# 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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

## HB 1218 - AS INTRODUCED

01-2257 10/09

### STATE OF NEW HAMPSHIRE

# In the Year of Our Lord Two Thousand One

AN ACT

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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

2 read as follows: XVI. "Prescription" means a verbal, or written, or facsimile or electronically transmitted 3 order for drugs, medicines and devices by a licensed practitioner, to be compounded and dispensed by 4 5 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 6 7 in a form complying with rules adopted pursuant to RSA 318:5-a, XV. Prescriptions may also

8 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.

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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.

# Committee Minutes

Date: 4/9/02 Time: 8:29 A.M.

Room: 103,LOB

The Senate Committee on Executive Departments and Administration held a hearing on the following:

HB 1218

relative to the regulation of pharmacists and prescription

drug orders.

Members of Committee present:

Senator Russell E. Prescott, D. 19: Senator Robert B. Flanders, D. 7: Senator Gary R. Francoeur, D. 14: Senator Sylvia B. Larsen, D. 15: Senator Lou D'Allesandro, D. 20:

The Chair, Senator Russell Prescott, opened the hearing by calling on the prime sponsor, Representative Millham.

Senator Russell E. Prescott, D. 19: Those that are speaking to the bill as passed by the House would be the ones with theirs ears most earnest to me at the beginning of the hearing so that I can call upon you. If I call upon somebody that would like to speak to the amendment, please stand up, say you would like to speak to the amendment at a later time so that we could get those who want to speak to the bill passed by the house, they would speak first. Representative Millham is here to represent the bill. Thank you very much Representative.

Representative Millham: Thank you. Do you want me to begin now or wait until you get the list?

Senator Russell E. Prescott, D. 19: If you would like, go right ahead.

Representative Millham: Thank you Senator Prescott and members of the committee. I am Alida Millham from Belknap District 4, Gilford and I am

here as the original sponsor of the bill but I am also here to introduce an amendment (See Attachment # 1A). Do you want me to give that to you right now?

Senator Russell E. Prescott, D. 19: Okay.

Representative Millham: As I said, I have two agendas with this bill today.

(See Attachment #1B).

I am open to any questions you have.

Senator Russell E. Prescott, D. 19: Any questions?

Representative Millham: Thank you very much.

<u>Senator Russell E. Prescott, D. 19</u>: Margaret Franckhauser, or should I first of all, see if there is anyone else here that wants to speak on the bill that are Representatives or Senators. Please come forward.

Maurice Goulet: Thank you Mr. Chairman. My name is Maurice Goulet from Hillsborough, District something, I don't know, whatever. I would like to support Representative Millham's amendment. In her testimony, she said ED&A has no problem across the wall, and I am here to assure you that the ED&A across the wall has no problem with Representative Millham's amendment and look favorably upon it's passage. Thank you.

Senator Russell E. Prescott, D. 19: Thank you.

Maurice Goulet: And, I will accept no questions because you don't need any.

Senator Russell E. Prescott, D. 19: I will move on to Margaret Franckhauser.

Margaret Franckhauser: Good morning and thank you. I am here to speak to Representative Millham's amendment to the bill. I am the Director of Community Health and Hospice in Laconia and I am also a member of the Board of Nursing. I am speaking in support of Representative Millham's amendment. As we stand, as we sit, I guess, some of us are standing, today there are about, I would say, several thousand people around the state of New Hampshire who have a visiting nurse fill one of these pill planner boxes. This is actually one of the more complicated boxes, some of them are only set up with seven days, this is set up to allow a patient to take medication four times a day.

As Representative Millham addressed to you, one of the things that she mentioned is, the current Pharmacy Practice Act defines the act of dispensing to mean the removal of a medication from a labeled container into an unlabeled container. Therefore, when the Attorney General was asked for an interpretation, they felt that the filling of pillboxes by nurses in home care agencies was in violation of the Practice Act. What this bill, what this amendment to the bill would do is clarify that to allow this practice to continue as it has been done in home setting throughout the state of New Hampshire.

I will simply put my comments into one statement; what this bill is set out to do is to protect the public safety. When nurses fill pill planners they are doing so to help patients with safety, many of them are unable to see or have dementia that makes it difficult for them to manage their own medications. When a registered nurse or a licensed practical nurse comes in and fills a pill planner, they are using their education, their knowledge of medications and pharmical therapeutics to help that patient in their home setting, with out that, many of those patients would be required to have a daily visit by a nurse and the cost would be extravagant, and many patients would not be able to be maintained in their own homes at all without the use of a pill planner.

Therefore, we are strongly in support of this. We believe that the Department of Health and Human Service is. We believe also that the Board of Pharmacy are in support of this amendment which would allow the practice to continue in home care and hospice settings. I do have a summary of my statement and I will just pass it around to you (See Attachment # 2). I will be happy to take any questions that you might have.

Senator Russell E. Prescott, D. 19: Seeing none, thank you very much.

Margaret Franckhauser: Okay, thank you.

Senator Russell E. Prescott, D. 19: Thank you for your testimony. We have signed up in favor, not wishing to speak is Representative Bob Mercer. Anyone else, I am going to name off a couple of names here, if you are in favor of the bill as coming from the House or the introduced amendment by Representative Millham, I would like you to speak now. Frank Case?

Frank Case: Yes.

Senator Russell E. Prescott, D. 19: Do you want to speak now?

Frank Case: I would.

Senator Russell E. Prescott, D. 19: Thank you.

Frank Case: Good morning Mr. Chairman, and members of the Committee. My name is Frank Case; I live in Nottingham, New Hampshire. I have the distinct pleasure and honor the honor to share a habitat with a Representative from General Court, Representative Margaret Case, or Peg Case, as she is known. I am her on behalf of the Board of Pharmacy as the President of the Board of Pharmacy asking that you look favorably on House Bill 1218.

House Bill 1218 has four objectives. Let me just back track a little, the technology has been going so fast that, you remember that I was here last year, I am here this year, I am absolutely sure that I am going to be here next year because of the changes in technology that is going on.

(See Attachment # 3, page #1 and #2).

So, what we are trying to do is make it so there are less errors because errors are very costly to the healthcare system and to the people who get hurt by them.

(See Attachment # 3, page #2 at Turning to HB 1218).

I as a pharmacist, work twelve hours a day and thought it was only for a half of a day that I was working.

# (See Attachment # 3, page # 2 at paragraph #2 of turning to HB 1218).

In other words, the patient thinks he has an emergency, a desperate emergency.

# (See Attachment #3, page #2 at paragraph#3 of Turning to HB1218).

The second different change is page 1, line 19 under the tittle "Central Prescription Processing". I think to make it as easy as I can, having owned and operated a place called the Raymond Drug, there was no such thing at that time but about 48% of the prescriptions that I filled were refill prescriptions, and 48% of all of the prescriptions filled are maintenance drugs.

So, if a patient came to the Raymond Drug or called me, a customer called me and said they were going to have a prescription refill, I am going to pick it up the next day; this is the type of prescription I could send to a central fill and have it filled by another pharmacy, believe it or not; they would put my label on it, they would put all my information on it that I would normally put on myself, send it back to me, then I would distribute it the next day to my customer.

And, there are going to be pharmacy that are central fills and I believe they exist already in some places. The community pharmacy and the information on the label would tell who the pharmacist was that filled it, by the way, plus my pharmacy name would be on it. So, that is what a central fill is, is to make the process a little bit more efficient than have everybody doing the same thing in their prescription departments.

It would work best for maintenance drugs and people are very used to making sure that they have their prescriptions ahead of time. Back in the days when I was working the store, which was 15 to 20 years ago, they would call and expect to have it ready when they walked in that day, people know better now with mail order pharmacies and everything that is going on in pharmacies. So, it's the concept that we feel we should at least have rules and regulations for in New Hampshire.

# (See Attachment #3, page #3).

What that would do is, we would have a printed document rather than a hand written document and that should really make it, take away the

problem of having the wrong drug. And, there are so many drugs that not only sound the same but certainly look the same, and I will go into that a little bit later. But, if you think about a drug called Pheldine and Seldine; it's not hard to have the handwriting of that person make a mistake on that, and that is the kind of thing that this bill would take care of.

(See Attachment # 3, page #3 paragraph # 2 of "Electronic transmission prescription").

We wold like to say that if any of you are, wonder about it, the Elliot Hospital has had a robotic system in for 2 or 3 years and as they work, we really have no rules or regulations to say that what they are doing is right. There is also the VA Hospital and I understand that there is a system now with the local prescription center that is a robotic system.

(See Attachment #3, page #4 last paragraph).

Are there any questions?

Senator Russell E. Prescott, D. 19: Thank you very much for your testimony.

Frank Case: Thank you very much, thank you for your time.

Senator Russell E. Prescott, D. 19: Mr. or Mrs. Gray for the New Hampshire Board of Pharmacy, I mean, Board of Nursing?

Cynthia Gray: Don't confuse us, although we do get along very well now. My name is Cynthia Gray; I'm from the Board of Nursing and we speak in support of the amendment but would actually consider expanding.

(See Attachment # 4).

Senator Russell E. Prescott, D. 19: Thank you very much for your testimony. Michael Cohen?

Michael Cohen: I 'm speaking to a different amendment.

Senator Russell E. Prescott, D. 19: Very good. Anybody else wish to speak on behalf of the House Bill 1218 as introduced? Please come forward.

<u>David Minnis</u>: I will just do it from right back here. My name is David Minnis. I am here representing the New Hampshire Pharmacists Association, and we are in support of the passage of House Bill 1218 as amended by the House, and we are also in support of the amendment that has been introduced.

Senator Russell E. Prescott, D. 19: Thank you very much. Anyone else wish to speak? We will go on to Representative Betsy Patten.

Rep. Patten: Thank you Mr. Chairman and members of the Committee. For the record, my name is Betsy Patten; I represent Carroll County, District 9, which is the town of Moultonborough. I also serve as the Vice-Chairman on the Joint Legislative Committee on Administrative Rules, also known as JLCAR. JLCAR is the Legislative Oversight Committee that approves or objects to rules promulgated by the Executive Departments in the state of New Hampshire.

We have basic criteria outlined in RSA 541A: 13:4 that we must use in determining the volatility and the appropriateness of any rule that comes before us; is the rule beyond the statutory authority of the agency, is the rule contrary to the content of the legislature; is the rule determined not to be in the public interest, and is the rule deemed by the Committee to have a substantial economic impact not recognized in the fiscal impact statement?

# (See Attachment #6).

The reason I come before you today, and I have an amendment and excuse me for not passing it out beforehand (See Attachment # 5).

(See Attachment #6, page #1, paragraph #2).

Senator Russell E. Prescott, D. 19: I have a question, concerning the submitted date and the, you mentioned two dates, October 25, 2001 and then November 2, 2001; could you describe what occurred on those two dates again?

Rep. Patten: On October 25, a notice was sent out to the pharmacist and the prescribers, the doctors, and Mr. Minnis may be able to give you exactly what the notice said, I didn't have that, but there was a notice, and there was a rule making hearing on November 1<sup>st</sup>. And, so that the notice was there, the hearing for the rulemaking process was held on November 1<sup>st</sup>.

Senator Russell E. Prescott, D. 19: Not November 2nd?

Rep. Patten: And, then November 2<sup>nd</sup>, the policy of doing prior authorization was implemented. And, I am also sure, Commissioner Shumway, if I am wrong, he will let me know, or he will let you know.

Senator Russell E. Prescott, D. 19: To get to this point... I would like to get your opinion. With our escalated costs of Medicaid reimbursements from pharmacies, I believe it was thought to be prudent to make purchasing coalitions, and this is the implementation of, the authorization was...between Maine and Vermont...

Rep. Patten: I believe they coalition to be able to pool everything together so that they could get better costs, and again, if I am wrong, I'm sure the Commissioner will let me know.

Senator Russell E. Prescott, D. 19: Would these questions be better asked of the Commissioner?

Rep. Patten: It could be, it might be better asked. I am, for the policy, I know that I am not able to help you in what you have to decide about the policy. I am not on Health and Human Services. I serve on JLCAR, and the process itself is what has brought me to bring this amendment to you and to ask for your guidance and your decisions, so that between the two houses, between the House and the Senate, a policy can either be determined to be appropriate or not, so that we at JLCAR will be able to determine if this Committee and the House determine that prior authorization and medical pharmacy lock-in is not a appropriate policy, then the Department should not implement that program.

There has been, there is a contract that is out there, and I will pass in copies of the contract that were signed in June of 2001(See Attachment # 7).

There is a process in rule-making in front of JLCAR, that if a Department needs to get rules in place quickly...and there are many times... and we understand that... that they are able to do this, either through emergency rules, which is usually for the health and safety of the public, or they can do interim rules, which gives them about 120 days to be able to put the rules in place and then go forward with formal long-time rule-making.

The department chose not to do interim rules. The Commissioner did tell us at our meeting in JLCAR that he wanted the rules to be the rules, and the is why he didn't go with interim. And, so again, the policy is something I know... I don't take a stand on the policy. I take a very strong stand that the process of JLCAR was overridden.

