. Document all pertinent clinical data and forward it to the Pharmacist Supervisor or First Health Clinical Manager who will contact the State.

Criteria for Denial:

- Greater than three times a day dose.
- Concurrent use of other extended release opioids.

Length of Authorizations: **Initial: 3 months** **Follow-up: 6 months**

Long Term Care: **Initial: 3 months** **Follow-up: 6 months**

Dispensing Limits: 34-day supply or 100 dosage units, whichever is less in accordance with the Federal Law.

References:

1. A Report by the American Society of Anesthesiologists on Pain Management. Practice Guidelines for Cancer Pain Management. Anesthesiology. 1996 May;84 (5):1243-57.
2. Tallahassee (FL): State of Florida. Medical Practice Guidelines; Management of Pain Using Dangerous Drugs and Controlled Substances. Agency for Health Care Administration; 1996 Oct 25. p16.
3. Efacts: Copyright © 2001 by Facts and Comparisons.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

COX II INHIBITORS CRITERIA

Pharmacology:

Two COX isoenzymes have been identified: COX-1 and COX-2. COX-2's main function is induced during pain and inflammatory stimuli. The mechanism of action of celecoxib, rofecoxib and valdecoxib is primarily selective inhibition of COX-2 in the treatment of pain and inflammation; at therapeutic concentrations, the COX-1 isoenzyme is not inhibited thus GI toxicity may be decreased.

Medications:

Brand Names	Generic Names	Dosage Strengths
Bextra®	Valdecoxib	10 mg, 20 mg
Celebrex®	Celecoxib	100 mg, 200 mg
Vioxx®	Rofecoxib	12.5 mg, 25 mg, 12.5 mg/5ml, 25 mg/5 ml

Criteria for Authorization:

- Patients 60 years or older will NOT need prior authorization
- Patient must have at least 2 points from the following list of complicating factors:

POINT VALUE	COMPLICATING FACTOR
2 POINTS	Previous history of upper GI bleed
1 POINT	Concomitant oral corticosteroid
2 POINTS	Concomitant oral anticoagulant
1 POINT	Intolerance to one non COX II Inhibitor
1 POINT	Intolerance to a second non COX II Inhibitor

Criteria for Denial:

- Contraindication to Celebrex®: Sulfonamide allergy

Denial

Length of Authorization: **12 Months**

References:

1. Will the Promise of the COX-2 Selective NSAIDs Come to Fruition? Drug & Ther Perspect 17(11):6-10, 2001.
2. Simon L, MD. Treatment Strategies in Osteoarthritis. Medscape Conference Summaries from the American College of Rheumatology, 2000. Annual Scientific Meeting.
3. University of Texas. Recommendations for the Treatment of Dysmenorrhea.
4. Noble S, King D, Olutade J,. Cyclooxygenase-2 Enzyme Inhibitors: Place in Therapy. Am. Fam. Physician 2000;61:3669-76.
5. Tucker G, More A, et al. A Cost Analysis of Four Benefit Strategies for Managing a Cox II Inhibitor. J. Managed Care Pharm 7 (3):224-227, 2001.
6. Efacts: Copyright © 2001 by Facts and Comparisons.
7. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.
8. Bextra® Package Insert, Pharmacia Corporation, 2001.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

BRAND NAME NSAIDS

Criteria for Authorization:

The prescriber must submit a MedWatch form to verify a documented failure and/or adverse reaction on an A-B rated generic product.

Length of Authorization: **12 Months**

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

(BRAND NAME MULTI-SOURCE) ANTI-ULCER MEDICATIONS

Criteria for Authorization:

The prescriber must submit a MedWatch form to verify a documented failure and/or adverse reaction on an A-B rated generic product.

Length of Authorization: **12 Months**

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

(MULTI-SOURCE BRAND NAME) NARCOTICS

Criteria For Authorization:

The prescriber must submit a MedWatch form to verify a documented failure and/or adverse reaction on an A-B rated generic product.

Length Of Authorization: **Up to 12 Months**

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

XENICAL® (ORLISTAT) FOR HYPERCHOLESTEROLEMIA CRITERIA

Pharmacology:

Orlistat: Reverse lipase inhibitor that acts by inhibiting the absorption of dietary fats.

Medication:

Brand Names	Generic Names	Dosage Strengths
Xenical®	orlistat	120 mg

Criteria For Approval:

1. Patient must be at least 18 years of age.
2. Patient must have a diagnosis of hypercholesterolemia **with** treatment failures.
3. Patients **must** have experienced an adverse reaction as a direct result of **each** of the FDA approved drug classes for treating hypercholesterolemia, including but not limited to:
   a) Hepatotoxicity with HMG CoA Reductase Inhibitors, or fibric acids, or nicotinic acid
   b) Rhabdomyolysis or myopathy with HMG CoA Reductase Inhibitors or fibric acid
   c) Biliary obstruction or GI obstruction with bile acid sequestrants

Length Of Authorization: **3 months**

Approved agents for hypercholesterolemia:

HMG CoA Reductase Inhibitors:
- atorvastatin (Lipitor®)
- fluvastatin (Lescol®)
- lovastatin (Mevacor®)
- pravastatin (Pravachol®)
- simvastatin (Zocor®)

Fibric Acid Derivatives:
- clofibrate (Atromid-S®)
- fenofibrate (Tricor®)
- gemfibrozil (Lopid®)

Bile Acid Sequestrants:
- cholestyramine (Questran®)
- colestipol (Colestid®)

Nicotinic Acid:
- nicotinic acid

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

ANTI-OBESITY MEDICATIONS CRITERIA

Pharmacology:

Orlistat:	Reverse lipase inhibitor that acts by inhibiting the absorption of dietary fats.
Phentermine:	Indirect acting sympathomimetic amine that suppresses appetite by a direct stimulant effect on the satiety center in the hypothalamic and limbic regions.
Sibutramine:	Nonamphetamine appetite suppressant that produces its therapeutic effects by norepinephrine, serotonin and dopamine reuptake inhibition.

Medications:

Brand Names	Generic Names	Dosage Strengths
Fastin®/ Ionamin®	phentermine	8 mg, 15 mg, 30 mg
Meridia®	sibutramine	5 mg, 10 mg, 15 mg
Xenical®	orlistat	120 mg

Criteria For Approval:

A. Initial approval requires:

1. Documented failure of at least a 3 month trial on a low calorie diet **AND** a regimen of increased physical activity unless medically contraindicated by co-morbidity.
2. Baseline body mass (BMI) must be:
   - Greater than or equal to 30 kg/m^2 with no risk factors **OR**
   - Greater than or equal to 27 kg/m^2 with at least 1 very high risk factor **OR** at least 2 other risk factors (See Table 1)

   OR

   Waist circumference must be:
   - >102 cm for men and > 88 cm for women with at least 1 very high risk factor **OR** at least 2 other risk factors (See Table 1)
3. No contraindications (disease state or current therapy) should exist, unless prescriber documents that benefits outweigh risks. (See Table 2)
4. Patient must be at least 16 years of age.

B. Subsequent approval requires:

1. On-going prescriber documentation of adherence to a low calorie diet **AND** a regimen of increased physical activity (unless medically contraindicated by co-morbidity) during anti-obesity therapy.
2. No contraindications (disease state or current therapy) should exist, unless prescriber documents that benefits outweigh risks. (See Table 2)
3. See Special Instructions below for weight loss requirements.

Special Instructions:

- First approval will be for 1 month.
- After one month, patient must lose at least 4 lbs. to be granted approval for one more month.
- Thereafter, patient must lose at least 1 lb/month for a 1-month prior authorization until six months of therapy are completed.
- After six months of therapy, a six month approval may be granted if a 5% weight reduction has been achieved.*
- After 1 year of therapy, additional six (6) month approvals may be granted if a 10% weight reduction has been achieved and the patient continues to maintain weight loss.
- After lapses of therapy, additional trials may be approved if criteria requirements are met.

* Phentermine may not be approved for therapy beyond 9 months.

Table 1: Risk Factors

Very high risk	• Type 2 diabetes • Established coronary heart disease • Other atherosclerotic disease • Sleep apnea
Other risk factors	• Hypertension • Dyslipidemia • Impaired fasting glucose concentration • Cigarette smoking • Family history of premature heart disease • Age (men > 45 years, women > 55 years or postmenopausal) • Gynecologic abnormalities • Osteoarthritis • Gallstones • Stress incontinence

Table 2: Contraindications, Precautions, Drug Interactions

	ORLISTAT	PHENTERMINE	SIBUTRAMINE
Contraindications	Chronic malabsorption syndrome Cholestasis	Hx of glaucoma Hx of hypertension (mod to severe) Hx of hyperthyroidism Hx of cardiovascular disease	Poorly controlled hypertension Hx of coronary heart disease Hx of congestive heart failure Hx of arrhythmias Hx of strokes
Precautions	Hx of hyperoxaluria or Ca oxalate nephrolithiasis Patients with deficiency of any fat soluble vitamins	Hx of drug abuse Hx of anxiety disorders	Hx of narrow angle glaucoma
Drug Interactions	-	MAOIs: contraindicated	MAOIs: contraindicated SSRIs Ephedrine, Pseudoephedrine Sumatriptan Dihydroergotamine Opioids Lithium Tryptophan

References:

1. AMA Department of Drugs: AMA Drug Evaluations. 5th ed. American Medical Association. Chicago, IL. 1983.
2. Clinical Guidelines on the identification, evaluation and treatment of overweight and obesity in adults: The Evidence Report. National Institutes of Health. National Heart, Lung and Blood Institute.
3. AACE/ACE Position Statement on the Prevention, Diagnosis and Treatment of Obesity (1998 Revision). Endocrine Practice Vol 4, No 5. Sept-Oct 98. p 297- 330.
4. Miki L. Campbell and Monica L. Mathys. Pharmacologic Options for the Treatment of Obesity. Am J Health-Syst Pharm 58(14): 1301-1308, 2001.
5. Efacts: Copyright © 2001 by Fact and Comparisons.
6. Drugdex 1974 - 2001 MICROMEDEX, INC.
7. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

ATTACHMENT B

9.19.02 MIN

Minutes of the Meeting
HB 1218
Legislative Oversight of the Medicaid
Prescription Drug Benefits Management Program
September 19, 2002

10:00 AM – Meeting called to order by Rep. Dalrymple. Rep. Johnson, Rep. Dexter and Sen. Larsen are present. Sen. Prescott and Sen. Gatsas were absent.

Sen. Larsen asked to reconsider the current chairmanship of the committee, as Rep. Dalrymple and Rep. Johnson currently serve as co-chairs. Sen. Larsen now believes that she will have the time to serve in that capacity as the other study committee she chairs will not interfere with the duties associated with this committee. Rep. Johnson remarked that the only reason he assumed the title of co-chair was due to his familiarity with the subject matter and Sen. Larsen's hesitancy to take the role at the August 13 committee meeting because of her prior committee responsibilities.

None-the-less, Sen. Larsen was now ready to assume the position as Vice Chair of the committee, a role that is a matter of tradition for joint study committees. A voice vote was held to make Sen. Larsen Vice Chair of the committee. Sen. Larsen, Rep. Dalrymple and Rep. Dexter voting in the affirmative, and Rep. Johnson voting in the negative. Therefore, Rep. Dalrymple is the Committee Chair and Sen. Larsen is the Committee Vice Chair.

Rep. Dalrymple introduced Lori Real of the Department of Health and Human Services to make a presentation. Ms. Real subsequently introduced Roland Lamy and Dr. William Kassler, both of the Department.

Mr. Lamy discussed the inherent cost inequities within drug company expenditures. In essence, it is the departments' claim that drug companies spend almost four times the amount in revenues for marketing, advertising and compensation than they spend in research and development of new drugs. Mr. Lamy expressed the department's claim that the program to date has saved the state a substantial amount of money since inception.

Rep. Johnson questioned the validity of the data used to support Mr. Lamys' expenditure claims. The main source for the data presented in Mr. Lamys presentation came from a Families USA report entitled Profiting from Pain: Where Prescription Drug Dollars Go, written in July of 2002. It is well known that Families USA is an ardent critic of prescription drug companies; therefore the data included in the report is subject to some question.

Dr. Kassler made his presentation relative to the meetings of the PTAC committee and the public hearings relating to that meeting. Dr. Kassler could only respond in general terms as he had not as of that time had a chance to review the minutes of the meetings.

Rep. Dalrymple, Rep. Dexter and Rep. Johnson expressed interest and concern as to the prior authorization process established by FirstHealth, the prescription drug management firm.

Dr. Kassler replied that there would be some changes based upon the PTAC recommendations that should positively impact the prior authorization procedure.

The next meeting will be held on November 13, at 10:00 AM. The subject matter will be the PTAC report, the appeals process and the report to the Governor.

There being no other business to come before the committee, the meeting adjourned at 11:45.

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

129 PLEASANT STREET, CONCORD, NH 03301-3857
603-271-5254/5256 TDD Access: 1-800-735-2964

Kathleen G. Sgambati
Acting Commissioner

Lori H. Real
Director

September 13, 2002

The Honorable Janeen Dalrymple
7 Penobscott Avenue
Salem, NH 03079

Dear Representative Dalrymple:

As requested, the purpose of this letter is to provide meeting materials in preparation for the September 19th meeting of the Legislative Oversight Committee on Prescription Benefit Management (PBM). This package contains the following information:

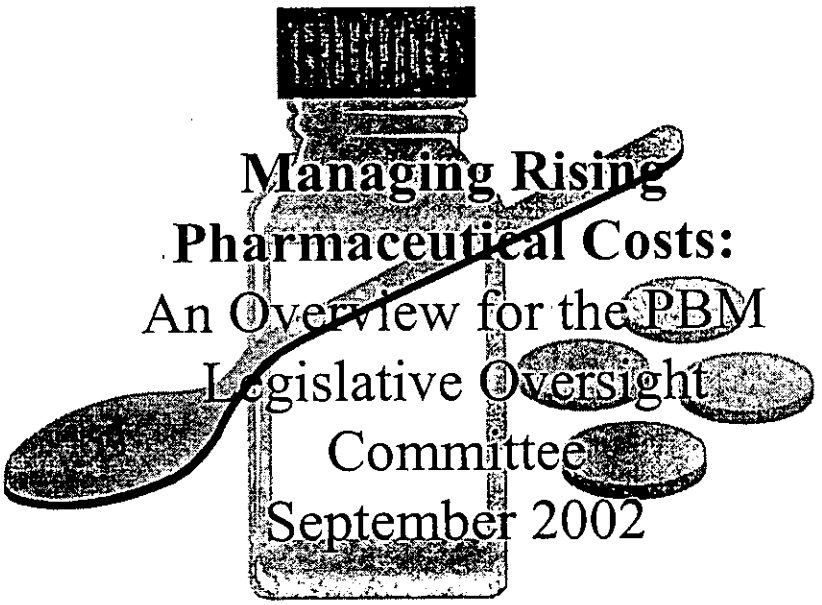
- PBM overview – a presentation outlining: 1) purpose of the Legislative Oversight Committee, 2) why pharmaceutical costs are rising, 3) how the Department of Health and Human Services is managing rising pharmaceutical costs.
- A summary of the Public Hearing held on August 26, 2002.
- Pharmacy and Therapeutics Advisory Committee (PTAC) – this information contains the agenda and criteria provided to the members of the Pharmacy and Therapeutics Advisory Committee for review prior to their meeting on August 27, 2002. A listing of the PTAC members is also enclosed.
- The minutes of the Pharmacy and Therapeutics Advisory Committee meeting on August 27, 2002 are being finalized and will be distributed to you at the meeting.

If you have any questions regarding the contents of this package please feel free to contact me at your convenience at 271-3676. The Department looks forward to meeting with you on September 19th to review this information.

Sincerely,

Lori H. Real, M.H.A.
Director

Enclosures
cc: Senator Sylvia Larsen
Senator Theodore Gatsas
Senator Russell Prescott
Representative Rogers Johnson
Representative Judson Dexter



Managing Rising Pharmaceutical Costs:

An Overview for the PBM Legislative Oversight Committee

September 2002

Purpose

- Review Purpose of Legislative Oversight Committee;
- Review Why Pharmaceutical Costs are Rising?
- Review How the Department of Health and Human Services is Managing Rising Pharmaceutical Costs.

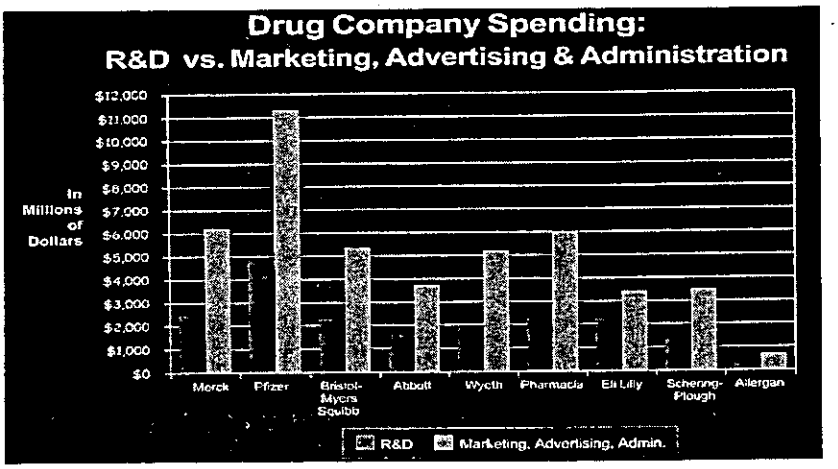
Pharmacy Benefit Management Legislative Oversight Committee

1. Review Department of Health and Human Services Annual Report (due November 1st);
2. Review report of actions taken by the Pharmacy and Therapeutics Advisory Committee;
3. May request assistance of legislative budget assistant in auditing the program; and
4. May make recommendations for proposed legislation, report findings and make recommendations to the speaker, president, governor and JLCAR by January 1 each year.

Why are pharmaceutical costs rising?

Drug Company Marketing & Advertising

Source: Families USA



DHHS Office of Health Planning and Medicaid

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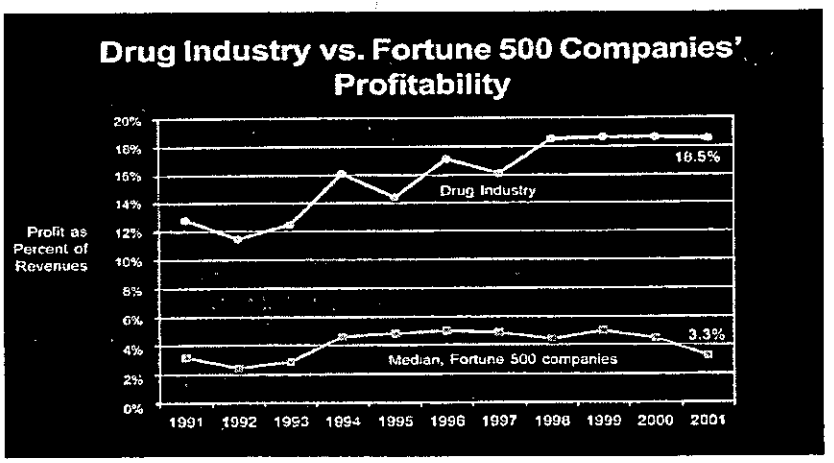
Drug Industry Profits

Source: Families USA



DHHS Office of Health Planning and Medicaid

6

Prescription Drugs have become the primary driver of medical care costs

- Availability of home infusions (IV drug) therapy has decreased hospitalizations
- Direct to consumer advertising
- Newer drugs to market are capable of doing more than ever before, often replacing surgery or other invasive treatments

How is the Department of Health and Human Services (DHHS) managing rising pharmaceutical costs?

Pharmacy Benefit Management
Components Implemented

- Prior Authorization – for medications that require prior authorization, recipients must meet approved criteria before a drug will be authorized.
- Prospective Drug Utilization Review Edits - Such as Early Refill, Therapeutic Duplication, Drug to Drug Interaction
- Maximum Allowable Cost Pricing for multi-source products. Adjustment to average wholesale price (AWP) to reflect true cost of the drug
- Third Party Liability Cost Avoidance –Medicaid is the payer of last resort

Pharmacy and Therapeutics Advisory Committee (PTAC) Responsibilities

- Advise DHHS on:
  - Medications subject to prior authorization;
  - Criteria for approving prior authorization; and
  - Criteria for a pharmacy lock-in program.
- PTAC shall hold a public hearing to seek input on medications to be prior authorized and criteria. Notice shall be given 30 days in advance of the public hearing.