And having to sit as Senator Flanders has many a time with us on Fridays from 9:00, and sometimes, one time until 7:00, and Senator Below will never get us to stay that long again. We do, once a month, give our Fridays, and I think it is a very important rule that we take and I enjoy JLCAR, and yet I think it is important that the Executive Departments realize that we don't sit there just for enjoyment sake.

<u>Senator Russell E. Prescott, D. 19</u>: Since there is no policy reviewing, I think that the procedure was backwards. What is expected from you for a timetable to allow your deadline date of April 23rd to continue the process of authorizing this program? You have an April 19th JLCAR meeting?

Rep. Patten: Yes.

<u>Senator Russell E. Prescott, D. 19</u>: And you believe that this amendment, whether it's inexpediant to legislate or ought to pass, needs to be passed by the Senate, or does it just need to be with a favorable report from the Committee? Does it have to be passed by the Senate, passed by the House, signed by the Governor?

Rep. Patten: It is my contention, and I think that this is a place where Commissioner Shumway and I disagree. I do not feel that looking at what has transpired and looking at the RSA's, and going through, that the Department has the statutory authority to implement these rules. In order for the rules to go forward, and I know that Doctor Kesslier (?) has told us that they have suspended some of the rules, some of the prior authorization procedure.

And, I feel though it is...the scenario wold be: if this Committee feels that this procedure is appropriate and this policy is appropriate, and you take it through to the House, I mean to the Senate, and then the, because it is a change, as we all do, that you would need to bring it back to the House and ask for concurrence or not. And, I know that the time limit is very short, but once the policy is accepted by or rejected by the Senate, then JLCAR wold know what it is that it's going to do. I do believe that in order to get it into statute... we would hope that the Governer would... if we ever got that far this fast...that I would hope that the Governor would not veto this.

Senator Russell E. Prescott, D. 19: So, in your opinion, this process should of taken place months ago?

Rep. Patten: Yes.

<u>Senator Russell E. Prescott, D. 19</u>: And, you mentioned that it could of started with emergency rules?

Rep. Patten: Either emergency rules or if they felt that if it wasn't because there wasn't a dire emergency to the health and safety of the state, then the interim rules could have been put in place. The contract was signed in June, there could have been some... and again, this is something that the Commissioner and I had talked about and he does not fell that he needed to go that route. But I feel, having worked on JLCAR, that is sometimes the way to go even though it is not, the permanent rules will not go in place.

<u>Senator Russell E. Prescott, D. 19</u>: So, my final question is, do you believe that this needs to become law before JLCAR can take its rule-making authority?

Rep. Patten: I would believe so. Either that, or an ITL out of the Senate, and we would know. Because what will happen is that if the Senate says that this is not a appropriate policy for the Department to make, then what happens is that the prior authorization procedure... and I know that the lockin has not been implemented yet...those could be done a joint resolution on and the Department, in my view, could not put those rules forward.

Senator Russell E. Prescott, D. 19: Very good. Any questions from the Committee?

Rep. Patten: And, I thank you for taking the time and I am putting it in your lap.

Senator Russell E. Prescott, D. 19: Are there any other Representatives or Senators that wish to speak on behalf of this amendment introduced by Representative Patten? I am going to just start from the top of the list that signed up and we will just go down the list in no particular order. If there is anybody here who has time constraints and wishes to speak at this time? Michael Cohen?

<u>Michael Cohen</u>: Good morning, my name is Michael Cohen and I am the Executive Director of the National Alliance for the Mentally Ill. I am here to speak in favor of the amendment to House Bill 1218, and this is the current amendment the Representative Patten just proposed. However, I would like to suggest that you consider some of the additions to that amendment or some other considerations, and I will turn those in to you in a written form after my oral testimony (See Attachment # 8).

I commented on some of the similar comments to the hearing that occurred yesterday for the DHHS, Rules and Regulations Committee heard my testimony on this same issue around prior authorization. In the Patten amendment, I believe it is lines, section 13B, lines 15 through 18, which my, I will speak to that section.

As an organization that is made up of family members and consumers, we are very interested in this issue of prior authorization. And, we want to make sure that the citizens of New Hampshire who are on Medicaid insurance are entitled to the most efficacious and have as much open access to medications as any other citizen not on Medicaid insurance.

(See Attachment #8).

<u>Senator Russell E. Prescott, D. 19</u>: Any questions? You mentioned that you don't want on the prior authorization, you do not want to force the use of alternative drug (inaudible)?

Michael Cohen: That is correct.

Senator Russell E. Prescott, D. 19: What is the criteria to that, your stand?

Michael Cohen: There are many... using anti-psychotic drugs is an illustration. There are new medications, I need to say there is no anti-psychotic medication on any prior authorization list now, and we hope it would stay that way. As an example, the older medications called nerolemkis have many more adverse side effects that athlough they may be efficacious in eliminating the symptoms of the illness, he side effects tend to be permanent. You may have seen persons with mental illness who sometimes have movement disorders; some of those movement disorders are caused by these older medications.

The newer medications do not have that kind of effect any longer. So, although the newer medications take care of some of the positive symptoms, they do not have these negative side effects. In addition, many of the new medications take care of a broader range of signs and symptoms than the older medications do. So, we wouldn't want someone, a family member to go through that older medication, even though it might be less expensive with the possibility of getting negative side effects; we would prefer that the newer medication, more efficacious medication be used.

Senator Russell E. Prescott, D. 19: If Representative Patten's amendment did not come before this Committee, would you have had a opportunity to speak publicly, your opinion of prior authorization as a state policy?

<u>Michael Cohen</u>: Yes, we were given opportunity and the draft rules that came out back in November, I think. We did write to the Commissioner and to Doctor Kesslier, and notified him of these similar concerns.

<u>Senator Russell E. Prescott, D. 19</u>: Do you feel as though that was a fairer hearing than what you are hearing today and bringing it before the legislature of the state?

Michael Cohen: I think it was as fair.

Senator Russell E. Prescott, D. 19: Any questions from the Committee? Thank you for your testimony.

Michael Cohen: Thank you.

Senator Russell E. Prescott, D. 19: Cinde Warmington?

<u>Cinde Warmington</u>: Cinde Warmington; I'm from the law firm Shaheen & Gordon and I have retained to represent Purdue Pharma, the maker of Oxycontin, which is now subject to prior authorization under the Departments current policies and procedures. I have with me today, Doctor Cherylynn Griffin, she is here in the audience; I would like for her to be able to speak after I finish here.

We are here in opposition to this amendment. This amendment as proposed and already implemented allows the Department of Health and Human Services to inappropriately limit the access to medically necessary medications. At the outset, we would like to say that we are not talking about generic substitution here. We are not talking about substituting a clinically equilvalant medication for another medication. Purdue Pharma has no objection to generic substitution. In fact, Purdue Pharma is the maker of another medication, MS Contin, which is subject to the generic substitution under the Departments policies; we do not object to that.

What we do object to are policies and procedures that deny access to medications that have a clinically meaningful therapeutic advantage over other medications available to patients. We would like to start with a short discussion of prior authorization in general. There is no evidence that prior authorization saves money overall. There is plenty of evidence that prior authorization will save money on prescription drugs but no evidence the by restricting access to medication, that you will not increase the over all cost, Medicaid cost to the program resulting from increased Doctor office visits, hospital emergency room visits, and other unintended consequences.

In fact, studies show that that increase in overall cost is exactly what happens when we arbitrarily and inappropriately restrict access to medically necessary medications. In 1981, New Hampshire undertook a program where it attempted to limit its Medicaid expenditures by limiting the access to prescription drugs. The program limited Medicaid beneficiaries to 3 prescriptions per month. This experiment took place for a period of 11 months and was then suspended.

In the 1990's, this experiment became the subject of 2 New England Journal of Medicine articles, which demonstrated that the overall cost to the Medicare program increased by great multiples as a result of the restriction to prescription drugs, and it was an utter failure.

This program does not arbitrarily limit access to drugs in that same way. However, it does arbitrarily, and allow the Department to arbitrary limit access to drugs that have a clinically meaningful therapeutic advantage over other drugs. With respect to Oxycontin, the Department has already implemented the prior authorization; we don't need to speculate about what the Department might do in this case. In this case, the criteria for allowing someone access to Oxycontin requires either that the patient have cancer, be in an acute sickle cell phase, or have failed on 3 other narcotics.

It is this requirement that a patient fail on 3 other narcotics that we object to. The failure on 3 other narcotics before being allowed access to Oxycontin is not supported by clinical data, it places patients at risk, and it restricts access even when there is a distinct clinically therapeutic advantage to Oxycontin; I am going to let Doctor Griffin speak in more detail to that.

We suggest that if there is a prior authorization in place, there need to be appropriate safeguards. These safeguards would include that the Pharmacy and Therapeutics Committee, which considers which drugs are to be restricted, be appointed by independent, professional organizations, as well as the Commission. For instance, members appointed by the Medical Society, by the Pharmacist Association, other professional organizations as well as the Commissioner's Office. We also request and expect that an appropriate process for listing drugs for prior authorization, and the criteria allow for meaningful public input.

The process that the Department now has in place, or it has proposed allows for the public to submit written comments to the Committee. In fact, when the criteria that are currently in place were developed, no public input was sought. Additionally, if the Department is going to subject medications to prior authorization, there needs to be some standard of what they can restrict. We suggest that that standard be that a drug can only be restricted if it has no clinically therapeutic advantage over another lesser-cost drug.

In this case, in the case of Oxycontin, as I said, we don't have to speculate, we know what the criteria are that the Department has proposed, we know that they are clinically inappropriate. Doctor Cherylynn Griffin works for Purdue Pharmaceuticals; she is a Doctor of pharmacy, she is a Professor at the Mass College of Pharmacy, and prior to joining Purdue, she worked at Brigham

and Women's Hospital on the pain and management specialty team. She is here today to speak to you, specifically, about the criteria that is in place and why that criteria is inappropriate. Thank you for your time.

<u>Senator Russell E. Prescott, D. 19</u>: Do you believe then, that this policy decision before us would be targeting certain drugs as, to implement a program, it would say try 3 others first, and therefore targeting certain drugs that are expensive, what is your opinion on this?

<u>Cinde Warmington</u>: It is unclear to me what criteria the Department uses in selecting which drugs to prior authorize.

Senator Sylvia B. Larsen, D. 15: Would you not consider Oxycontin, a well-known drug, to have a high potential for misuse or abuse, it tends to be a high cost, and in fact, wouldn't you agree that it should be monitored for its appearance to clinical protocol knowing Oxycontin's reputation and usage, pharmaceutical wise?

<u>Cinde Warmington</u>: I'm going to forego questions about the clinical addiction potential of Oxycontin to Doctor Griffin. But, to say that Oxycontin has been abused, it certainly has been in the press, I think that we can all say that, that it is a drug of abuse as are all narcotics. It is not the most abused narcotic in the state of New Hampshire. But, it is a drug of abuse, it is attractive to abusers and it is an issue that is of great concern to Purdue Pharmaceuticals. The problem here is...to a drug that has truly been a medical breakthrough for patients who need it.

Restricting access to all of those patients as a means of preventing abuse is inappropriate. Doctor Kesslier's testimony before the Joint Legislative Commission... he testified... a Committee on Rules... he testified that one of the factors that they considered in selecting Oxycontin was that about 20 % of the patients who they looked at had an A typical psychosis as a diagnosis for Oxycontin, and that that was inappropriate.

We would say under those circumstances, are using a sledgehammer to kill an ant here. I mean, shouldn't you use a more appropriate and targeted program to target abuse rather then restricting access to the 80% of patients who have an appropriate diagnosis. Understand that we have heard from patients, this program didn't just all of a sudden say, Doctors, when you are treating a patient, you need to consider these factors. These are patients that were well managed on Oxycontin, and in some cases, for years, and are now being told; you have to fail on 3 other narcotics.

And, failure means that the side effects for these patients are so severe that they can't tolerate it or that they are in pain, breakthrough pain throughout the day, and that is what we are putting people through. Make no mistake about it; this is a very serious issue. It also requires that a patient that is doing well on Percocet or Perkadium, that all of a sudden they're pain is more persistent and they need a long-acting narcotic, the physician can not move them to Oxycontin, the only drug that makes any sense, it is the same active ingredient, patients tolerating this one well, it clinically only makes good sense to move them to it.

This program fundamentally changes the available options for physicians. Oxycontin is a miracle drug for many patients, and that's why it has been so popular, that's why it is used so much because it has very few side effects and it is able to address patient's pain. And, I have overstepped my bounds on speaking to the pharmacology issues.

<u>Senator Sylvia B. Larsen, D. 15</u>: Would you not agree that in fact we have under most people's health insurance plans, a restriction of access to certain medications, a preferred list. Would that not be the case that we are already existing under certain restrictions, those of us who have health insurance?