Pharmacy and Therapeutics Advisory Committee (PTAC) Membership

- Medical Director of the DHHS;
- Five persons appointed by DHHS Commissioner;
- Four physicians nominated by the NH Medical Society from 1) Internal Medicine, 2) Pediatric, 3) Family Practice and 4) Psychiatry specialties.
- Two pharmacists (1 a Pharm.D.) nominated by the NH Pharmacists Association.

Medications Requiring Prior Authorization

- Less than 1% of all pharmaceutical claims require prior authorization:
  - Gastrointestinal Meds
  - Controlled Substances
  - Arthritis Meds/Non-Steroidal Anti-Inflammatory Drugs
  - Erectile Dysfunction Treatment Meds
  - Anti-obesity Meds

Improving the Quality of Care

- Prospective Drug Utilization Review - prevents potentially harmful drug interactions/contraindications
- Retrospective Drug Utilization Review – post payment utilization review. Providers are notified of potentially harmful drug interactions/ contraindications
- Prior Authorization - assures clinically appropriate drug therapy
- Provider Education – targeted to providers and issues identified in the retro-Drug Utilization Review

Summary

- Pharmacy Cost Drivers: Drug Industry Marketing, Advertising and Profits
- Pharmacy Benefit Cost Management Quality Initiatives implemented in SFY 02
  - Prospective Drug Utilization Review Edits
  - Maximum Allowable Cost Pricing for Generics
  - Prior Authorization
  - Third Party Liability Cost Avoidance

Questions?

- Call NH Department of Health and Human Services:
  - Roland Lamy, Assistant Director, Office of Health Planning and Medicaid 271-5254 or email at rlamy@dhhs.state.nh.us

SUMMARY OF PUBLIC COMMENTS

PTAC PUBLIC HEARING, AUGUST 26, 2002

Purpose of Hearing: To solicit public comment regarding prior authorization criteria and drugs and classes of drugs subject to prior authorization

Testimony was presented by 17 individuals, including: Ann Blair, NH Hospice & Palliative Care Organization; Dr. Joe Miller, SCOA; Cherylnn Griffin, Purdue Pharma; Shannon Benedetto, PharmD, Pfizer; David Anderson, Astra-Zeneca; Tina Cowgill, Astra-Zeneca; Mary Kaysen, Purdue Pharma; Paul Arnstein, RN, PhD, Family Nurse Practitioner; Client (name protected for confidentiality purposes); Anne Marie Durant, nurse and citizen; Cinde Warmington, Atty, Shaheen & Gordon, representing Purdue; Valerie Acres, Sheehan Phinney Capitol Group; Dr. Sedan Savage, NH Medical Society; Rep Rogers Johnson, PBM Legislative Oversight Committee; Nancy Galli, concerned citizen; Robert Howes, long term care pharmacist, Neighbor Care; Judith Griffin, long term care ombudsman.

PTAC Members Present: Dr. Doris Lotz, Dr. Bryan King, Peg Clifford, R.Ph., Paul Santos, PharmD, Dr. William Kassler, Lenny Parker, R.Ph., Robert Lenza, R.Ph.

General Prior Authorization Comments:

- One drug company testified that PA limits access, imposes a clerical burden, and adds cost.
- Dr. Miller noted that there is a real financial problem in this country, people are underinsured, uninsured, etc. It was suggested that, rather than fighting for coverage of drugs, that the drug companies show some benevolence to the needy.
- A concerned citizen expressed her opinion that illegal aliens get better treatment than we do.
- The long-term care ombudsman stated that PA places a bureaucratic red tape burden on physicians; such further barriers may drive more physicians away from participating.
- PA program creates a two-tiered system with the neediest being denied care.

General Process Comments:

- Committee was encouraged to hear comments directly and give adequate time to hear/review written testimony.
- A letter was sent by Sheehan Phinney and entered into the record suggesting that the hearing be held in conjunction with the PTAC meeting so all can directly hear the testimony.
- Dr. Miller suggested, with all the emphasis on pain management, that an anesthesiologist with great experience in pain be added to the PTAC committee.
- Member of legislative oversight committee expressed disappointment that hearing was Monday with PTAC being the next day. He would have expected a 2 week time period between the two meetings. He hopes that ALL the information will be available to the PTAC and to the Legislative Committee.
- Dr. Miller noted that when he was practicing, he always gave the drug rep "detail men" an audience, but when it came to considering the appropriate medications for his patients, he always went to the peer review journals. He noted that PTAC is made up of very well qualified medical professionals in whom he has a lot of faith.

NH Medical Society Task Force on Pain Comments:

- Dr. Sedan Savage testified that this group has reactivated their task force. Data gathering is ongoing. Report completion is expected for October, 2002. They welcome input.

Client Experience:

- Testimony was provided by a client, age 53, insulin dependent, with diabetic neuropathy. She noted that the doctors fought for her oxycontin. If she is in pain, she can't sleep, can't eat, etc. If she can't eat, she can't take her insulin. She has tried other meds. She experiences great anxiety over the wait for approval, which has happened several times over the past nine months.

Oxycontin Related Comments:

- Multiple comments were presented by drug companies and patient advocates regarding pain being an individual factor, people respond differently to pain and to different opiods in differing ways.
- Limiting access to certain opiod meds lowers the quality of life and may reduce life expectancy; also promotes the expansion of health disparities.
- An exception was requested by NH Hospice and Palliative Care for life threatening illness.
- Above organization also requested that PTAC reconsider the oxycontin exception of "hospice" to be reworded to "palliative care," as there is no hospice benefit in NH Medicaid.
- It was suggested by some drug companies and by a family nurse practitioner at Dartmouth-Hitchcock Clinic that oxycontin should be tied to level of pain—not disease state. Recommend using the criteria of pain.

- Recommend by drug company that there be more education of physicians and young people.
- Recommend by drug company that PA be required only if dosing interval is more frequently than every 12 hours or daily dose is greater than 320 mg.
- Nurse practitioner requested we please distinguish between the medical and criminal issues at hand. Overturn policy that excuses pharmacies and payors from their obligation to facilitate access to all drugs that are necessary to meet the medical needs of the communities that they serve.
- Nurse practitioner posed the question of "why is it OK to treat cancer pain, but not other pain?" All deserve humane, compassionate care. Criteria should not be diagnosis based.
- Criteria of "failure on 3 other narcotics" received several comments from drug companies, practitioners, and client. There was noted the concern about proper patient care; it is clinically inappropriate to switch and then return to one that works. Cycling on and off is not appropriate for constant pain. Alternatives such as the fentanyl patch and methadone, may remain in system when switching and/or may accumulate in system w/ resultant side effects. Alternatives such as morphine may not be appropriate for renal impaired, diabetics, elderly, etc. Should not have to endure multiple treatment failures.

Cox II Inhibitor Related Comments:

- Recommend by drug company that concomitant oral corticosteroid factor should be a 2 point value to be consistent with private health plans.
- Recommend by drug company the addition of Bextra to cox II inhibitors requiring PA and updating the PA request form as there are now 3 Cox II's on the market.
- Recommend by long term care pharmacist continuing with current elderly exemption.
- Recommend by drug company adding cardiovascular disease to the criteria.

Viagra Related Comments:

- A cost model was presented by a drug company with the conclusion drawn that PA'ing Viagra may cost more in administrative costs ($15/prescription) than is saved. It was also stated that standard practice is to re-evaluate the need to PA if the approval rate is greater than 90-95%.
- If PTAC continues with the PA requirement, above drug company suggests that SSRI (selective serotonin reuptake inhibitor) induced sexual dysfunction be added to the list of approved criteria [disease states]. (would result in improved compliance and reduction in relapse of depression)

Proton Pump Inhibitor Comments:

- Prior authorization was opposed.
- If continue with PA, drug company states that process and criteria should be applied equally and consistently across all PPI's. Commend the Department for such.
- Recommend by one drug company that gastroenterologists be exempt from having to request PA's. At the point at which a patient is under gastroenterology care, appropriate diagnoses, testing, and alternative therapies have likely occurred.
- Recommended by above drug company that PTAC solicit input on PA criteria by specialists.
- Above drug company also disagrees with new 8 week lifetime therapy limit before PA is required. It should remain at 12 weeks. Twelve weeks is consistent with package insert, limit is lifetime, conditions are often chronic with relapse common.

NOTICE OF NEW HAMPSHIRE PHARMACY AND THERAPEUTICS COMMITTEE PUBLIC HEARING AUGUST 26, 2002

The New Hampshire Pharmacy and Therapeutics Committee invites you to attend a public hearing on August 26, 2002 at 10 a.m. until 12 noon in the auditorium of the Health and Human Services Building, 6 Hazen Drive, Concord, New Hampshire. The purpose of the hearing is to solicit information and provide an opportunity for the public to present its views for the Committee regarding the following agenda for the New Hampshire Pharmacy and Therapeutic Committee meeting on August 27, 2002:

AGENDA FOR PHARMACY AND THERAPEUTICS COMMITTEE MEETING AUGUST 27, 2002

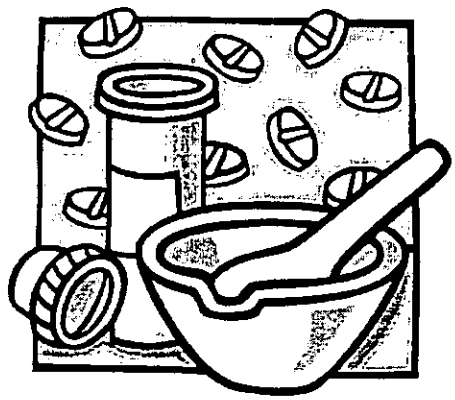
1. Introductions and welcome to Committee members.
2. Review of the prior authorization criteria for the following drugs and classes of drugs:

Therapeutic Class	Products Requiring Prior Authorization
Gastrointestinal Medications	• All brand name products that have an approved generic equivalent such as **Zantac®, Tagamet® and Pepcid®** • All Proton Pump Inhibitors such as **Prilosec®, Nexium®, Aciphex®, Protonix® and Prevacid®** will be allowed for **twelve (12)** weeks within a lifetime before a prior authorization is required
Controlled Substances	• All brand name products that have an approved generic equivalent such as Percocet®, Darvocet®, Tylenol® #3, Fiorinal®, MS Contin®, Vicodin®, Demerol® • All **Oxycontin®** products
Arthritis Medication/Non-Steroidal Anti-Inflammatory (NSAIDs):	• All brand name products that have an approved generic equivalent such as **Motrin®, Naprosyn®, Ansaid®, Anaprox®, Relafen®, Daypro®** • All Cyclooxygenase II (COX II) Inhibitors such as **Celebrex® and Vioxx®** for patients under the age of 60; patients 60 years or older will not need prior authorization
Erectile Dysfunction Treatment Medications:	• All drugs for erectile dysfunction treatment require a prior authorization
Anti-obesity Medications:	• All anti-obesity medications require a prior authorization

3. Discussion of prescription quantity limits.
4. Adjourn.

If you need further information concerning this public hearing, please contact Janice C. Paterson, Esq., Office of Health Planning and Medicaid, Legal Services Unit, at 1-800-852-3345, ext. 8946 (in state only) or (603) 271-8946.

PROPOSED CRITERIA RECOMMENDATIONS



P&T Committee
August 27th 2002

CRITERIA FOR PRIOR AUTHORIZATION

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ERECTILE DYSFUNCTION MEDICATIONS CRITERIA

Pharmacology:

Sildenafil: A selective competitive inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5) that involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation.

Alprostadil: Alprostadil induces erection by relaxation of trabecular smooth muscle and by dilation of cavernosal arteries.

Medications:

Brand Name	Generic Names	Dosage Strengths	Quantity Limits/month
Viagra®	Sildenafil citrate	25mg, 50mg, 100mg	6
Edex®	Alprostadil (Prostaglandin E1; PGE1)	12.45mcg, 24.9mcg, 49.8mcg	6
Caverject®	Alprostadil (Prostaglandin E1; PGE1)	6.15mcg, 11.9mcg, 23.2mcg	6
Muse®	Alprostadil (Prostaglandin E1; PGE1)	125mcg, 250mcg, 500mcg, 1000mcg	6

Criteria for Authorization:

- Patient must be male and 21 years of age or older.
- Diagnosis of erectile dysfunction must result from one of the following disease states:

CORONARY ARTERY DISEASE	MULTIPLE SCLEROSIS
HYPERTENSION OR OTHER CARDIAC DISEASE	RADICAL PROSTATECTOMY
PERIPHERAL VASCULAR DISEASE	TRANS-URETHRAL RESECTION OF PROSTATE*
DIABETES MELLITUS	SURGERY FOR THE COLON
CORONARY BYPASS	SPINAL CORD INJURY
CHEMOTHERAPY	

* not an indication for Viagra® use.

- Patient's current medication history must NOT have nitrates present, unless they are being used for a non-cardiac reason. No other exceptions are to be made.

Length of Authorization: **12 Months**

References:

1. Urology Forum. Prostate BPH. Urology Channel. www.urologychannel.com. October 2001.
2. Understanding Cancer of the Prostate. Cancer BACUP booklet series. www.cancerbacup.com. October 2001.
3. AACE Clinical Practice Guidelines for the Evaluation and Treatment of Male Sexual Dysfunction. Endocrine Practice. 1998 Jul-Aug;4(4):219-35.
4. Efacts: Copyright © 2001 by Facts and Comparisons.
5. Drugdex, 1974 – 2001. MICROMEDEX, INC.
6. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

PROTON PUMP INHIBITORS CRITERIA

Pharmacology:

Proton pump inhibitors belong to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the H^+/K^+ ATPase enzyme system at the secretory surface of the gastric parietal cell. This enzyme system is the "acid (proton) pump" within the gastric mucosa; therefore, these agents have been characterized as gastric acid pump inhibitors. They block the final step of acid production.

Medications:

Brand Names	Generic Names	Dosage Strengths
Aciphex®	Rabeprazole	20 mg
Nexium®	Esomeprazole	20 mg , 40 mg
Prevacid®	Lansoprazole	15 mg , 30 mg
Prilosec®	Omeprazole	10 mg , 20 mg , 40 mg
Protonix®	Pantoprazole	20 mg , 40 mg , 40 mg/vial (IV)

ALL DOSES REQUIRE AUTHORIZATION AFTER 8 WEEKS[1] PER LIFETIME OF THERAPY

Criteria for Authorization:

1. **Erosive Esophagitis Grade 2 or greater:**
   - Diagnosed by endoscopy.
   - Authorize for 6 months and can be renewed for up to 2 years from the date of endoscopy.
2. **Barrett's Esophagus:**
   - Diagnosed by endoscopy.
   - Authorize for up to one year and can be renewed for up to 2 years from the date of endoscopy.
3. **Pathological Hypersecretory Condition (Zollinger-Ellison Syndrome):**
   - Diagnosed by serum gastrin (while patient was not on a PPI for 1-2 weeks) and serum secretin stimulation test.
   - Authorize for up to one year.
4. **GERD:**
   - The prescriber must document that one of the following conditions has been met:
     - An upper GI series, barium swallow or endoscopy with positive results within the past 2 years. **OR**
     - A failure on an acute dose of a H2RA within the past 2 years.
   - If the patient has had an EGD, authorize for 6 months and can be renewed for up to two years from the date of endoscopy.
   - Otherwise, authorize for up to 6 months.

5. **Positive H. pylori diagnosis:**
   - Authorize BID dosing for one month.
   - H2RAs are used for maintenance therapy after the H. pylori regimen.
6. **Active GI Bleed:**
   - Authorize QD dosing for one month.
   - H2RAs are used for maintenance therapy.
7. **Hyperacidity in Cystic Fibrosis Patients:**
   - An upper GI procedure is not required, but the prescriber must document a failure on an acute dose of an H2RA within the past 2 years.
   - Authorize for up to 6 months.

Length of Authorization: **As indicated above**

PPI Dosage Chart

Conditions	Omeprazole Prilosec®	Esomeprazole Nexium®	Lansoprazole Prevacid®	Rabeprazole Aciphex®	Pantoprazole Protonix®
GERD	20 mg qd	20 mg qd	15 mg qd	20 mg qd	40 mg qd
Erosive Esophagitis	20 mg qd	20-40 mg qd (healing) 20 mg qd (maintenance)	30 mg qd (healing) 15 mg qd (maintenance)	20 mg qd	40 mg qd
Barrett's Esophagus	20-40 mg qd	-	30-60 mg qd	-	-
Pathological Hypersecretory Conditions (Zollinger-Ellison Syndrome)	Up to 360 mg/d (in divided doses)	-	Up to 180 mg/d (in divided doses)	Up to 120 mg/d (in divided doses)	-
H. pylori	Triple therapy: 20 mg bid X 10 days Dual therapy: 40 mg qd X 14 days	Triple therapy: 40 mg qd X 10 days	Triple therapy: 30 mg bid X 10-14 d Dual therapy: 30 mg qd X 14 days	-	-

References:

1. American Journal of Gastroenterology 2000:95 (Supplement 8):54-8. Kathy P. Castello
2. Kenneth R. DeVault, M.D., F.A.C.G., Donald O. Castell, M.D., F.A.C.G., and The Practice Parameters Committee of the American College of Gastroenterology. Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. American Journal of Gastroenterology. June 1999, Volume 94, Number 6: Pages 1434-1442.
3. University of Michigan Health System Guidelines for Clinical Care. Peptic Ulcer Disease.
4. Samir Malhotra, M.D., DM. Regimens for the Eradication of Helicobacter Pylori: A "Meta-Analysis" of Meta-Analyses. Medscape Pharmacotherapy, 2001.
5. Storr M, Meining A, Allescher HD. Pharmacoeconomic Issues of the Treatment of Gastroesophageal Reflux Disease. Expert Opin Pharmacother 2001 Jul;2(7):1099-1108.
6. Colin W. Howden, M.D., F.A.C.G., and Richard H. Hunt, F.R.C.P., F.A.C.G. Guidelines for the Management of Helicobacter Pylori Infection. American Journal of Gastroenterology. December 1998 Volume 93, Number 12: Pages 2330-2338.
7. American Gastroenterological Association Medical Position Statement. Evaluation of Dyspepsia. Gastroenterology. 1998;114:579-581.
8. Bonnie B. Dean, Reshmi M. Siddique, Beverly D. Yamashita, Ashoke S. Bhattacharjya, and Joshua J. Ofman. Cost-Effectiveness of Proton-Pump Inhibitors for Maintenance Therapy of Erosive Reflux Esophagitis. Am J Health-Syst Pharm 58(14): 1338-1346, 2001.
9. Gastroenterology Treatment Updates. Management Issues in Acid Peptic Disorders: GERD and Erosive Esophagitis. Medscape 2000.
10. Fennerty B, M.D. Update on Barrett's Esophagus. Digestive Disease Week 2001. May 22nd 2001.
11. Efacts: Copyright © 2001 by Facts and Comparisons.
12. Drugdex, 1974 – 2001. MICROMEDEX, INC.
13. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

OXYCONTIN® CRITERIA

Pharmacology:

Oxycontin® is a semisynthetic analog classified as a narcotic analgesic agonist.

Medications:

Brand Name	Generic Name	Dosage Strengths
Oxycontin®	Oxycodone	10 mg, 20 mg, 40 mg, 80 mg

Criteria for Authorization:

All requests for Oxycontin® will reject at the pharmacy EXCEPT for requests for hospice patients.