<u>Cinde Warmington</u>: Yes, and that's called a formulary. Most programs have a formulary where they list the medications that are available. Under federal law, the state of New Hampshire could devise a formulary and the law provides for that. But, if they were going to do that, they can not exclude a drug from a formulary if it has a clinically meaningful therapeutic advantage over other drugs. That is exactly the standard that we have promoted here.

Senator Sylvia B. Larsen, D. 15: Further question?

Senator Russell E. Prescott, D. 19: Certainly.

Senator Sylvia B. Larsen, D. 15: Has the state of Florida not created a preferred drug list, and in fact has restricted access through it's own program?

<u>Cinde Warmington</u>: I have no idea what's going on in the state of Florida. I can speak to other states who have tried to, who have had First Health as their pharmacy benefits manager, and who have proceeded down a path similar to the state of New Hampshire in attempting to restrict access to medication. And in some of those states, they have already backed off of that and have found that that is just not simply working for them, South Carolina is a good example. The state of Pennsylvania recently put in a prior authorization that doesn't require patients to fail on 3 other narcotics. The state of Maine initially had a much more restrictive prior authorization and found that that did not work.

Senator Russell E. Prescott, D. 19: So your presentation here is that you would like to change the make-up of the Pharmacy and Therapeutic Committee, which drafts the lists of those drugs to be allowed in the preauthorization program?

Cinde Warmington: Yes.

Senator Russell E. Prescott, D. 19: You also wish to have more public input for that preferred drug list? How would you implement that?

<u>Cinde Warmington</u>: We actually have a draft amendment in process here that we would be happy to provide to the Committee. The public input process would allow for public hearing, which allows notice and an opportunity to be heard.

Senator Russell E. Prescott, D. 19: The same question that I asked of Michael Cohen was...I believe it was Michael Cohen... do you believe that this is the first time that you have really had a public hearing before the legislature to express your concerns over the implementation of the Pharmacy Benefit Management Program?

<u>Cinde Warmington</u>: It is the first time before a legislature policy Committee. Prior to this we have spoken with respect to the rules. And, in fact, I would like to say that we have made the suggestions, the suggestions that we have made here today, we have already made both orally and in writing to the Department, and these suggestions have been rejected.

<u>Senator Russell E. Prescott, D. 19</u>: Any other questions from the Committee? Thank you.

Cinde Warmington: Thank you.

Senator Russell E. Prescott, D. 19: Cherylynn Griffin?

Cherylynn Griffin: Good morning Mr. Chairman and members of the Committee. My name is Cherylynn Griffin; I am a medical liaison with Purdue Pharma. And, I hope to take only about 5 to 7 minutes of your time this morning to talk about the clinical criteria for the authorization of Oxycontin. As you may or may not know, managing a patient's pain can be extremely challenging.

And, when a physician is making a decision to use a narcotic... and I will refer to a narcotic as an opioid...when he or she is making that decision, the physician recognizes that different patients respond to different opioids in different ways such that their pain relief may be different on different opioids and the side effects that they experience may be different. So, when a patient is well managed on an opioid such as Oxycontin, it does not make clinical sense to disrupt this therapy and force the patient then to fail other opioids.

I need to draw your attention to point number 3 for the clinical criteria for authorization, which is failure on 3 other narcotics. This criteria further complicates the physicians ability to manage a patient's pain effectively. When a physician assesses a patient who is in pain, he or she determines if the patient is experiencing intermittent pain or persistent, constant pain.

For those patients who are experiencing intermittent pain, it makes clinical sense to provide them with a short-acting pain medicine like Percocet. However, when the patient has constant pain, it no longer makes sense to force the patient to take a short-acting medicine because that forces the patient to go in and out of pain, cycling constantly throughout the day and also throughout the night-time hours.

When the physician then decides that it is appropriate for a patient to receive a long-acting opioid, currently there are 3 commonly prescribed medications that can be used for this, and again, patients will need to fail 3 other narcotics. The 3 that are currently for use is the Fentanyl Patch, long-acting Morphine, and Methadone. Each of these has it's own problems that need to

be considered. Beginning first with the Fentanyl Patch, according to the American Pain Society guidelines, they recommend that if a patient can swallow a pain medicine that the oral route of administration is preferred. Therefore, the Fentanyl Patch is most appropriately used in patients who can not swallow. Another concern regarding the Fentanyl Patch is that it has a relatively long half-life, and what does this mean.

Well, it means that if a patient is on the Fentanyl and the physician decides to transition this patient because of side effects, for example, onto a different opioid, that this product, the Fentanyl Patch, will remain in the patient's system for up to 3 to 4 days, this is going to complicate the dosing of the new opioid that the patient will be placed on. If we look at long-acting Morphine, Morphine is not appropriate in patients who are renally impaired, meaning that their kidneys are not working the way they once did.

Whose is renally impaired? We need to be concerned about the elderly population, our older adults because as a factor of their age, their kidneys don't always work the way they once did; so morphine in that case would not be appropriate. Morphine would also not be appropriate in diabetic patients, if diabetes has impaired their kidney function. Our last choice, which is Methadone, this is a product that many physicians are not comfortable prescribing. And, the reason for that is because it has a very long half-life and really requires training in the dosing of this product for the safety of the patient.

This long half-life again, can force this drug to accumulate in the patient's body and place the patient at a high risk for side effects. So you can see, alough there are other options available for a patient who is not allowed Oxycontin, there are serious concerns and problems with the other choices that are available. Another concern that I have regarding the failure on 3 other narcotics requirement under the current criteria, is that if a patient is maintained on a short-acting opioid, one that the patient is tolerating, for example, Percocet. Percocet, the active ingredient is Oxycodone. It does not make sense that if the patient has constant pain, that we not allow that same active ingredient that the patient has tolerated to be continued in the form of Oxycontin.

So in short, the clinical criteria for the authorization of Oxycontin is greatly limiting the patients access to a product that has proven to be beneficial to thousands of patients who suffer from chronic pain. Thank you.

Senator Russell E. Prescott, D. 19: Thank you for your testimony. Any questions from the Committee? Thank you very much for your testimony.

Cherlynn Griffin: Thank you.

Senator Russell E. Prescott, D. 19: Commissioner Donald Shumway?

<u>Donald Shumway</u>: Good morning Mr. Chairman, members of the Committee. If I could pass out my testimony, I will get started (See Attachment # 9). I appreciate the opportunity to talk with you. This is an extremely important subject, and one, which I believe, represents a fundamental policy decision for this General Court, and ultimately, extremely important polices for New Hampshire as a whole.

This is not a small matter, this is not a technical matter; it is a matter of basic access to services questions. It's a matter of basic control capability; it is also a matter of tax policy for this state. You have asked us to manage a program, you have given us specific instructions in managing that program, and we are doing it. We have before you, the fundamental questions of whether or not we should proceed in doing that, and I appreciate the opportunity to testify to that purpose.

In testifying before you this morning, I have with me some other members of the Department. John Wallace is here, an attorney with the Department, and I would hope that he might be given an opportunity to speak briefly to the latter amendment that is being considered. Also with me is, our clinical and management team from the Medicaid program, Laurie Reel, it's Director, Doctor William Kesslier; our medical Director, and Peg Cliffant; our Pharmacist.

The amendment that is before you really has 2 portions. One specifically speaks to rules, and the other speaks to an annual report that the Department would submit to you on quality and cost issues in relation to the Pharmacy Benefit Management Program. I am here to testify in support of the annual report and in opposition to the rules component of the proposed amendment. So again, I want to be clear, we are not opposed to an amendment, we are definitely not opposed to working with you on the content and direction of this policy. But, we believe that the regulatory portion that is in this rule-making is flawed, and would in fact lead to the defeat of the efforts that we are trying to undertake at your direction at this time.

The Pharmacy Benefit Management effort that we are engaged in, as Senator Larsen indicated, is one that is widely used to improve quality and to control

costs in health plans. Pharmacy Benefit Management can reduce medication errors, prevent fraud and abuse, can assure careful control of limited resources, and it can moderate the effects of manufacture marketing. In New Hampshire, Medicaid would began work in Pharmacy Benefit Management with an initial implementation done by our vendor, EDS, per our directions upon February 2001. We expanded implementation in regards to First Health's contract in November of 2001.

We engaged in extensive legislative testimony on Pharmacy Benefit Management, and prior to any implementation. And, I have just listed the Finance Committees only, we also testified extensively to the Policy Committees. In September 2000, on the 2002,2003 agency budget submission, we talked about the necessity under the escalating cost of the Medicaid program to look at a Pharmacy Benefit Management effort. November 15<sup>th</sup>, we again testified as to that effort. On March 5<sup>th</sup>, we presented to the full House Finance Committee and included a chart about drug expenses and PBM. There were no questions by the way, from Committee members.

By the way, these are all straight from notes that we take from the different hearings, and so I just lifted them precisely. On March 17, our Office of Community Public Health testified before House Finance Division III on Pharmacy Benefit Management, again, listing exactly what we are doing and providing certain overhead slides which I have included in this presentation; there were extensive questions about it.

On March 19<sup>th</sup>, we submitted to Senate Finance, included a chart. Again, these charts on Pharmacy benefit Management. Senator Barnes and Senator Larsen asked us questions about it. On March 30<sup>th</sup>, again, more prescription drug discussions with House Finance, Division III. On May 16<sup>th</sup>, Senate Finance questions, including questions from Senator Boyce about it. I want to be clear that we have been very up front and very open in working with the public on this effort.

I would like to talk a little bit about our Senate Finance testimony, if I may. On March 19, 01, we talked about Department of Financial Management during the education crisis, that is we had a enormous tax constraint that the state was facing and enormous resource constraint. We had to make existing programs work or we were not implementing new programs. We had to contain costs and we had to generate revenues. And by the way, those are the policies that we have continued to implement, obviously as this biennium has gone underway.

The next page, I think is important because we specifically furnished this slide to the Finance Committees saying, here is one of Medicaid cost control efforts in relation to a Pharmacy Benefit Manager. And, what it did was track the pharmacy expenditures under the Medicaid Program and demonstrated the excellerating rate of growth in the pharmacy area; and that that rate of growth, which is currying out about 20% per year level, had to be tailed off if we were to hope to have the ability to implement the Medicaid Program near it's actual appropriations level.

And in fact, what we were suggesting was that with a Pharmacy Benefit Manager, we would attempt to lower the rate of growth in the Medicaid pharmacy area instead of the 20 plus percent level that is occurring in the general market place to closer to 10% and indeed that we had to do that. If you look at the next page, you will see our actual and projected experience in the Medicaid cost trend area. And you may recall that I said we began an initial implementation working with what I call PBMA here; this is an initial set of controls on medication availability and it began to taper off some of the rate of growth and that is basically the purple line there that shows that we are starting to slow the rate of growth.

And then, as we went to the First Health contract, we have been able to slow the rate growth further. It is still growing, it's growing at about 6.74% but it is growing far less than the 20 plus percent that the industry overall is showing, and what are earlier our efforts would have been able to achieve for us. I would also like to point out that next year, our Medicaid budget is also very constrained and we will have to continue this effort in order to show any ability to live within our budget or close to it.

The basis for these saving are that we are trying to reduce things like multiple medication filling, that an individual would have essientaly identical prescriptions going to perhaps two different pharmacies. We are trying to reduce drug to drug interactions. It gives us inability for much better clinical control, looking at things such as drug to drug interactions, and we have already been able to demonstrate substantial reduction in areas such as this.

We have been looking at trying to reduce the excessive duration of addictive substances. Basically, substance abuse is a serious issue with prescribed medications. We are also, the state agency, charged with the responsibility of substance abuse prevention and treatment, we take this responsibility very seriously and we have been attempting to reduce the impact of addictive substances. Quantity management, for example, how much would be available for a given day supply. Often, we had been seeing that quantity management was not coming in appropriately in prescriptions, we now have

the ability to control that. Therapeutic duplication, two prescriptions doing essentially the same thing. Early refills, the same thing. We have been able to also show improvements in, for example, checks on patients age and the relationship to a medication, for example, a very young child getting a medication that is not appropriate for a young child.

We have been able to restore Medicaid as a payer of last resort, this basically brings us back into compliance or conformance of how all of the other states in the country exist, where if someone else has another source of insurance, that it would get billed first. We have been able to improve on a one-time basis cash flow, switching from weekly to bi-weekly payments. We have been able to implement, as you have heard, extensively, prior authorization based alternatives. By the way, this is .4 of 1%, 4/10ths of 1% of all Medicaid prescriptions are prior authorized; this is a tiny, tiny percent of the Medicaid Program and a tiny percent of what PBM is all about.

We have been able to increase the use of generics and we have been able to begin the use of state Medicaid allowable cost limit effort. The last page gives you the numbers. You are talking about a program that as you can see in the top column under state fiscal year 02, estimated, by the end of this year, we expect to expand about 93.9 million dollars on medications under the Medicaid program.