There are 3 circumstances allowing approval:

- Pain associated with cancer
- Pain associated with acute sickle cell disease. There is a 10-day supply limit
- Failure on three other narcotics

The following guidelines should be used:

- A maximum quantity of 6 tablets per day or 480 mg per day.
  - ➢ If the prescriber is using more than 480 mg per day for an approved indication, and indicates that the dose is medically necessary, the higher dose may be approved.
  - ➢ If the number of tablets is over 6 per day, suggestions on how to reduce the number of tablets should be made when appropriate (a smaller number of larger doses).
- If the prescriber wants to use Oxycontin® in a circumstance other than one of the above allowed circumstances, inform him/her that there are other analgesic products available.
- If the prescriber is adamant about not switching, tell him/her that First Health will need to contact the State for permission to approve. Document all pertinent clinical data and forward it to the Pharmacist Supervisor or First Health Clinical Manager who will contact the State.

Criteria for Denial:

- Greater than three times a day dose.
- Concurrent use of other extended release opioids.

Length of Authorizations: **Initial: 3 months** **Follow-up: 6 months** **Long Term Care: Initial: 3 months** **Follow-up: 6 months**

Dispensing Limits: 34-day supply or 100 dosage units, whichever is less in accordance with the Federal Law.

References:

1. A Report by the American Society of Anesthesiologists on Pain Management. Practice Guidelines for Cancer Pain Management. Anesthesiology. 1996 May;84 (5):1243-57.
2. Tallahassee (FL): State of Florida. Medical Practice Guidelines; Management of Pain Using Dangerous Drugs and Controlled Substances. Agency for Health Care Administration; 1996 Oct 25. p16.
3. Efacts: Copyright © 2001 by Facts and Comparisons.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

COX II INHIBITORS CRITERIA

Pharmacology:

Two COX isoenzymes have been identified: COX-1 and COX-2. COX-2's main function is induced during pain and inflammatory stimuli. The mechanism of action of celecoxib, rofecoxib and valdecoxib is primarily selective inhibition of COX-2 in the treatment of pain and inflammation; at therapeutic concentrations, the COX-1 isoenzyme is not inhibited thus GI toxicity may be decreased.

Medications:

Brand Names	Generic Names	Dosage Strengths
Bextra®	Valdecoxib	10 mg, 20 mg
Celebrex®	Celecoxib	100 mg, 200 mg
Vioxx®	Rofecoxib	12.5 mg, 25 mg, 12.5 mg/5ml, 25 mg/5 ml

Criteria for Authorization:

- Patients 60 years or older will NOT need prior authorization
- Patient must have at least 2 points from the following list of complicating factors:

POINT VALUE	COMPLICATING FACTOR
2 POINTS	Previous history of upper GI bleed
1 POINT	Concomitant oral corticosteroid
2 POINTS	Concomitant oral anticoagulant
1 POINT	Intolerance to one non COX II Inhibitor
1 POINT	Intolerance to a second non COX II Inhibitor

Criteria for Denial:

- Contraindication to Celebrex®: Sulfonamide allergy

Length of Authorization: **12 Months**

References:

1. Will the Promise of the COX-2 Selective NSAIDs Come to Fruition? Drug & Ther Perspect 17(11):6-10, 2001.
2. Simon L, MD. Treatment Strategies in Osteoarthritis. Medscape Conference Summaries from the American College of Rheumatology, 2000. Annual Scientific Meeting.
3. University of Texas. Recommendations for the Treatment of Dysmenorrhea.
4. Noble S, King D, Olutade J,. Cyclooxygenase-2 Enzyme Inhibitors: Place in Therapy. Am. Fam. Physician 2000;61:3669-76.
5. Tucker G, More A, et al. A Cost Analysis of Four Benefit Strategies for Managing a Cox II Inhibitor. J. Managed Care Pharm 7 (3):224-227, 2001.
6. Efacts: Copyright © 2001 by Facts and Comparisons.
7. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.
8. Bextra® Package Insert, Pharmacia Corporation, 2001.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

BRAND NAME NSAIDS

Criteria for Authorization:

The prescriber must submit a MedWatch form to verify a documented failure and/or adverse reaction on an A-B rated generic product.

Length of Authorization: **12 Months**

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

(BRAND NAME MULTI-SOURCE) ANTI-ULCER MEDICATIONS

Criteria for Authorization:

The prescriber must submit a MedWatch form to verify a documented failure and/or adverse reaction on an A-B rated generic product.

Length of Authorization: **12 Months**

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

(MULTI-SOURCE BRAND NAME) NARCOTICS

Criteria For Authorization:

The prescriber must submit a MedWatch form to verify a documented failure and/or adverse reaction on an A-B rated generic product.

Length Of Authorization: **Up to 12 Months**

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

XENICAL® (ORLISTAT) FOR HYPERCHOLESTEROLEMIA CRITERIA

Pharmacology:

Orlistat: Reverse lipase inhibitor that acts by inhibiting the absorption of dietary fats.

Medication:

Brand Names	Generic Names	Dosage Strengths
Xenical®	orlistat	120 mg

Criteria For Approval:

1. Patient must be at least 18 years of age.
2. Patient must have a diagnosis of hypercholesterolemia **with** treatment failures.
3. Patients **must** have experienced an adverse reaction as a direct result of **each** of the FDA approved drug classes for treating hypercholesterolemia, including but not limited to:
   a) Hepatotoxicity with HMG CoA Reductase Inhibitors, or fibric acids, or nicotinic acid
   b) Rhabdomyolysis or myopathy with HMG CoA Reductase Inhibitors or fibric acid
   c) Biliary obstruction or GI obstruction with bile acid sequestrants

Length Of Authorization: **3 months**

Approved agents for hypercholesterolemia:

HMG CoA Reductase Inhibitors:
- atorvastatin (Lipitor®)
- fluvastatin (Lescol®)
- lovastatin (Mevacor®)
- pravastatin (Pravachol®)
- simvastatin (Zocor®)

Fibric Acid Derivatives:
- clofibrate (Atromid-S®)
- fenofibrate (Tricor®)
- gemfibrozil (Lopid®)

Bile Acid Sequestrants:
- cholestyramine (Questran®)
- colestipol (Colestid®)

Nicotinic Acid:
- nicotinic acid

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

ANTI-OBESITY MEDICATIONS CRITERIA

Pharmacology:

Orlistat:	Reverse lipase inhibitor that acts by inhibiting the absorption of dietary fats.
Phentermine:	Indirect acting sympathomimetic amine that suppresses appetite by a direct stimulant effect on the satiety center in the hypothalamic and limbic regions.
Sibutramine:	Nonamphetamine appetite suppressant that produces its therapeutic effects by norepinephrine, serotonin and dopamine reuptake inhibition.

Medications:

Brand Names	Generic Names	Dosage Strengths
Fastin®/ Ionamin®	phentermine	8 mg, 15 mg, 30 mg
Meridia®	sibutramine	5 mg, 10 mg, 15 mg
Xenical®	orlistat	120 mg

Criteria For Approval:

A. Initial approval requires:

1. Documented failure of at least a 3 month trial on a low calorie diet **AND** a regimen of increased physical activity unless medically contraindicated by co-morbidity.
2. Baseline body mass (BMI) must be:
   - Greater than or equal to 30 kg/m^2 with no risk factors **OR**
   - Greater than or equal to 27 kg/m^2 with at least 1 very high risk factor **OR** at least 2 other risk factors (See Table 1)

   OR

   Waist circumference must be:
   - >102 cm for men and > 88 cm for women with at least 1 very high risk factor **OR** at least 2 other risk factors (See Table 1)
3. No contraindications (disease state or current therapy) should exist, unless prescriber documents that benefits outweigh risks. (See Table 2)
4. Patient must be at least 16 years of age.

B. Subsequent approval requires:

1. On-going prescriber documentation of adherence to a low calorie diet **AND** a regimen of increased physical activity (unless medically contraindicated by co-morbidity) during anti-obesity therapy.
2. No contraindications (disease state or current therapy) should exist, unless prescriber documents that benefits outweigh risks. (See Table 2)
3. See Special Instructions below for weight loss requirements.

Special Instructions:

- First approval will be for 1 month.
- After one month, patient must lose at least 4 lbs. to be granted approval for one more month.
- Thereafter, patient must lose at least 1 lb/month for a 1-month prior authorization until six months of therapy are completed.
- After six months of therapy, a six month approval may be granted if a 5% weight reduction has been achieved.*
- After 1 year of therapy, additional six (6) month approvals may be granted if a 10% weight reduction has been achieved and the patient continues to maintain weight loss.
- After lapses of therapy, additional trials may be approved if criteria requirements are met.

* Phentermine may not be approved for therapy beyond 9 months.

Table 1: Risk Factors

Very high risk	• Type 2 diabetes • Established coronary heart disease • Other atherosclerotic disease • Sleep apnea
Other risk factors	• Hypertension • Dyslipidemia • Impaired fasting glucose concentration • Cigarette smoking • Family history of premature heart disease • Age (men > 45 years, women > 55 years or postmenopausal) • Gynecologic abnormalities • Osteoarthritis • Gallstones • Stress incontinence

Table 2: Contraindications, Precautions, Drug Interactions

	ORLISTAT	PHENTERMINE	SIBUTRAMINE
Contraindications	Chronic malabsorption syndrome Cholestasis	Hx of glaucoma Hx of hypertension (mod to severe) Hx of hyperthyroidism Hx of cardiovascular disease	Poorly controlled hypertension Hx of coronary heart disease Hx of congestive heart failure Hx of arrhythmias Hx of strokes
Precautions	Hx of hyperoxaluria or Ca oxalate nephrolithiasis Patients with deficiency of any fat soluble vitamins	Hx of drug abuse Hx of anxiety disorders	Hx of narrow angle glaucoma
Drug Interactions	-	MAOIs: contraindicated	MAOIs: contraindicated SSRIs Ephedrine, Pseudoephedrine Sumatriptan Dihydroergotamine Opioids Lithium Tryptophan

References:

1. AMA Department of Drugs: AMA Drug Evaluations. 5th ed. American Medical Association. Chicago, IL. 1983.
2. Clinical Guidelines on the identification, evaluation and treatment of overweight and obesity in adults: The Evidence Report. National Institutes of Health. National Heart, Lung and Blood Institute.
3. AACE/ACE Position Statement on the Prevention, Diagnosis and Treatment of Obesity (1998 Revision). Endocrine Practice Vol 4, No 5. Sept-Oct 98. p 297- 330.
4. Miki L. Campbell and Monica L. Mathys. Pharmacologic Options for the Treatment of Obesity. Am J Health-Syst Pharm 58(14): 1301-1308, 2001.
5. Efacts: Copyright © 2001 by Fact and Comparisons.
6. Drugdex 1974 - 2001 MICROMEDEX, INC.
7. AHFS © 2001. American Society of Health-System Pharmacists Version 1.1.