It is not like we are saying that no medications can be made available. We are paying for over 90 million dollars in medications this year that had grown from about 87 million dollars in the prior year. If we had not implemented the two efforts of Pharmacy Benefit Management, we would be spending about 16.8 million dollars more this year. Just the First Health contract alone, its portion of that is better than 7 million. And, we are just getting the March numbers added in, and it does look like it is staying consistent with that rate of savings, and in fact, maybe slightly greater.

Next year, we need to save even more because of the budget condition. For us, if you compare that with what we would have been spending if we would of allowed the uncontrolled pharmacy program to move forward, it would have been more than 110 million dollars this year; we don't have that money, we don't have it and it did not seem to be likely to be forthcoming.

We have three choices here, either we can come back to you for tax increases, 16 million dollars, or we can kick people off the Medicaid roles putting them into a uninsurnace level, giving them no medications furnished by the state, no other healthcare either furnished by the state... and, by the way, just the value of the First Health contract has over 7 million dollars this year, that is more than 14 hundred people that we would have to kick of the Medicaid

rolls if we reduced eligibility...or we can institute quality and cost controls in the program and that is what we have done.

We did it after extensive testimony to House and Senate. We did it after extensive public hearings in the House and Senate. We did it after extensive informal and formal meeting with virtually all of the stakeholders that you will have before you... and I believe Mike Cohen from NAMI acknowledged that he had an opportunity to testify... we meet many times with pharmacists, we meet many times with physicians groups, we meet many times with all groups that wanted to work with us on this topic.

By the way, is it a perfect program, no it's not, and I don't want to sit here and tell you there is any perfect program, but when you look at what was going on in the Medicaid program, and you look at the resources that we had available, this is the best alternative by far for meeting the needs of people who are uninsured, otherwise, who are very indigent, and who need this healthcare. If we were to simply remove 14 hundred eligables, they would become uninsured, they would still go to emergency rooms, they would still need surgeries, they would still need doctors, and all of that would kick onto employer based premiums and just keep pushing up the cost of what business's are paying for healthcare.

Instead, we have done the responsible thing, which is to control the cost in the Medicaid program. We are authorized to do that by law. We are also, I believe, expressly authorized to do it by budget after extensive testimony in the Finance Committees. In state and public law, we are told that prior authorization and PBM is an allowable and appropriate administrative tool for the Medicaid program. We are told expressly in state law that we are to make maximum use of generics. We are told expressly in state law that we are to develop and implement management systems in relation to the Medicaid pharmaceutical program that will achieve those objectives.

That is what we have based our effort on, in law and federal law. I will admit that federal regulations are somewhat more extensive than everything you could possibly imagine in this area. And yes, we are also in conformance with federal regulation. In doing so, we have engaged in extensive public discussion. Could there be more, of course there could always be more, and in fact, it is ongoing. In the last weeks we met again with the Representatives of Purdue Pharma, and Jon Wallace, I believe, met with them last week.

They stated that we have rejected their concerns, we haven't rejected anyone's concerns. We maintain an open ear to all concerns. And in fact, we have continued to modify the program as we have been implementing it, as was noted earlier, we have relaxed some of the prior authorization approvals.

But, we also take serious our responsibilities to save money, improve quality, and avoid the disruption to society that can and does occur.

When you look at the cost studies that are described to you, please ask them, when they said that Pharmacy Benefit Management didn't take consideration of all costs, if their studies did. Ask them if their studies looked at the individual cost of addiction, it ruins lives and it kills people. Ask them if their studies looked at the impact on families of what happens when a young person in a family gets out of control, addicted and driven by an addictive medication. Ask them if they include the cost of police of investigating drug store robberies, and the cost to the state of New Hampshire of imprisoning people for that. I doubt if they have included those costs and they are important to consider.

The Union Leader, published on September 27,01 a description of Oxycontin robberies proving a major concern in our society (See Attachment # 10). While we are all worried about bio-terrorism, what we are also seeing was that the impact of this medication, this very addictive medication was becoming a major problem for our state, and it has continued to be so with additional drugstore robberies in other parts of the state reported, every few weeks, you see yet another one. These are important issues and they are part of our responsibility to manage, we take those issues very seriously.

I would also like to indicate to you that we take seriously the responsibility to make sure that people have their healthcare needs met. This week we will be having a conference on evidence based practice in mental illness, where I will be speaking, where many others are being brought into the state to help us with this. We are working on what are called disease management related programs. We sought after and were able to gain a federal grant to help us establish am asthma disease management program. We are working in other areas...and in fact, are included in the First Health contract, that they would help us with disease management programs. We take those initiatives very seriously, they are underway.

But, I also need to be clear, they are very costly and they produce savings gradually. And, the studies that say they produce large amounts of savings, are typically not with Medicaid patients, who can be very difficult serve and provide support to in making sure that they adhere to those various regiments. I would be happy to answer questions that you may have. And, again, would indicate that John Wallace would like to speak briefly to the amendment and that other staff from the department are available, and certainly, Doctor Kesslier, Peg Cliffant and others on a detailed clinical basis, are far better than I.

Senator Russell E. Prescott, D. 19: Thank you for your testimony. I understand that it is very prudent for purchasing practices to be developed because of increase of cost of the prescription program that Medicaid has. And, you mentioned that, a whole page of legislative testimony...really, I was in one of those, I believe, during my training as part as part of the Public Health and Human Services, I do not consider that testimony on a policy before a policy making committee, it is not respected to a bill that would of become law to allow something of this nature to take place. I believe that right now, that you are in violation by going into a prior authorization program in November, of any policy allowed by this state, to allow you to go ahead and do that.

**Donald Shumway**: May I ask a question?

Senator Russell E. Prescott, D. 19: Sure.

<u>Donald Shumway</u>: Does that include a review of RSA 126, and its specific requirements that we establish a generic pharmaceutical basis for our prescription of medications and arrangement system on that.

Senator Russell E. Prescott, D. 19: What it does is, it brings me up to a question like this...Whenever my father says, how are things going, and I ask for something more when I was a child, he used to say that, didn't I take care of you last week with something, well, I'm asking what have you done for lately...that is kind of where this is...What have you done lately is, you have already implemented by law, all of those things, substitution of generic drugs is by law; public policy has gone through those things. But, lately what you have done is you served that, and even in your own public testimony this morning, you said, "at our direction at this time, we want to move forward with prior authorization".

It was inappropriate for you last fall to move on that, whereas today, we are saying that we want your lead. And, this is just my point, that you got out of step with the system. And if you don't think that you are out of step with the system, then my question is, why is this amendment before us by Representative Patten, who is the Vice-Chair of JLCAR, she brought those very points to us with what is the purpose of JLCAR. And, the purpose of JLCAR isn't to make public policy, and they think that this was a public

policy decision that was made in November, November 1st, and implementation of this program.

I'm not objection to the implementation of the program. I'm objecting to the user patient of the authority of this body to oversee these types of policies that are going to be helping the state survive a pharmacy cost crunch in structure. And, when you come before us and say that you had plenty of testimony before the legislature, it's just what you have told the legislature. I was there at one of them, it wasn't really an interaction to say that, are you sure that you know what you are doing, are you sure that this is a policy that the state wants to take place; it was an assumption by some federal law that this was going to be the policy, and I object to that, and I think that is why we are here.

So, I have a question... if you know the national conference of state legislatures has many, many topics of things they talk about, and they say that the only way that this type of a program is going to get accomplished is number one, that you have political will to get it accomplished, and I believe that we need that political will to get it accomplished, and number two, no legislative restrictions. And, I believe that no legislature restrictions is going to be done in two ways. One is get permission from the state, from all of the House members, all the Senate legislatures, and from your Governor, or just bypass it. So, my question is, did you purposefully do this, or is this just some kind of a thing where I am just being blind sighted with lately?

<u>Donald Shumway</u>: My answer to that is, I purposefully testified more than seven times before the Finance Committees alone, and I testified before the policy committees, and I testified before joint committees of House and Senate on PBM. How many times do I have to say, this is what we will have to do before people will understand that that is what we believe we have to do.

Senator Russell E. Prescott, D. 19: I believe that you could of done that through the interim JLCAR rules, or emergency JLCAR rules, and I think it would of come to head far quicker. Now, you are asking this committee, in three weeks to make a public policy decision that can not even be heard by ED&A in the house.

<u>Donald Shumway</u>: Actually, I'm not. I'm not actually asking you to do that. We implemented...

Senator Russell E. Prescott, D. 19: You put us in that position.

<u>Donald Shumway</u>: No, I did not, Sir, if I may. We meet with stakeholders extensively through the spring, summer, and fall. We held public hearing; yes, we were working very hard and very fast and doing many other things at the same time, and in doing so, we then brought the rules before JLCAR. Those rules have been commented on by JLCAR staff and JLCAR members. We have listened to that comment, we have adopted wherever possible, those comments, and those rules stay tabled in JLCAR.

What I need is for JLCAR to pass the rules. We believe those rules are authorized. We believe that we have testified and meet with the public many, many times. And, we believe that you have established a combination of statutory and financial policies that say do this. I am happy to report on this, I am very glad to be able to do that.

I think that conclusion as an amendment is a good thing, and I would like to testify in support of that. But, I believe that it would be absolutely wrong to insert that regulatory language because it would imply that we are not currently able to implement the program under rules. And, I believe you will see the folks who, I assure you have more lawyers than you can imagine, would come at us with litigation in this area, would attempt to suspend the program, and the cost impact of that on the state budget would be very sizeable, that should not be done.

Senator Russell E. Prescott, D. 19: Further question, the implementation of the program that you had done in the 1<sup>st</sup> of November, that was termed as prior authorization?

<u>Donald Shumway</u>: No, with pharmacy benefit management, but we do have 4/10 of 1% of the claims going through prior authorization.

Senator Russell E. Prescott, D. 19: Has there been a cost savings since that implementation that is shown on your charts that didn't have the public policy hearing on that point .4%, this program where you generate a list to force people to try 3 other drugs before they get back onto their preferred drug?

Donald Shumway: Very minor cost savings. The primary importance of prior authorization in that particular, Oxycontin, is quality issues, that is, we believe that Purdue Pharma has manufactured a drug which is highly addictive and it's in a form... they produced in a form which makes it abuseable; that is a problem that they need to correct, and I hope they do. And, we value that medication and want it to be available to Medicaid recipients in this state. But, when we are seeing not an ant of a problem of 20% of the Medicaid recipients having mental health diagnosis, primarily of depression, and A typical psychosis as being the prescribing reason for them.

This is a physical pain medication, it is not appropriately prescribed for depression or A typical psychosis, and that was a real problem and it was a problem that we believe, was potentially leading to serious addiction, serious abuse, and ultimately, individual family and community disruption. And, we had to step in and stop that, and we are doing that, and I hope you will support us in continuing to do that.

Senator Russell E. Prescott, D. 19: The second question is, the lock-in is a part of this amendment, what are the cost savings for the lock-in, can you describe those?

<u>Donald Shumway</u>: We have not implemented lock-in. It is an allowable provision under the contract and statute that we have, but we gone forward with implementation. We are holding off, making sure that we understand people's concerns, making sure that the rules go into place, finally, making sure that we have clarity on what should be there. We, presumably will implement it at a fairly low level; it is not a common tool that is used, but it is an important tool.

Senator Russell E. Prescott, D. 19: For the first part of implementation, do you have a certain amount of cost savings since November 1<sup>st</sup>or 2nd? And, if you had public policy accomplished with political will behind you and no legislative hurtles to overcome, like today; could you of implemented the complete program, the lock-in program, at that same time?

<u>Donald Shumway</u>: I'm not sure I understand your question exactly, I apologize but...

Senator Russell E. Prescott, D. 19: I know that I am very confusing, my wife always tells me that I don't make any sense.

Donald Shumway: Could I ask for that one more time please?

Senator Russell E. Prescott, D. 19: The question is, again, comes back to you...my opinion, that you didn't do your job properly by coming before the legislature and getting all you needed to save the state as much money as possible in managing our pharmacy costs, you didn't do that. My question then becomes, is if you had, and then on November 1st, able to fully implement this program knowing that everybody is behind you, what more cost saving could we of had?

<u>Donald Shumway</u>: Well, as I said, the lock-in program is a very, very small program; it is also not done primarily in relation to cost savings. It's really a quality issue like with prior authorization of Oxycontin. It would not have produced significant savings.

<u>Senator Russell E. Prescott, D. 19</u>: Then the rush now to implement the lockin program isn't really a rush for savings of cost for the state of New Hampshire?

Donald Shumway: It's a quality issue.

Senator Russell E. Prescott, D. 19: It's a quality issue. Senator?

Senator Sylvia B. Larsen, D. 15: Did I hear you say that First Health has already saved the state 7 million?

Donald Shumway: Yes.

Senator Sylvia B. Larsen, D. 15: Am I right in believing...

<u>Donald Shumway</u>: Excuse me, my apologizes, that is what the expected annual savings will be for this fiscal year, my apologies.