Committee Review:	Reason for Review:	Date Committee Approved:
Pharmacy & Therapeutic Committee		

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

6 HAZEN DRIVE, CONCORD, NH 03301-6527
603-271-4796 800-852-3345, Ext. 8946 TDD Access: 1-800-735-2964

Kathleen G. Sgambati
Acting Commissioner

Lori H. Real
Director

NEW HAMPSHIRE PHARMACY & THERAPEUTICS ADVISORY COMMITTEE

New Hampshire Department of Health and Human Services

APPOINTED LIST OF MEMBERS

August 2002

Commissioner Appointments

William Kassler, MD, MPH
Department of Health & Human Services
State Medical Director
6 Hazen Drive
Concord, New Hampshire 03301

Stephen Bartels, MD
Medical Director
Dartmouth Psychiatric Research Center
105 Pleasant Street
Concord, New Hampshire 03301

Doris Lotz, MD
Medicaid Medical Director
Office of Health Planning and Medicaid
129 Pleasant Street
Concord, New Hampshire 03301

Robert Lenza, R.Ph.
Pharmacy Director
Anthem Blue Cross and Blue Shield
3000 Goffs Falls Road
Manchester, New Hampshire 03111

Lenny Parker, R.Ph.
Executive Director
Unicare Health Services, Inc.
23 Parameter Road
Londonderry, New Hampshire 03053

Margaret Clifford, R.Ph.
Office of Health Planning & Medicaid
Medicaid Administrative Services
6 Hazen Drive
Concord, New Hampshire 03301

NH Medical Society Nominees Appointed by the Commissioner

Richard Lafleur, MD — Internal Medicine
Southern NH Internal Medicine Associates
44 Birch Street, Suite 300
Derry, New Hampshire 03038

Steven Paris, MD — Pediatrics
Dartmouth Hitchcock Medical Center
100 Hitchcock Way
Manchester, New Hampshire 03104

Eric Pollak, MD, MPH — Family Practice
Concord Family Medicine
141 East Side Drive
Concord, New Hampshire 03301

Bryan King, MD — Psychiatry
Department of Child & Adolescent Psychiatry
Dartmouth Hitchcock Medical Center
One Medical Center Drive
Hanover, New Hampshire 03855

NH Pharmacy Association Nominees Appointed by the Commissioner

Roger Hebert, R.Ph.
Rice's Pharmacy
59 Main Street
Nashua, New Hampshire 03060

Paul Santos, Pharm. D. — Pharm. D.
Lakes Region General Hospital
80 Highland Street
Laconia, New Hampshire 03246

Attachment C

11.13.02 HJR

Minutes of the Meeting
HB 1218
Legislative Oversight of the Medicaid
Prescription Drug Benefits Management Program
November 13, 2002

10:15 AM – Meeting called to order by Committee Vice Chair Senator Larsen. Present, Representative Rogers Johnson. Absent, Rep. Judson Dexter and Rep. Dalrymple, Senators Prescott and Gatsas.

Lisa Swanson was introduced to the committee as a new employee of DHHS. Also in attendance was Peg Clifford, Prescription Drug Administrator and a Pharmacist, Jan Patterson, DHHS Legal Counsel and Lori Real of DHHS.

Lisa Swanson began a presentation on how the department arrived at the cost savings estimates for the program. The savings are based upon the EDS contract changes implemented in early 2001 and the establishment of the program in November of 2001. The Department cannot specifically identify what savings in program costs can be directly attributed to the FirstHealth contract. They would rather focus on the effect the program has had on prescription drug trend in the Medicaid population.

The drug trend for 2000 was 25%. For 2001 it was 19%. Now it is estimated to be 9%.

10:40 AM – Committee Chair Dalrymple arrived for the meeting.

Lisa Swanson continued her presentation. The Department looked at all prior authorizations and identified those that had subsequent issues based upon health interactions. They found that no adverse effects were based upon prior authorization. The Department stated that prior authorization accounted for only .3% of all drugs in the program.

FirstHealth has reported to DHHS that they have met all of their performance goals to date for the contract. Rep. Johnson asked the Department if they had audited/validated the FirstHealth report, and the Department replied they had not.

The Department is in the rule making process, with specific recommendations as follows;

- Complete the PBM Rule Making
- Implement auditing, effective Jan. 1, 2003

- Implement clinical detailing
- Implement disease state management for Asthma
- Implement pharmacy lock-in

Additional discussions took place regarding lock-in. Rep. Johnson remarked that it was a formulary, but the department quickly disagreed. The Department would like to discuss the grievance and appeal process at our next meeting, which has been scheduled for Wed., Feb. 5 at 3:00 PM.

There being no other business to come before the committee, the meeting adjourned at 11:35 AM.

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF HEALTH PLANNING & MEDICAID

129 PLEASANT STREET, CONCORD, NH 03301-3857
603-271-5254/5256 TDD Access: 1-800-735-2964

Kathleen G. Sgambati
Acting Commissioner

Lori H. Real
Director

November 1, 2002

The Honorable Janeen Dalrymple
7 Penobscott Avenue
Salem, NH 03079

Re: Legislative Oversight Committee for Medicaid Prescription Drug Benefit Management

Dear Representative Dalrymple:

Enclosed, as required by Chapter 281, Laws of 2002, please find the Annual Report of the Department of Health and Human Services regarding the Medicaid prescription drug benefits management program. In accordance with the law this report includes the following:

1. Prescription Cost savings to the state realized during SFY 02.

2. Any unintended costs in other Medicaid healthcare services, including long-term care admissions, hospital admissions, emergency room visits and physician visits during the current budget biennium from the institution of a prior authorization program.

3. A report on the volume of prior authorizations as a percentage of total claims, average call waiting time and other issues that the state's pharmacy benefit administrator is required to comply with under the terms of the pharmacy benefit management contract.

4. Recommendations for other opportunities to improve the management of pharmacy services or to expand pharmacy benefits to additional populations.

This report does not contain information regarding the effectiveness for "lock in" as that program has not been implemented.

As requested at our last meeting, also enclosed are: the minutes from the August 27, 2002 Pharmacy and Therapeutics Committee meeting, the Grievance and Appeals policy, and a copy of the First Health contract.

We will look forward to meeting with the Medicaid Pharmacy Benefit Management Legislative Oversight Committee on Wednesday, November 13, 2002 at 10:00 a.m. to review this information.

Sincerely,

Lori Real

Lori H. Real, M.H.A., Director
Health Planning and Medicaid

Enclosures

cc: Senator Sylvia Larsen
Senator Theodore Gatsas
Senator Russell Prescott
Representative Rogers Johnson
Representative Judson Dexter

Department of Health and Human Services
Medicaid Pharmacy Benefit Management
SFY 02 Annual Report
Prepared for the
Legislative Oversight Committee

Cost Savings Realized

Methodology:

- Total drug expenditures for SFY 01 were calculated and trended by 18%. ($88 M x 1.18= $103.8M)
- Total drug expenditures for SFY 02 were calculated for the full twelve-month period. ($94.5M)
- The difference between these two figures has been identified as savings.

Savings SFY 02: $ 9.3 M

Unintended Costs

Methodology:

- All prior authorization requests that had been changed or denied from 11/3/01-6/30/02 were identified. (1,478 changed/denied prior authorization requests)
- Medicaid pharmacists, registered nurses, and the medical director reviewed medical claims from 8/1/01- 7/31/02 for all changed/denied prior authorization requests. (50,554 claims)
- Additional clinical information was obtained from hospital medical records and reviewed by Medicaid registered nurses and the medical director. (4 medical records)

Results:

- An extensive review was undertaken to assure an accurate evaluation of any causal relationship between the change/denial of a prior authorization and any medical outcomes. While three prior authorization decisions were temporally related to recipient inpatient hospitalizations, none of the variables reviewed could definitively be implicated in a causal relationship. Therefore, no unintended costs are being reported as a direct result of the prior authorization process.

Prior Authorization Volume

Prior Authorization	Total Claims	Total PA Requests	PA as % of Claims
11/01-6/02	2,509,037	7,485	0.30%

First Health Key Performance Indicators

Indicator	Measure	Actual Results	Notes
Call Center Wait Time	95% of calls answered within 30 seconds	100% of calls answered within 31 seconds	*Start Up Phase: 43 seconds Operational: 24 seconds
Call Center Abandoned Call Rate	3% or less	3.61%	*Start Up Phase: 4.73% Operational: 2.24%
Claims Processing Financial Accuracy	98%	99.8%	
Claims Processing System Downtime	< 2 times per contract year < 24 hour duration	8 times Average duration per episode: 1.9 hours	
Rebate Reporting & Payment	Within 30 days of Receipt	100% within 30 days	
Prior Authorization Processing	100% within 24 hours	100% within 24 hours	

* Start Up Phase includes the initial implementation period of November 2001 through January 2002.

Recommendations

In SFY03, the Department of Health and Human Services is working to fully implement all components of the Pharmacy Benefit Management program. This includes:

- Completing the PBM Rule Making;
- Implementing Auditing;
- Implementing Clinical Detailing;
- Implementing Disease State Management for Asthma; and
- Implementing Pharmacy Lock In.

In addition, the Department is:

- Assessing whether additional medications should be subject to prior authorization;
- Planning to implement Disease State Management for Diabetes in SFY04; and
- Conducting an Operational Assessment of the feasibility of implementing a Preferred Drug List.

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE (PTAC) MEETING MINUTES

August 27, 2002

Members Present: William Kassler, Chair; Stephen Bartels, Behavioral Health; Doris Lotz, Medicaid; Robert Lenza, Commercial Health Plan; Lenny Parker, Long Term Care Pharmacist; Margaret Clifford, Medicaid; Eric Pollak, Family Practice; Bryan King, Psychiatry; Roger Hebert, Independent Pharmacist; Paul Santos, Hospital Based Pharmacist

Members Absent: Richard Lafleur, Internal Medicine; Steven Paris, Pediatrics

Presenters and Technical Staff: Barbara Dowd and Farah Jiwa, First Health Pharmacists; Jan Paterson, Legal Counsel, DHHS; James Carney, MD, First Health Medical Director

Agenda: Attached (Note that item #3, prescription quantity limits, was tabled until the next PTAC meeting.)