Senator Sylvia B. Larsen, D. 15: Am I right in believing that persons who are privately insured have some restrictions even on their own abilities without pushing very hard, do they not have some drug restrictions, is there not a standard formulary for many people who are insured through private insurance, as a cost control measure?

<u>Donald Shumway</u>: Yes, indeed. And, certainly that would be true, for example, in the state employee's health plan. It is true in most of the employer-based programs.

<u>Senator Sylvia B. Larsen, D. 15</u>: Have there been formulary or a preferred pharmaceutical benefits program for Medicaid receptients prior to this or was there restriction on the pharmaceuticals available to Medicaid receptionents prior to this?

Donald Shumway: There had not been substantial restrictions prior to this.

Senator Sylvia B. Larsen, D. 15: So, a person who is paying their own insurance has restrictions but a person who had been in the years past on Medicaid, could basically get any prescription without any listing of regulation or any restrictions other than...I mean, there was no formulary or no preferred benefit, preferred pharmaceutical list for those Medicaid recipients, is that correct?

<u>Donald Shumway</u>: That is correct. The list that I went through, one of the components of the basis for saving, those things are not available in relation to the Medicaid program. And what had happened was that when I came into the Department, the pharmacy costs had been traveling at a rate of inflation that was serious.

My first testimony before House Finance in the 1999 legislative session, I testified, I remember, in response to questions by Representative Kurk as to what we would do about that. That we needed to begin looking at pharmacy benefit management as being a necessary control in relation to that area. And, that than lead us to those first efforts that did start the slowing down of the rate. And the, after the full legislative session, where we brought the

much more extensive testimony of our intent to do PBM, what it would be about and so forth before them; that is when we moved forward with the First Health contract for July 01, and were able to more completely implement it and do what we had to do.

Senator Sylvia B. Larsen, D. 15: Have you heard about the Florida pharmaceutical benefits program which was instituted not long ago under President Bush, that in fact has saved the state of Florida significant amounts, and it is in fact more restrictive than what is being proposed in New Hampshire in terms of prior authorization, you know, the kind of approved list. They met...I understood... with pharmaceutical companies to negotiate the best price, and they in fact have quite a few medications not on that benefits list. Currently there is some reaction from companies, but it has saved the state of Florid. Have you heard of that program?

<u>Donald Shumway</u>: I have. Also have reviewed the litigation that was filed against it a couple weeks ago. In addition, I reviewed the cost saving and there are elements of it that seem very promising. There are some other elements that we are not engaged in that look like they maybe of concern.

The way in which they went about disease state management is pharmaceutical manufacture specific so that they have contracts with individual manufactures that ultimately are leading to such a huge escalation of that manufactures drug sales under the Medicaid program in Florida, that the savings that those manufactures are claiming in relation to Medicaid program, are dwarfed by their marketing success and the sales that are going on in the program.

Senator Sylvia B. Larsen, D. 15: That was really a side kind of benefit that they provided which was we will do a preferred drug list with you and then we will also try to manage some diseases and we will use our own medications to do that.

<u>Donald Shumway</u>: So, we have not engaged in that side set of contracts with them; we feel at this time that that would not be appropriate.

Senator Sylvia B. Larsen, D. 15: You stated that RSA 126, in fact...and I don't have the law in front of me...but that in fact encourages and requires the department to seek management systems in pharmaceutical

savings...I don't know quite what it said...So, under that authorization would you not in fact, would it not be reasonable for you to bring rules which implement what that law said? And, you in fact did bring to each the of Finance Committee I sit on, and as you said, the policy committees; an outline of the kinds of rules that you were thinking of doing.

But, it's not normal, is it, as a Commissioner, to bring a rule, a list of rules and a review to a policy after you have been authorized by law to implement the savings. I am assuming that you believe what you did was reasonable in following RSA 126, and then implementing the rules to seek the savings that we are trying to accomplish without tax increases?

Donald Shumway: It is that legislative direction that we are following. And, I only want to work with JLCAR. I only want to follow their process. This is not a question about whether or not we had any desire to not respect that process, that is not the case. But, the people that were writing the rules, were the same people who were trying to figure out how to run the public health lab shifts 20 hours a day in September, October, and November, and they are the same people that were educating the hasmate responders, Doctor Kesslier, in how to handle various situations that they might get in, the same people meeting with the hospitals and doing the surveillance of diseases during those months.

And, I want to be clear, they are extraordinary people, they did an extraordinary job, and they did an extraordinary job with this and it is successful. And the fact that they are continuing to be berated for their efforts, I think is inappropriate and sending an absolute wrong message about saving money and making sure that the taxpayers dollars and the state are protected. And, I urge caution to the Committee to not send the wrong message on this, please.

Senator Russell E. Prescott, D. 19: I have a question, the law states implementing cost savings, are there some decisions that you make that you believe that should not be made just based on a cost savings but also should have an overview of the legislature?

Donald Shumway: I believe that there should be an overview by the legislature and that is why we welcomed the reporting process. I also believe that there should be overview by clinical processes. And so, our P&T Committee, for example, is made up of clinicians, including both state and private clinicians, pharmacist, and others. It includes a Dartmouth Doctor

for testimony in the mental health area, Doctor Steve Bartells is also under contract with us and he serves on the P&T Committee. He is one of the state's leading experts on mental health medications; he is on the P&T Committee.

Certainly, we would welcome greater clinical input into that and we will be establishing contracts for that; it is an important process. And, earlier, when it said that we have rejected, the center rejected input from attorneys and clinicians that had met with John Wallace and myself, we don't actually make the decisions, John and I; it is made by a P&T Committee, it is made by clinicians as to what these procedures are. And, we will make sure that their input is transferred to the P&T Committee, make sure that it is reviewed, but it will be clinicians who make those decisions.

Senator Russell E. Prescott, D. 19: Is it true that in the contract with First Health that there is no real timeline for implementation of their duties?

<u>Donald Shumway</u>: ...that included a whole range of implementation efforts that took place in July, August, September, October, November and up to the present. And what it doesn't say is that any particular clinical policy will be followed at any particular moment rather it is up to the state of New Hampshire, its P&T Committee, etc. to control that on a ongoing and evolving basis. That is within our province to maintain control over, and something that we absolutely do maintain control over.

<u>Senator Russell E. Prescott, D. 19</u>: Would you believe that the public policy hearings proceeded this event, would help in that process to give us a assurances that all is being done?

**Donald Shumway**: Yes.

Senator Russell E. Prescott, D. 19: This is my real bone of contention.

Donald Shumway: Understood.

Senator Russell E. Prescott, D. 19: Senator Francoeur?

<u>Senator Gary R. Francoeur, D. 14</u>: As far as the rules that are formed down in JLCAR, what is the status? Have you withdrawn your rules at this time, until further legislation goes through, or...what status are you with JLCAR right now?

Donald Shumway: The rules are directly before JLCAR at this time. They adjourned their last meeting in the mid-process of the ongoing review of them. We had testified extensively on them prior to that and at the last meeting and assume they will engage in some sort of decision at the coming meeting. We would strongly urge that they not be withdrawn because we would be basically starting the program all over again, and it would subject us to, I believe, very costly litigation of our implementation of it at this time. It would basically put the brakes on the cost savings and quality improvements that we have put in place.

At the same time we think that they are good rules. We think that with further evolution modification, they are the right rules to build off of. So, we hope to not withdraw them and reject them but rather to see them put in place and built off of and improved in the future.

Senator Gary R. Francoeur, D. 14: You already implemented the program, did you implement program before the rules were in place?

<u>Donald Shumway</u>: We implemented, yes, before the rules were passed by JLCAR. We did hold a public hearing prior to implementation. We submitted the rules to JLCAR, but we did have to go forward with the implementation of the program, and we were pressed by a number of factors. Among those factors were the quality issues that I have referenced, and also the cost savings necessity, we had to do that. And finally, simply, the **pressive** duties, we had many things that had to be done.

Senator Gary R. Francoeur, D. 14: But normally, you would go through he rules process before the implementation?

<u>Donald Shumway</u>: Absolutely, absolutely. And it's not a matter that we didn't want to or didn't try to, we just missed. And, it was not what we want to do, it is not what we want to do the next time, but it is what happened.

Senator Sylvia B. Larsen, D. 15: Further question?

Senator Russell E. Prescott, D. 19: Certainly, Senator Larsen?

Senator Sylvia B. Larsen, D. 15: Is it reasonable to assume that knowing that in others, many, many other states large sums of money by the state has been spended by in trying to defend the pharmaceutical management programs that other states have tried to implement. I know Florida is in litigation, Maine is in litigation, Michigan, I believe, is in litigation. Is it reasonable to believe that or you had asserted that, somehow making up retroactive statement to this amendment would in fact, put us into highly costly litigation for what is unnecessary language in that we already have RSA 126, and that somehow, maybe retroactive language could in fact process a huge some of money, delay, and in fact, perhaps a 16 million cost as what you have said was the figure, if we don't implement a program of this sort of (inaudible).

<u>Donald Shumway</u>: Yes, that is my concern. And, what you will note in that amendment, it takes effect upon passage. It has a mandatory requirement of rule making. And so, you would of, in essence, passed something that there is simply no way that we could have gone through the JLCAR process. So, the way in which JLCAR has proposed the rules, would make us immediately violate JLCAR's process again; and we don't want to do that. We don't want to start that whole process over again, that would be sending a very confusing message then to the public, and I believe, to any judge that would review what our status is in the implementation of the program, we don't want to see that happen.

Senator Sylvia B. Larsen, D. 15: So, that line 12, 11 and 12; it says, the Commissioner shall adopt rules; would make you go back and start the rule process all over again, and in fact, null and void the rules that you already have proposed and are before JLCAR?

<u>Donald Shumway</u>: Yes. And again, on page 3, it does say that the remainder of this act could take effect 60 days after its passage, I believe, Roman numeral II. So, we would have to go through that process, for 60 days or is it immediate, I don't recall on that part?

Senator Sylvia B. Larsen, D. 15: Page 2, line 4.

<u>Donald Shumway</u>: Well in any case, we believe we would be out of compliance with it upon its passage.

Senator Sylvia B. Larsen, D. 15: Thank you.

Senator Russell E. Prescott, D. 19: Would you believe that in Pharmacy Benefit Management around the country, there are states that pass laws such as Texas, that didn't take the route that the ends justifies the means; we just got to implement it without legislative authority... do you believe that they knew from these NCSL conferences that we need the political will and you need to have the legislation behind you... would you believe that those other states in this country, did those things, other than what New Hampshire did?

<u>Donald Shumway</u>: I don't know whether they did or not, but what I do know is that this is, what we are debating here involves one of the most profitable business's in the world, the pharmaceutical manufacturing and sales of pharmaceuticals. And these industries have developed a lobbying effort which has been widely reported in the news over the last year that is intense and will stay intense, and they will push against what we are doing here, now and in the future; this will not stop.

And, it is not a question of being able to line up everybody, they will keep trying to divide ands spilt people off, and they will litigate one way or another, they will try to find ways to get handle against this. And, we have to stay together and say there are quality problems with what you are doing, and you have to own those quality problems and don't come here and say that we are denying people's medications when you are knowingly producing bad, addictive medications that are leading to social problems that must be dealt with. Don't tell our legislature that that is not something you should deal with, they should fix their medications; I'm sorry, but they got to do that.

And they are marketing extensively to the general public to say use my medication, and they are leading to an extensive effort to speak directly to the consumer to drive their medication in front of others. And, we have to make sure that there is clinical logic in the way in which medications are

prescribed. And ultimately, we have to retain control over the health benefit, the health insurance that the state New Hampshire provides to poor people, and that is the Medicaid program. And we can not give that control up to the marketing employees of the pharmaceutical manufactures.

Senator Russell E. Prescott, D. 19: I believe in those ends, I disagree with the means. I would like to call upon the next person to speak.

Donald Shumway: Thank you.

Senator Russell E. Prescott, D. 19: Representative Johnson?

Representative Johnson: Good morning Mr. Chairman, members of the Committee. For the record, my name is Roger Johnson; I'm a state Representative from Rockingham, District 25; representing the towns of Stratham and North Hampton. I am here today, obviosouly, to testify on this bill now before you and this amendment. I have some issues with the Health and Human Services PBM program.

## (See Attachment # 11).

I would be more than happy to answer any questions along these lines.

<u>Senator Russell E. Prescott, D. 19</u>: Representative Johnson, you are aware of the time constraints that we are under?

Representative Johnson: Yup.

Senator Russell E. Prescott, D. 19: And you mentioned an independent audit Committee for oversight. Would this be the proper way to further amend this bill to allow us to still have public policy input on further implementation of this Benefit Management Program?

Representative Johnson: Thank you for the question, Senator. The independent audit function is designed primarily to verify the cost savings of the program. I don't think that it gets in the way of the implementation of

the program, but I don't know of another way, quite frankly, to look at what the perceived, what the reported cost savings are without going through a independent audit. From my claim audit background; every time I see a system that goes into place in a place in a certain month, the claim data that is available for evaluation doesn't really appear until 2,3, 4 months after the fact. For a plan that went into effect Nvember1, the initial November 1<sup>st</sup> data should be showing up sometime late January, early February.

So, it is going to take time for us to have some real quantitative data to look at to see if this program is actually working. In order to project ahead statistically, in order to project ahead for an entire year, I need really 3 years of data to be statistically accurate. In order to project ahead for any 1 month, I need 3 months of data; I don't even think that we have 3 months of data, I don't know, but that is the point of having the audit process. I can't sit here right now and say that we are saving a dollar, 5 dollars, 500 thousand, 7 million, 10 million; I do not know. But, in order to make sure, we need to have an independent audit system set up, so we can determine whether or not we are saving money from the program.

That independent audit function should also entail one other aspect, looking at those individuals from which we are theoretically saving money because of the change from a name brand to a generic, and then what happened to that individual from a medical standpoint; was the change from name brand to generic causing a problem for them from a medical standpoint because if we made them save money from the reduction from name brand to generic, we may of caused them the medical problem which cost us money; so then, is there really any savings relative to that one patient.

<u>Senator Russell E. Prescott, D. 19</u>: So, you believe that the overview of this implementation program should be audits for proven savings, and also oversight of the General Court, so the General court would be that oversight to protect the public health?

Representative Johnson: Well, there is a quality issue that need be in place. As I mentioned in my testimony, one aspect of having an ongoing audit process is to make sure that by implementing a policy, we are not harming this very fragile population. If we are so doing, then we implement the proper policy. I would suggest that...let me take a step back. If the desire is to save money and in so doing we actually harm people, then are we doing the right thing? I don't have an answer to that question; I think that is a policy decision that need be made.

When this was presented to us in Finance; it was presented that this was something that we were going to do, which is why I was raising my initial concerns at the time, very fiercefully, I might add.

Senator Russell E. Prescott, D. 19: So, what is presented to JLCAR now, which they need to vote on by the 19th of this month, is something that does not take of those issues which is, independent audit to prove that there is cost saving and a reason for doing this, and second, oversight by the General court to make sure that the protection for public health is there, is that true?

Representative Johnson: The short answer is, that is true. There is a longer answer, I'm not sure I'm even qualified to make that longer answer only because I have only been here a year and a half; I'm not sure what tool place in this building or subsequent buildings prior to that. I do know that based on my own knowledge of how this works and how we put this in, in a number of different instances nationwide...I have to be careful about how I state that...we go through a very specific procedure to make sure that all of these things are in place. And, we have a constant review process to make sure that anything that goes on that is unintended is corrected, can be corrected immediately; I had not seen that in this process.

And the reason why I haven't seen it is maybe I haven't been here long enough. But, when I am sitting in a room and someone says that we are going to do this because we are going to save money, the first thing I say is hold it, what is the intent, to save money or can we have a better ethics to see putting in a program to serve those people that we are elected here to serve. And that was my question from the very beginning when I had this November 7th, excuse me, March 7th or march 15th, whatever the date was.

Senator Russell E. Prescott, D. 19: Thank you. Any questions from the Committee? Thank you very much for your testimony.

Representative Johnson: My pleasure.

Senator Russell E. Prescott, D. 19: David Minnis?

<u>David Minnis</u>: Thank you Mr. Chairman and members of the Committee. For the record, my name is David Minnis and I am here representing the New

Hampshire Pharmacists Association, and I will be brief. I just have a couple of quick comments about this thing. I am here speaking about Representative Patten's amendment, so my comments here are a little more negative than my previous from the back room testimony in support of the bill itself. I would like to put in context, very quickly, the commissioner. I don't think there is anybody is this room that oppose the intent or the ability of the Department of Health and Human Services to contract with a PBM, First Health, to better mange, better control the state's Medicaid prescription costs; that is not the issue that is before you.

The issue before you is whether the state went ahead and implemented a prior authorization program without legislative intent. So, let's be very clear here that what ever you do with this amendment, whether you reject it, or whether you amend the amendment, or whether you pass it as is, the state is still going to be able to operate the Medicaid program using a PBM to do so. And, so I don't want us to think that if you pass this amendment or if JLCAR decides to vote against the rules, that it is going to vote against all of the rules.

It is going to say that these specific rules dealing with prior authorization of Medicaid lock-in did not have legislative authority, therefore you can not implement them. The rest of the program, even though it was implemented on November 3<sup>rd</sup>, when the First Health took over the Prescription Benefit Management, the prescription program for the state; those rules are in place now, and they will continue to be in place, so I just want o make it very clear.

Senator Russell E. Prescott, D. 19: Question?

David Minnis: Yes.

Senator Russell E. Prescott, D. 19: Is that similar to what EDS was doing prior to First Health?

David Minnis: Yes.

Senator Russell E. Prescott, D. 19: The programs are in there, they must substitute generics for name brands in this program?

<u>David Minnis</u>: That is correct. The generic for brand name piece of the statute has been in place since 1995, and that has been the law unless the Doctor specifically writes on the prescription "no substitution", the pharmacist is compelled by state law to substitute a generic. And, that has been the law since 1995, 1996, I believe.

<u>Senator Lou D'Allesandro, D. 20:</u> Did this legislature fight strongly to get that law in place because of the fact that generics were out there and weren't being used properly?

David Minnis: Yes.

Senator Lou D'Allesandro, D. 20: So that is a fight that we had after a long period of time?

<u>David Minnis</u>: It was part of the departmental reorganization of Health and Human Services, House Bill 32 is when that was done in October of 1995.

Senator Lou D'Allesandro, D. 20: The battle over generic drugs began a long time...

<u>David Minnis</u>: Began before that, that is correct, in the 70's.

Senator Russell E. Prescott, D. 19: May I further follow up?

David Minnis: Yes.

Senator Russell E. Prescott, D. 19: This was presented by the Commissioner as a savings basis program. I looked through here and really only picked out one that is being discussed with this amendment, which was the prior authorization. That means that all of these other things are being done as we speak and already have prior authorization or legislative intent, such as therapeutic duplication or early refill; all of those are implemented, it really is just one issue here that we were talking about and the rest was, we have already done that, now what do we do lately.

David Minnis: Right. In fact, the 3 that you mentioned Senator, were implemented in February of 2001 when EDS was the contract provider for prescription benefits. So all the First Health people did when they took over the contract in November was simply carry on and continue to do the drug to drug interaction, the hard halts for early refills and the rest of it; EDS had been doing that since February. And I believe, if you talk with the EDS officials, they will tell you that between February and November that by implementing that plan in cooperation and conjunction with the state that the state saved 4.2,4.5 million dollars by implementing those changes, and that those changes were simply carried forward by First Health and continue to be. And I don't think that anybody has any problem with those changes being implemented, none.

<u>Senator Russell E. Prescott, D. 19</u>: So therefore, this chart will continue as the savings we see, the future of New Hampshire whether we make a decision for or against the Patten amendment?

David Minnis: Yes, I believe...

<u>Senator Russell E. Prescott, D. 19</u>: So, we still have this cost savings going forward for the state of New Hampshire?

David Minnis: That is correct.

<u>Senator Russell E. Prescott, D. 19</u>: No matter how we decide on the preauthorization and lock-in program?

<u>David Minnis</u>: That is correct because the changes that have been made...I'm not sure that I have the right word here...were stematic, they have made basic changes to the system looking at drug to drug interaction, preventing early refills. Those are things that go across the board regardless of the Medicaid patient and regardless of the prescription that is being filled. Where as the prior authorization, which the Commissioner himself said, only effects 4/10ths of 1% of the drugs, that is a special little program and the Medicaid lock-in would be too if they did that.

Senator Russell E. Prescott, D. 19: If I may continue my question?

David Minnis: Sure.

Senator Russell E. Prescott, D. 19: Then, the issues that Representative Roger Johnson brought forward could be given longer time to be implemented than just this April 19th dead line?

David Minnis: That is correct.

<u>Senator Russell E. Prescott, D. 19</u>: So, we don't really have the gun to our head?

<u>David Minnis</u>: I believe that you need to give the JLCAR Committee some indication of how you would like it to proceed. And I see that Senator Flanders is shaking his head yes. They would like to have some indication from the Legislative Policy Committees what the legislator thinks about prior authorization and Medicaid lock-in, since those are the 2 specific issues it has brought to your attention. If you believe as the Senate Committee and as the full Senate that these 2 issues need further light of day, need more consideration by the Legislative Policy Committees, than you give that message to JLCAR.

I believe that it is within JLCAR's purview to go forward and allow the Department to adopt...even thought they are already in place...but to adopt the remaining rules but not do the prior authorization with a Medicaid lockin, I believe it is within their purview to do that. I would conclude my testimony by asking you to just keep in mind that these prior authorization decisions don't involve the New Hampshire physician per say, these decisions, the final decision is ironically being made by a pharmacist employed by First Health in Virginia. And, I think that the prior authorization rules really do need much more expansion and explanation and involvement in the public process.

And, I would also add that I noticed that the Commissioner testified that the P&T Committee is the one that makes the decisions regarding which drugs are prior authorized. I Attended both of the P&T Committee meetings, and at those meetings the public was not allowed to speak, and it was made very clear at those meetings that this was an Advisory Committee to the

Department but the decision about what drugs would or would not be prior authorized would be done by the Department, not by the P&T Committee. The P&T Committee is an Advisory Committee created by the Department. It is an Advisory Committee but the decision for what drugs are or are not prior authorized is the Departments.

<u>Senator Russell E. Prescott, D. 19</u>:Is that in direct contrast to Commissioner Shumway's testimony, that they are told by the P&T that this is what...?

David Minnis: The P&T Committee makes recommendations to the Commissioner or to the Department as to what drugs it thinks are appropriately prior authorized. But whether the Department agrees with the recommendation of the P&T Committee is the Departments decision. It is not the Committee that makes the decision; it is an advisory Committee. In fact, it is known as the Advisory P&T Committee. And there are, I believe 8 or 9 members of that Committee, of which 5 of them are state officials and 4 of them are outside or independently appointed.

Senator Russell E. Prescott, D. 19: Very Good.

David Minnis: I would like to say a quick comment. I heard the Commissioner testify about the drug store robberies. And, I obvisouly represent the pharmacists, so we are very aware of that. I don't think that we want to confuse here; drug store robberies are happening. But just because drug stores are being robbed because they have Oxycontin, doesn't mean that we should prohibit all patients from receiving narcotics; because there are plenty of narcotics in a drug store besides Oxycontin which they can go after. When they go in there, they would like to get the Oxycontin but if it is not available, they will take whatever the narcotics are that they can get; so, I just want to be clear on that.

And finally, Just for the record, they talked about wanting to do Disease State Management, and the Commissioner did say that they were looking at it with First Health and they would be moving slowly, that it need to be looked. I have heard other testimony that...the results aren't in yet on whether Disease State Management is good or not. I can sit here today and tell you that my pharmacists have entered into a contract with an instate Insurance Company to do Disease State Management over the next 12 to 18 months, and that Insurance Company believes that it will save them on a minimum of 500 thousand to a million dollars, and this is a pilot project that we are talking about.

So, Disease State Management is the way to go. I think that you better manage the patient rather than control the drug that they are on. And my pharmacists would welcome the opportunity to work with the state in any Disease State Management that they decide to do. Thank you very much for giving me this opportunity.

Senator Russell E. Prescott, D. 19: Any questions from the Committee?

David Minnis: Thank you.

Senator Russell E. Prescott, D. 19: Steven Lavwers and Debbie Stephens?

Steven Lavwers: I will come up first and then I will introduce Debbie Stephens afterwards, if that is okay with you. Mr. Chairman and members of the Committee; I am Steven Lavewrs, I am an attorney with the Law Firm of Rath, Young and Pignatelli; we represent First Health. And today we are representing First Health, and we have with us several people form First Health, most of whom are from Virginia but a couple of whom are the local people here in New Hampshire that are helping the implementation of the program. And after I speak, I' going to turn it over to Debbie Stephens, who is a licensed pharmacist in the common wealth of Virginia, and she is available to answer questions you might have about the actual ways in which First Health goes about going through these clinical protocols.

As I was sitting there, I keep amending this testimony; I am going to try to keep it as absolutely short as possible. One of the things that I do want to address though is a couple of statements; I just want to make sure that we get our facts straight on the cost savings. My understanding of prior authorization is alougth it is only a tiny sliver of the activity and the denial rate of all prescription drugs dispensed is extremely small, and that is what Commissioner Shumway was indicating. The First Health estimates are that the state saves 500 thousand dollars a quarter, or 2 million dollars a year from the implementation and activities associated with prior authorization.

So, it is not...I want to correct Mr. Minnis's statement...our understanding is that it is about 2 million dollars of savings to the state that are solely attributable to prior authorization. The other point that I want to make with regard to the prior testimony is that I think First Health is a very strong proponent of Disease State Management, it is provided for in this contract.