Introductory Comments: Meeting was called to order at 1:10 p.m. by Dr. Kassler, PTAC Chair.

(Note: Agreements or votes are shaded in the text.)

This PTAC meeting was the first to be held subsequent to implementation of new laws, new rules, new PTAC membership, and the first public hearing under the new law. The committee was provided with documents provided from the public hearing, including a full copy of the transcript from the hearing.

Due to legal requirements for public notice and task completion deadlines for PTAC, this particular public hearing could not take place any earlier than one day before the PTAC meeting. It was noted that public comment included suggestions for improvements in this process, i.e.,

(1) hold public hearing with PTAC meeting to directly follow so that all the PTAC members would be at the hearing (for the record, 7 PTAC members were in attendance at the public hearing); or

(2) hold public hearing two weeks prior to the PTAC meeting in order to give PTAC members the opportunity to study information provided at the hearing.

The Committee expressed consensus that scheduling the public hearing two weeks prior to the PTAC meeting was preferable so that they could study the information presented.

Housekeeping Issue: Members were reminded to complete and return the statement of financial interest found in the back of their packets to Jan Paterson. Reminder calls will be made if statements are not returned. If such statement is already on file for another Board, please let Jan know which Board; no additional statement is required.

Scheduling: PTAC meetings will be every other month.

REVIEW OF PRIOR AUTHORIZATION CRITERIA

Recommended prior authorization criteria and revisions to criteria based upon public comment, departmental input, and First Health input were presented to the PTAC for discussion and consideration.

(1) Gastrointestinal Medications

First Health, based on literature and claims review, recommended that all doses of PPI's require prior authorization after 8 weeks of use, versus the current 12 week criterion. First Health also recommended that the criteria in #4 be changed from "recently" to "within the past two years."

PTAC discussed the merits of an 8 week course of therapy vs. 12 weeks before prior authorization would be required. Discussion ensued regarding delays on PA's, data on relapse, reason for relapse, results of studies, whether or not there were data on 8 weeks vs. 12 weeks of therapy, noting that it was important to make data-based decisions. Questions arose around whether or not it was cost inflating to the entire Medicaid system to have physicians begin to do invasive testing such as endoscopies, and why PA's would need to be repeated at any interval if initial diagnostic criteria are met and are still pertinent. It was noted that Anthem does not prior authorize PPI's, but Cigna does.

Dosing frequencies and criteria were discussed. It was also noted that the dosage chart contains blanks because federal regulations do not allow FFP (federal financial participation) for off label use.

(Please note: For your convenience, portions of the March 1, 2002, provider notice have been included in an attached document in response to PTAC member questions about the PA, grievance, and appeal process.)

Action Items:

- The suggestion was made to exclude specialty care providers, specifically gastroenterologists, from prior authorization requirements. Further feasibility assessment is required on this issue, as the system currently does not have a field for specialty.

- It was noted that the long term care exemption for PPI's is still in effect. The document will be revised to include this exemption.

- Per a PTAC member's recommendation, reference to 8 weeks will be changed to 60 days in order to avoid system and technical issues.

- The Chair noted PTAC's concern regarding the importance of education; it will be discussed with First Health.

Motion: A motion was made to approve the criteria as recommended.
Approve: 9
Oppose: 1
Abstain: 0

(2) Erectile Dysfunction Medications

No recommended changes to the criteria were made by First Health. It was also noted that this service is a federally required Medicaid benefit.

A PTAC member suggested allowing the length of authorization to be for the person's lifetime if medically necessary.

Motion: A motion was made to accept the criteria with the addition of a PA exception for lifetime issues if technologically feasible.
Approve: 10
Oppose: 0
Abstain: 0

(3) Oxycontin

In response to public and other comment, the Chair recommended changing the Oxycontin criteria from a failure of trial on three narcotics to failure on two narcotics. This was supported by First Health based upon previous PA data. Also, based upon public comment, it was recognized that some form of exemption was needed for end of life care, as end of life may be broader than just hospice. The criteria recommended by First Health also included removing the PA exemption for long term care facility patients. Other recommended changes to the criteria included quantity changes from a maximum of eight tablets or 640 mg/day to six tablets or 480 mg/day, the addition of denial criteria and changes in length of authorizations.

PTAC members suggested that an additional approval circumstance be added to include that success with immediate release oxycodone should be a factor leading to prescribing and approving oxycontin. PTAC members also suggested that either PA not be required for life-long therapy or that reauthorization criteria be defined.

There was some discussion around issues of potential side effects of switching patients from oxycodone to other narcotics, the expense of oxycontin, and fiscal responsibility.

Action Items:

- After extensive discussion, the suggestion to add an approval criteria regarding success with immediate release oxycodone as a factor leading to prescribing and approving oxycontin was temporarily tabled. The department will examine the technical feasibility of step therapy and

will present process improvement suggestions to PTAC at the next meeting, to include whether or not the additional criteria improves the approval process.

- Re-visit, at next meeting, issue of reauthorization requirements for individuals already on oxycontin.

- First Health to bring data based upon PA's back to the PTAC.

Motion: A motion was made to add end of life care to the hospice exception.
Approve: 10
Oppose: 0
Abstain: 0

Motion: A motion was made to allow life-time length of authorization for life-long therapy.
Approve: 2
Oppose: 8
Abstain: 0

Motion: A motion was made to accept the proposed oxycontin criteria, as recommended by First Health, with the addition of end of life (as voted above) and with an amendment to change the failure criteria from three to two other narcotics.
Approve: 8
Oppose: 2
Abstain: 0

(4) Cox II Inhibitors

The proposal being considered included the addition of Bextra and some denial criteria. The Chair added that a point made at the public hearing was to change the point value on the concomitant oral corticosteroid factor from one point to two points, and that perhaps First Health should define the duration. Intent is chronic, i.e., more than 2-3 weeks. First Health will operationalize this using their best judgment.

PTAC member suggested that points be added for dyspepsia and history of ulcer. It was suggested that chronic renal disease be added with a point value of two.

Action Items:

- A discussion about exempting rheumatologists from PA requirements will be taken up at a later date as the technical aspects need to be researched in terms of whether or not the system can identify specialists.

Motion: A motion was made to accept the proposed criteria with the recommendation to change the point value for concomitant oral corticosteroids from one to two and with "chronic" being added, and to include the PTAC suggestions of adding history of peptic ulcer at two points, chronic renal disease at two points, and history of dyspepsia at one point.
Approve: 9
Oppose: 1
Abstain: 0

(5) Xenical

The chair noted that xenical is being presented separately for hypercholesterolemia and antiobesity.

A PTAC member raised the question of what constitutes a treatment failure and why reauthorization would occur in three months as the standards of medicine do not change in three months. Concurrence with 12 months was expressed. It was noted that clarification of treatment failure might better be a discussion between the physician and the Pharm D.

Motion: A motion was made to approve the recommendation with the length of authorization being changed from 3 to 12 months.
Approve: 9
Oppose: 0
Abstain: 1

(6) Anti-Obesity Medications

First Health explained that the change in criteria was a response to concern that if the physician indicates that physical activity is contraindicated, this should not be a reason for the patient to be denied medication.

PTAC discussed that one month may not be long enough to show weight loss as it takes a while to show results.

Motion: A motion was made to approve the proposed recommendations with a change from a one month to a three month approval in the "special instructions."
Approve: 9
Oppose: 0
Abstain: 1

Meeting was adjourned at 3:30 p.m.

Submitted by:

William J. Kassler, MD, MPH, Chair

Addendum to PTAC Minutes of August 27, 2002

Prior Authorization Information
Grievance and Appeal Process

Excerpt from March 1, 2002, Provider Notice

The protocol for requesting a prior authorization is for the prescriber's office to contact First Health directly. To facilitate patient access to treatment, the prescriber should contact First Health at the time the drug is being prescribed. If this does not occur, the patient's prescription claim will deny at the pharmacy, and the pharmacy will contact your office.

First Health's clinical staff is available to prescribing providers on site from 8:00 a.m. until 10:00 p.m., Monday through Friday. After hours, First Health's clinical staff are available by cell phone. Requests for prior authorization may be initiated via phone, fax or mail. The First Health phone number is (866) 675-7755 and the fax number is (888) 603-7696. A 72-hour emergency fill may be granted for all NH Medicaid covered medications under the following circumstances.

72-Hour Supply Procedure: All medications that require a prior authorization are covered under the following 72-hour supply procedure:

Should a patient arrive at a pharmacy with a prescription for a medication that requires a prior authorization, and the authorization is not in the claims processing system, the pharmacist should contact the prescriber. If the pharmacist cannot reach the prescriber within a reasonable period of time, the pharmacist should contact First Health Services' technical call center, at 1-866-664-4511, to obtain authorization for an emergency 72-hour supply of the medication. The call center personnel will enable the claim to be processed by entering an override into the claims processing system.

Please note that medications excluded from the New Hampshire Medicaid Pharmacy Program are not covered under this 72-hour supply procedure.

A Prior Authorization Process Flowchart illustrating the process follows. Please note that this process was as of March 1, 2002, and does not include the Pharm. D. process (see below).

Excerpt from May 21, 2002, provider notice:

Availability of Additonal Expertise as Part of the Prior Authorization Process:
Prescribing physicians may now request to speak with an FHS Pharm. D., if the FHS Pharmacist verbally denies a prior authorization request or suggests a change in therapy with which the prescriber does not agree. At your request, the FHS Pharm. D. will review your case and return your call within 24 hours.

Grievance and Appeal Procedure, revised May 21, 2002

The New Hampshire Medicaid Program will apply the following procedures to assure the prompt resolution of prescriber and recipient grievances or appeals relative to the denial of pharmaceutical services:

1. When the FHS pharmacy technician is unable to immediately grant a request for prior authorization, the request for prior authorization will be transferred to the FHS pharmacist who will collect the additional clinical information needed to either approve or deny the request. The FHS pharmacist will make a decision within 24 hours of receipt of all clinical information.