We believe that the only wise thing really to do is to make sure that we are not sifting cost or that the state isn't shifting cost out of prescription drugs into illnesses of another type; it's just not fair to the population and it is not good policy.

With regard to that, First Health would be very comfortable with any type of audit program or any type of oversight that the Committee or any other Committee of the legislature decide to put in place. We have clients in other states who regularly audit the function, both for cost savings and the quality of the interventions; it is something that we feel very comfortable with. So, we come certainly with that as a excellent idea.

What we are partiulary concerned about and what I learned from First Health is that this is a battle with pharmaceutical companies that occurs all over the United States; they have more experience with it than I do. But, essentially prior authorization is a critical, political objective of the pharmaceutical industry to really make sure that states do to permit prior authorization, it is a real battle cry that they have. And, the reason for that is essentially that prior authorization... just as you can see 2 million dollars swings through a tiny little piece of the Medicaid pie...prior authorization is a very powerful tool to control drug cost, and it is a very powerful tool for the state to be able to use to negotiate going forward with prescription drug companies.

So, it is a very significant issue from their perspective, we understand it. Right now there isn't a way to make it a win-win, and we understand that too. But, it is a very public and national battle right now. The only other point I want to make with regard to the prior testimony is that First health really is not making the determinations. They take the determinations and decisions that the P&T Committee have made, and they are guided by those exclusively.

There is an internal appeal process both within First Health, and then someone going through that process who is not satisfied can go into HHS and they can ultimately reach a position within HHS, if not Doctor Kesslier himself. So, there are multiple levels of appeal but at least from a First Health perspective, we want to share with you, argue that really the P&T Committee is the critical policy making body here in the state comprised of health experts who are local and they make the determinations of what is prior authorized and what is not.

I think that the last point that I want to make...and then I do want to introduce Debbie Stephens because she has some of this clinical background...is...and as a lawyer I can't let it pass...there is a legal issue

here and it really is with regard to whether the Commissioner has statutory authority as opposed to whether, as a matter of public policy, was more appropriate for him to come to the legislature; and that is certainly not our purview at all.

What we are worried about, frankly, we have seen litigation in a number of other states. We have been involved in litigation in other states or our client has been. And we are concerned that we take a path forward or we encourage the Committee to take a path forward from this point forward, whether it is putting auditing in place, careful strictures so that as this data is developed in New Hampshire, and really the only way to develop New Hampshire data is to run the program for a period of time and see what the data looks like, audit it, have whatever oversight is necessary.

But, we would be very concerned by a finding of either the Committee here or by JLCAR that indicated that there wasn't statutory authority for the Commissioner to engage in the program. What we believe would happen there is that would perhaps prompt litigation by third parties, which we were hoping would not occur in New Hampshire. So, at this point, I'm available for questions. So, I will pause, and if you don't have any questions, then I will introduce Debbie Stephens.

Senator Russell E. Prescott, D. 19: Do you have a question, Senator?

<u>Senator Gary R. Francoeur, D. 14</u>: If we do nothing, what are the legal implications, and if we do Representative Patten's amendment, what are the legal implications that you see?

Steven Lavwers: I think if you do nothing, you provide no guidance to JLCAR, and we go back to JLCAR on the 19th and if they make a determination and issue a joint resolution that there was not legal authority, then we do have a legal exposure with regard to that aspect of the program. At one level, we live to fight another day, on the 19th. And, I do appreciate...the Committee is being put in a very tough spot here with the timetable and everything else. If you adopt the amendment, I'm more along the lines of what Commissioner Shumway indicated, which is, it seems to me to indicate, and the amended analysis really indicates to me that the Commissioner doesn't have authority up until the time that this law passes or becomes, is put in place.

What I would much rather see honestly, is something that really maybe strengthens the oversight and the audit function but says, yes, continue with this program but do so in the following ways and subject to the following oversight. And I can't speak for the Commissioner and I shouldn't be going this far. But from a First Health perspective, we are comfortable with a audit sort of brawl. That is what we think legally is the best way to move forward from where we are, which isn't the best of places, to try to get to someplace that makes sense.

<u>Senator Russell E. Prescott, D. 19</u>: So, you agree with Representative Roger Johnson about the independent audit program and oversight by the General Court to maintain the public health's interest.

Steven Lavwers: Right. And I think that he made a very good point about getting the data, that it takes a period of time that you need certain amount of data to project forward to start to look at what makes good public policy.

Senator Russell E. Prescott, D. 19: Senator?

Senator Lou D'Allesandro, D. 20: Thank you. I think that we all like to see previous data so that we could project the future. I might say that if you don't have programs in place, you can't collect much data.

Steven Lavwers: That is what I am trying to say.

Senator Lou D'Allesandro, D. 20: So, are you saying that if JLCAR approved the rules on the next time that JLCAR meets, that there isn't a process in place for audit at this time? I thought that every one of these programs eventually is audited, would have to be audited, we are spending federal dollars, are we not?

Steven Lavwers: Yes, that is an excellent question. The audit programs in place right now are twofold. As to First Health, there are there are 2 audits. The state audits its performance and the Federal Government audits the performance of both the state and First Health. As to HHS, the Federal Government audits, and they audit extremely, extremely carefully. If one wanted to audit them for a particular New Hampshire public policy goal, one

could in addition create some sort of body that would be looking at a public policy issue and asking for data that would respond to them.

Senator Lou D'Allesandro, D. 20: Further question?

Senator Russell E. Prescott, D. 19: Yes.

Senator Lou D'Allesandro, D. 20: This legislature has the power to go to the legislative budget office through the audit division and say conduct an audit. I have been in this legislature for the last 30 years; I've seen a number of audits. That has always been the progative of the legislature and the legislature has that power and basically that responsibility, does it not?

Steven Lavwers: Yes, it would. So actually, the bill passed with simply the language about the oversight report from Health and Human Services is sufficient, the audit could be taken care of in any other type of proceeding.

Senator Lou D'Allesandro, D. 20: Thank you Mr. Chairman.

<u>Senator Russell E. Prescott, D. 19</u>: Any further questions from the Committee? Thank you. Debbie Stephens?

<u>Debbie Stephens</u>: Good morning Mr. Chairman, members of the Committee. My name is Debbie Stephens; I am a pharmacist with First Health Services from Richmond, Virginia. The Department asked me to briefly summarize for you some of our clinical programs that we either have in place now or that we are planning to implement in the near future. And, also to provide you with a couple of examples of positive clinical outcomes as a result of our current program.

We have talked about many of these already today, and I will be brief with my comments. First of course, is the produr or prospective drug utilization review system and of course this is the editing system that is tied to the point of sale transaction that the dispensing pharmacists utilizes when they are submitting claims, and this is where we screen for potentially dangerous medical conflict. As you have heard, currently New Hampshire denies for the

severe drug to drug interactions, therapeutic duplication, early refill, and so forth.

A pharmacist dispensing pharmacist may override these edits using special codes to get the claim to pay basically. So, if it is in the pharmacists judgement that the claim is or that the medication is suitable for the patient to consume, then they can certainly go through this process without calling the First Health call center to get that claim paid. As Mr. Minnis mentioned earlier, produr is certainly not new, it is a function that we took over from the previous contractor; lets a very important component of patient care for pharmacies and our First Health system assist in dispensing pharmacists with this duty.

I will say that the criteria approval and modification for the DUR or for the Produr piece is overseen by the DUR board, the state DUR board. First Health meets regularly with this DUR Board and that modification and oversight is an ongoing process. So, the DUR Board is familiar with where we started and we have a plan of action for moving forward in terms of modification. The second, as you know, prior authorization is an existing program, and again, this is a system of clinical protocols that are being used to evaluate selected drug therapies.

All of the protocols have been extensively reviewed by the P&T Committee and approved. And, I just want to reiterate that all of the protocols in place now were approved by the P&T Committee. We have pharmacists in our Glenallen, Virginia office who receive phone calls from physicians when heated requests come through as a result of a denied claim. And, these pharmacists are instructed to and do follow the protocols that have been established by the P&T Committee. So, rather than making their decisions, I will say to the Committee that these pharmacists are in deed following protocols that have been set by the P&T Committee.

Agents are targeted for prior authorization based on a number of factors; we have talked about a lot of those today. High utilization and expense, that is a pretty obvious one. Misuse, which a lot of times is overuse; a lot of classes of drugs just tend to be used extensively for a period of time and nobody really questions whether it is time to cut that medication use off. And certainly abused potential is another reason for considering prior authorization.

Again, our goal and the state's goal is to insure that patients receive the most appropriate medication to treat their medical problem and also encourage the use of more cost effective options within a therapeutic class if it is medically reasonable. What we want to do is to have pharmacists and prescribers stop and think about possible alternatives, the ultimate treatment goal for

particular disease or medical problem, the total duration of therapy, and so forth. Through the PA process, we try to sort through what is legitimate therapy and what is not legitimate therapy; that is our basic goal.

I will quickly just walk through some other programs that are being implemented now. One is retrodur and this is a program; it is a drug utilization review program that's as the name implies, after the fact, retrospective, where we profile patients to target them for potential problems in looking at patterns of substance use. And we are also looking at patterns of prescribing habits from physicians and also dispensing from pharmacists.

Basically, we generate profiles with medication history for these patients. Our intervention method might be to send a letter to a prescriber or to a pharmacist notifying them of a potential problem, perhaps providing education on appropriate prescription drug use, and possibly notifying them of potential abuse. This is an excellent way for us to look retrospectively at potential problems with abuse, and particularly with controlled substances. Again, the DUR criteria for the retrospective process is overseen by the DUR Board.

Other projects that are ongoing now, provider profiling, same kind of concept as retrospective DUR except that we will target providers, pharmacies and prescribers and do this same kind of profile generation where we might send a letter, an intervention letter notifying these individuals of potential therapy problems or advertent patterns in prescribing and so forth. Clinical detailing is another project that the state has asked us to pursue over the next couple of months, and this is where we will actually send a pharmacist out to visit with physicians where we have targeted that there may be some problem, and we want to provide an additional educational component.

Disease Management will kind of tie all of these products in, Produr, retrodur, provider profiling and so forth. And again, what we want to do is target diseases that are considered high risk and potently cost more. In addition, Disease Management may also factor in case management for the worst of the worst cases, if you will. So we may target some individuals who need more the one on one attention. In those cases there may be some direct patient education as well as provider education about the particular disease state.

All of these programs provide us with an opportunity to provide patient and provider education so that we can better manage the more complicated disease cases. Finally, I will just mention pharmacy auditing, fraud and abuse, and the lock-in program, these are particularly clinical in nature but they are very important. One of the things that First Health will be doing on

behalf of the state is to audit pharmacies periodically to make sure that they are consistent with appropriate state practice, identify potentially fraud and abuse trends within the pharmacy both from the prescriber and the pharmacy provider, as well as patient utilization. And from there we may identify potential lock-in recipients that we would like to restrict either to a pharmacy or a physician, or both, we have that capability in our system.

Ultimately, I would say that all of these programs ought to be integrated so that they compliment one another in an effort to make a difference in health related quality of life issues, quality of care for New Hampshire Medicaid patients. We have a number of clinical initiatives that are focused not only on cost issues, even though cost is a very important consideration, but I would say that there is also a big focus on the quality of life issues and the quality of care, and just good basic clinical management; that is truly our philosophy as well as the state's.

The state asked me also to share with you a couple of specific examples from our Produr system just to give you a sense of some of the interactions that have been avoided through this system; and I will briefly walk through these. There was a 59 year old female who presented a prescription to a New Hampshire pharmacy recently for a drug called lipitor, it is very commonly used for reducing cholesterol, the patient was also on another drug called jemfibrozil, another drug used to reduce triglicerite levels; our system was able to detect that the patient was using these drugs concurrently when the pharmacist tried to submit claim at the point of sale for the lipitor, and indeed, the pharmacist chose not to dispense the drug lipitor because of a potentially severe interaction.

Basically, something called myopathy, where there is muscle damage, muscle weakness and severe pain could potentially result, and these two drugs are not recommended to be given together. So, the pharmacist, the dispensing pharmacist stopped the dispensing of that lipitor, which is a very positive outcome for this patient.

Again, a 42-year-old female presented to a New Hampshire pharmacy with a prescription for chlorpromazine, it's a anti-psychotic agents. It turns out that this patient was also taking lithium and again, these two drugs are recommend not to be given together because of potentially severe interaction that may induce disorientation, unconsciousness, and even brain damage in some cases. Again, the dispensing pharmacist chose not to dispense the chlorpromazine, the anti-psychotic agent. Most likely the pharmacist contacted this patient's prescriber and another regiment was agreed upon. So, these are just two specific examples of instances where the New Hampshire pharmacists have intervened on the patient's behalf based on a

systematic approach to identifying medication problems. And again, these are just two examples among thousands that are detected every year. And because your good pharmacists in New Hampshire are paying attention to these alerts, together we are avoiding many potential adverse effects of medication use including reducing medication errors. I, at this point thank you for the opportunity to present and summarize our programs. I would welcome any questions you might have.