- An approval will be communicated verbally to the prescriber and to the dispensing pharmacy, if known, by the FHS pharmacist.

- If the request is not approved, a denial will be communicated verbally to the prescriber at the time of the denial.

    - **If the prescribing physician does not request to speak with a FHS Pharm. D., a formal notice of denial will be mailed to the recipient and the prescriber. The notice will contain information about the party's right to a formal appeal by the Department of Health and Human Services (DHHS) Administrative Appeals Unit.**
    - **If the prescribing physician requests to speak with a FHS Pharm. D., the FHS Pharm. D. will review the clinical information, return the call to the prescribing physician within the 24 hour time period, and request any additional information as needed. Approvals will be processed as per the above. Denials will be communicated verbally and through a formal notice mailed to the recipient and the prescriber as per the above. If the FHS Pharm. D. is not able to respond to the prescriber within the 24 hour time period, the FHS Pharm. D. shall offer a 72 hour emergency supply of the prescription.**

2. If the prescriber and/or recipient disagree with First Health Services' decision to deny the request for prior authorization, either party may request an informal grievance conducted by the Medicaid Administrative Services (MAS) pharmacist. This informal grievance process can occur concurrently with a request for formal appeal of the FHS decision. The MAS pharmacist will review the clinical data already collected by FHS, may request additional data from the prescriber, and will review the request with the MAS physician consultant. If at any time physician-to-physician communication is desired, the MAS pharmacist will direct the request to the MAS Physician Consultant or the Medical Director. Medicaid Administrative Services will make a decision within 24 hours of receipt of all additional clinical information.

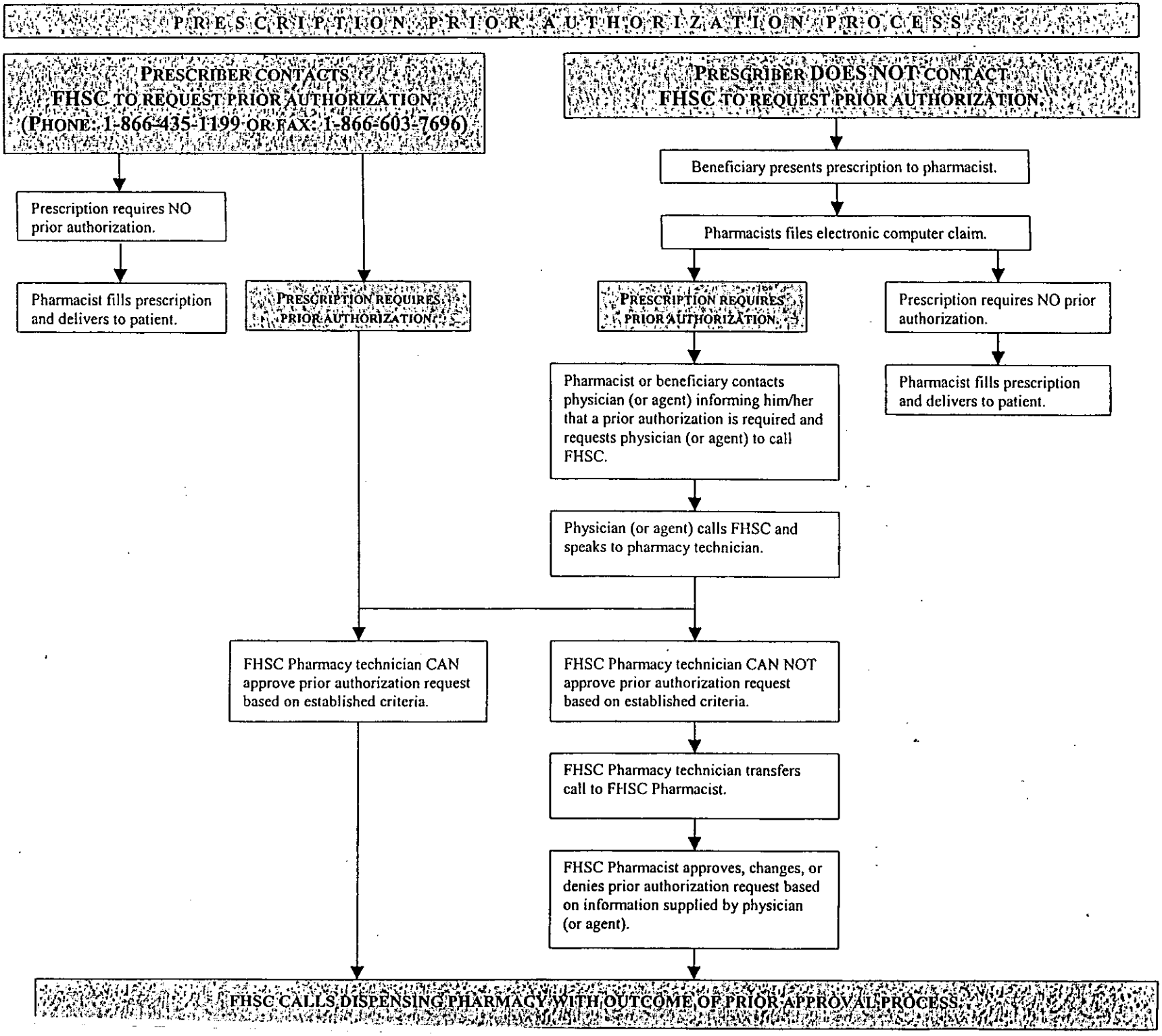
- An approval will be communicated verbally to the prescriber and dispensing pharmacy, if known, by the MAS pharmacist.

- A denial will be communicated verbally by the MAS pharmacist to the prescriber. This decision will include the supporting clinical rationale. In addition, a letter will be sent stating the outcome of this step of the informal grievance process. This letter will include information that describes the recipient's right to a formal appeal and fair hearing by the Department's Administrative Appeals Unit.

The formal appeal process may take thirty days or longer to conclude.

Prior Authorizations:	FHS Call Center	1-866-675-7755
Informal Grievance:	Medicaid Administrative Services	(603) 271-4419 or 4210
Formal Appeal:	Administrative Appeals Unit	1-800-852-3345, ext 4292 (in state only) or (603) 271-4292

PRESCRIPTION PRIOR AUTHORIZATION PROCESS



Voting Sheets

HOUSE COMMITTEE ON EXECUTIVE DEPARTMENTS AND ADMINISTRATION

EXECUTIVE SESSION on HB 1218

BILL TITLE: **relative to the regulation of pharmacists and prescription drug orders.**

DATE: 2-20-2002

LOB ROOM: 100 SH

Amendments:

Sponsor: Rep. OLS Document #:

Sponsor: Rep. OLS Document #:

Sponsor: Rep. OLS Document #:

Motions: (OTP) OTP/A, ITL, Interim Study (Please circle one.)

Moved by Rep. O'Neil

Seconded by Rep. Goulet

Vote: 14-0 (Please attach record of roll call vote.)

Motions: OTP, OTP/A, ITL, Interim Study (Please circle one.)

Moved by Rep.

Seconded by Rep.

Vote: (Please attach record of roll call vote.)

CONSENT CALENDAR VOTE: NK

(Vote to place on Consent Calendar must be unanimous.)

Statement of Intent: Refer to Committee Report

Respectfully submitted,

Rep. Ray F. Langer, Clerk

EXECUTIVE DEPARTMENTS AND ADMINISTRATION

Bill #: HB1218 Title: _____

PH Date: ___/___/___ Exec Session Date: 2/20/2002

Motion: OTP Amendment #: _____

MEMBER	YEAS	NAYS
Peterson, Andrew R, Chairman		
Dyer, Merton S, V Chairman	1	
Langer, Ray F, Clerk	2	
Goulet, Maurice E	3	
Hamel, Albert W	4	
~~Poulin, David G~~ O'Neil	5	
Zolla, William R	6	
~~Dodge, Robert K~~		
Allan, Nelson S	7	
Cummings, Raymond C	8	
Dexter, Judson K		
Hall, Charles Q	9	
Robertson, Carl G	10	
Lent, Donald R		
Landers, Dana L	11	
Andosca, Mary L	12	
Clayton, William K		
Pawlek, Marion J		
Schulze, Joan H	13	
Drabinowicz, A Theresa	14	
	14 - 0	

TOTAL VOTE:
Printed: 1/26/2001

Committee Report

COMMITTEE REPORT

COMMITTEE: **Executive Departments and Administration**

BILL NUMBER: **HB 1218**

TITLE: relative to the regulation of pharmacists and prescription drug orders.

DATE: February 20, 2002 CONSENT CALENDAR YES ☒ NO ☐

☒ OUGHT TO PASS

☐ OUGHT TO PASS WITH AMENDMENT

☐ INEXPEDIENT TO LEGISLATE

☐ REFER TO COMMITTEE FOR INTERIM STUDY
(Available only in second year of biennium.)

STATEMENT OF INTENT
(Include Committee Vote)

This is a housekeeping bill requested by the Board of Pharmacy. It will allow the board to promulgate rules on electronic transmission of prescriptions, clarify and provide a complete audit trail of drugs dispensed through a centralized prescription processing system.

Vote 14-0.

Rep. Michael O'Neil
FOR THE COMMITTEE

Original: House Clerk
cc: Committee Bill file

USE ANOTHER REPORT FOR MINORITY REPORT

CONSENT CALENDAR

Executive Departments and Administration

HB 1218, relative to the regulation of pharmacists and prescription drug orders. **OUGHT TO PASS**

Rep. Michael O'Neil for Executive Departments and Administration: This is a housekeeping bill requested by the Board of Pharmacy. It will allow the board to promulgate rules on electronic transmission of prescriptions, clarify and provide a complete audit trail of drugs dispensed through a centralized prescription processing system. **Vote 14-0.**

"Block" HB 1218

This is a housekeeping Bill requested by the Board of Pharmacy. It will allow the Board to promulgate Rules on Electronic transmission of prescriptions, clarify and provide a complete audit trail of drugs dispensed through a centralized prescription processing system.

Vote: 14-0 OTP

Michael D Vaz