Senator Russell E. Prescott, D. 19: For reducing medication errors that, that program is not in question today in Representative Patten's amendment?

<u>Debbie Stephens</u>: Not to my knowledge.

Senator Russell E. Prescott, D. 19: Thank you very much. Any questions from the Committee? We have come to the end of those who have signed to testify on behalf of this bill. Anybody else wish to speak, come forward. Mr. Wallace?

John Wallace: Thank you very much. John Wallace, representing the Department of Health and Human Services. As Commissioner Shumway mentioned... I was going to talk briefly about some of the legal issues with respect to the amendment as proposed. It's not entirely clear to me what the Committee or what JLCAR wants to accomplish with this particular amendment. I think that you can particularly see this in that people who are opposed to those aspects of our program have testified both for and against this particular amendment leaving it uncertain as to what its significance is or what it would accomplish.

I think from our perspective, what we do think it will accomplish, it will appear to call into question the legal status of our, both the rules we have proposed and our operation of the current program, and it raised the question as to whether the legislature would expect us to withdraw the rules and start again with new authority, or start at the effective date in your legislation, whenever that would be and raise a question as to whether we have the authority to operate those parts of the program that aren't mentioned specifically in those rules.

And so, it essentially confuses our legal position with respect to this program. And, we think makes us exceedingly vulnerable to litigation, both to stop the

plan or various aspects of the program, as well as to incur in our path, substantial cost of defending litigation in these areas.

If the Committee...JLCAR, I am talking about here...has a desire to assure that we have rules in place before we went forward with the program, they have a very simple solution to that, which is on the 19<sup>th</sup> to pass the rules; that takes care of that problem, that takes care of what appears to be the reason that these rules are before you. So, that again confuses me as to what it is that they are trying to accomplish here.

One of the issues that they raised about our rule-making authority is why we did not proceed with either emergency rules or interim rules; and the reason that we did not do that is that the criteria in the rules committee for promulgating those rules were not met, so that we would of, they would of objected to those rules on the basis that we failed to meet criteria for filing either emergency or interim rules. As Commissioner Shumway indicated, we are not adverse to having oversight, either audits or reports, however you want to accomplish that.

I think that what we don't want to have happen is that this program be stopped in its tracks or that the legal picture be so clouded that we be unclear as to what we do or that invite the litigation. If the Committee wants to go forward with legislation, which would affirmatively provide for the legislative oversight of this program, that would be allowed and not get in the way of having the rules go forward as they are before the current Committee, is that that would be the avenue that would be most appropriate.

And, I would think that the only other issue I had with respect to the proposed amendment had to do with what I would say, the open-ended reporting, the annual reporting till the end of time as it is. It would probably be helpful if that...because programs change so much over that... that there be some limit be out on that responsibility. I don't want to take anymore of your time. Questions?

<u>Senator Russell E. Prescott, D. 19</u>: Any questions from the Committee? Marjorie Powell?

Marjorie Powell: Thank you Mr. Chairman. My name is Marjorie Powell, I'm the Assistant General Council of the Pharmaceutical Research and Manufactures of America, which is the trade association for the companies that are developing and getting approval to market new, innovative medications. We do, as you have heard from the Commissioner have it and

from the Representative from First Health, have a concern with prior authorization. I would like to address three major concerns that we have with that; that there are health consequences for patients, there are administrative costs to implement and to administer on an ongoing basis of a prior authorization program, and there are unintended consequences to the health care system.

But, first if I may, I would like to address a couple of questions that Senator Larsen had earlier, which I think provides some perspective. Back in 1990, the Federal Congress decided that State Medicaid programs were trying to restrict patient access to drugs and trying to negotiate with individual manufactures to get the kinds of discounts that the private sector health plans were able to get, and that that was interfering with the Medicaid patients access to prescription drugs and that the state agencies weren't particularly effective at negotiating because that wasn't what they did most of the time; they did regulations in administered programs.

So, Congress decided that they would give the State Medicaid Agencies the advantage of the very best price that any private sector plan could negotiate with any prescription drug manufacture, at least the innovative drug manufactures, that they created a Medicaid rebate program, they said to manufactures that if you want available in Medicaid, you will give back to every State Medicaid Agency in the Country, a rebate equal to the very best price that you give to any commercial program

At the same time, they said, we would like to discourage drug price inflation. So they said, if you raise your price more than the rate of inflation, you will give that price difference back to every State Medicaid program, now this applies only to innovative drugs, not to generic drugs. But, what that does is that it gives the State the benefit of any private sector negotiation and an added benefit of an inflation adjuster. In return for that, Congress said because Medicaid patients are the poorest, sickest people in the Country; by definition, that is what makes them eligible for Medicaid; we are going to say that the decisions about which drug or drugs that they need should be made between the patient and the physician without ... or in case of anyone else authorized to prescribe, the prescriber.

Those decisions should be made on medical basis based on the patient's current medical needs and medical history. They should not be made by a third party without the patient's records or all of the information about what else is going on with that patient. The reason is that those patients are in fact the sickest, neediest patients; it is most important that their health care be organized and managed carefully and not distributed by a trip to the pharmacy learning that I can't get my prescription filled today, I have to

come back in three days or whatever that might be, and I may frankly just not come back because if I am that sick or that semi-functional, I may not make it back to the pharmacy.

Now, within many private sector health plans including apparently the State employee's health plan, there are restrictions on drugs available. But, if my employer restricts my drugs and I think I need a particular drug and my doctor tells me that I need that drug which is restricted under my plan, I can go to my employer and ask my employer to go to bat for me at the insurer or the health plan to make an exception for me because I am a valuable employee. If I am a Medicaid patient, particularly a Medicaid patient with multiple medical conditions, I may not have the skills or the time or the energy to go find somebody to go to bat for me with the State Medicaid Agency.

In Florida, which implemented a prior authorization program and a script limit...many, many patients went to their pharmacy, were told that they couldn't have the drug because they didn't have prior authorization and they simply never bothered to go back, nobody bothered to tell the doctor that they patient hadn't gotten the drug. In Florida, the legal services organization has filed a lawsuit against the State asking the State to implement a mandatory program to inform patients at the time their script is denied, the reason for the denial and what the appeal process is, and to implement a very simple appeal process.

So, the prior authorization in Florida is having patient health consequences in their filings with the court, they document individual patients who have had medical problems and who have incurred greater expenses within the state Medicaid system through hospitalizations, emergency room visits. It has administrative costs, if the court decides that the state needs to follow the Federal law and enact or implement immediate appeal procedure with information to the patient about how to appeal, there will be extra administrative costs to implement that appeal program.

In Florida, because less than half of the drugs normally available to Medicaid patients were available to Medicaid patients in Florida. In Michigan, which has also implemented a prior authorization program, the state, as the state is here is paying First Health on a per call basis. So, the more drugs that First Health puts on the prior authorization list, the more drugs for which doctors or pharmacist will have to make a call to First Health, the more payments the state will owe to First Health.

I understand from a staff member to a legislature in Michigan who is proposing some amendments to that program that the state expended in the first month of implementation, it's entire years budget to pay for those calls because of the way the program was implemented and because of the numbers of products that were on the list for prior authorization. That's frankly, one of the reasons that we say there are going to be costs both to implement and cost to run a program.

Let me take one minute... because I now this has been a very long hearing...and talk about some of the unintended consequences from prior authorization programs. I was speaking with a doctor in Florida who treats a number of Medicaid patients and who in fact staffs a clinic for Medicaid patients. At that clinic, physician interns spend six month rotations treating Medicaid patients as part of their physician education, and he pointed out that during the six months those interns are at his clinic, they learn which drugs to select among from the drugs on the preferred drug list or formulary in Florida. They do not learn when and how to select one of the newer drugs not on the preferred formulary list.

Then, when they go out and practice, they suddenly discover when they are dealing with people with private health insurance that there are whole ranges of drugs for which they have had no experience; they don't know what the kinds of drug interactions might be, when a drug might be contraindicated so that the patient should not be prescribed that drug. So, a prior authorization program can have consequences for physician education as well as for patient quality of care.

It is for those reason that we think that prior authorization within Medicaid is an inappropriate cost saving tool. Many of the other activities that you have heard about this morning like prospective and retrospective drug utilization review are in fact part of required by the Federal Medicaid program. The are a way of trying to manage the program, both to ensure quality of health care and to ensure that the state is spending its money on drugs that are appropriate and effective and not spending it on drugs that duplicate other therapy.

So, I would urge you to think very carefully about any prior authorization program. I would also note that the New York Times Today has a story about a report (See Attachment # 12)...I have not seen the report but the report indicates that with various state efforts in Medicaid to cut back on access to drugs... 26% of Medicaid beneficiaries... excluding children and seniors... ages 18 to 64...the large bulk of those of us...although not necessarily the large bulk of Medicaid patients because many Medicaid patients are seniors... but 26 % of people in that age range said they could not get all of the medications their doctors wanted them to have because of restrictions in the Medicaid program.

That doesn't actually result in quality care for Medicaid patients. Let me stop and I will be happy to answer any questions if there are any.

Senator Russell E. Prescott, D. 19: Yes, Senator?

<u>Senator Robert B. Flanders, D. 7</u>: Just one question. Your testimony is that you feel that the business of the prescription should be between the patient and the Doctor?

Marjorie Powell: That is correct.

Senator Robert B. Flanders, D. 7: And that the pharmacists should have no say on it?

<u>Marjorie Powell</u>: I'm sorry, that is perhaps using shorthand that negates the role of the pharmacist. We do think that the pharmacist, particularly in Medicaid, have a very important role and that role is implemented through drug use utilization review through looking at the records and the edits that come up on the computer screen. It is also, I think true that in many state Medicaid programs they are looking at Disease State Management and in some of those programs, the Disease State Management is being operated by the pharmacist.

I think pharmacists are probably an underutilized source within the system and I didn't mean to exclude them. But I don't think the drug prescribing decision should be made by somebody without access to the patient records without access to the patient.

Senator Robert B. Flanders, D. 7: It is my understanding that marketing done by drug companies is done directly with the doctors, is that correct?

Marjorie Powell: The large proportion of the drug company marketing is to the doctors because the reality is that particular pill is a dangerous compound unless the prescriber knows how and when to prescribe it and when and how not to prescribe it. And as drugs become more complex, that physician education becomes more important. There is however marketing to patients through direct to consumer advertising. And, there is marketing to

pharmacist and to a variety of other people in the Health care system because they also need to know what the risks and benefits of the drug are.

Senator Robert B. Flanders, D. 7: Thank you.

Senator Russell E. Prescott, D. 19: Any further questions? Thank you very much for your testimony.

Marjorie Powell: Thank you.

Senator Russell E. Prescott, D. 19: Anybody else wish to testify, please come forward.

Janet Monihan: Good morning. For the record, I am Janet Monihan, representing the New Hampshire Medical Society. The Medical Society has been involved with this issue since last fall and we have been wrestling with it. We have a lot of folks that would like us to weigh in on this issue. In general, physicians don't like prior authorization programs and they have gotten used to it, and a lot of the health plans require it for diagnostic testing. But, the physicians also see the need for the sate to save money.

We are looking for the least distributive way to do a prior authorization program, the least distributive between the doctor-patient relationship. We have been working with the Department and we have been able to get an additional member on the P&T Committee from the Medical Society. We met most recently, last week, and made suggestions, possible changes to the prior authorization form that would make it user-friendlier. We will continue to meet with the Department. And we hope to see in the future, more physician education.

Physicians, probably don't all know what drugs cost that they prescribe, they might know if is \$25.00 a month or if it is \$125.00 a month. And I think that kind of information would be very helpful to the physician. And I think that the current DUR program is great to see some of the misuses; physicians don't like to be outliers, so if they find out that they are under-prescribing or over-prescribing, they will usually pay attention. But we will continue to work with the Department and try to answer questions.

<u>Senator Russell E. Prescott, D. 19</u>: Any questions from the Committee? Thank you very much for your testimony. Anyone else wish to testify?

Nancy Wiggins: Good Morning Chairman and Senators. My name is Nancy Wiggins from the New Hampshire State Police of the drug unit and I investigate pharmaceutical drug diversion cases. Probably about 4 or 5 years ago... in fact I forwarded letters to Public Health regarding concerns about pharmaceutical drug diversion and that is what I am going to be speaking about regarding today with Oxycontin. I would just like to tell you that first I recognize the potential concern regarding medication when I was reviewing control to prescriptions in area pharmacies.

At one time, the majority of these prescriptions being prescribed that I viewed in the C2 schedule were Ritalin and Percocet and other Oxycodone of prescriptions like those. There came a time when we went to review these prescriptions, and they seem to be changing, and the majority of the prescriptions that were being issued and seen in the schedule 2 was Oxycontin.

The second thing that I noticed is that more pharmacists were reporting crimes of doctor shopping for Oxycontin. And when I say doctor shopping, I don't mean going to multiple practitioners but I mean going for a second opinion. I am talking about going to multiple practitioners to get additional control drug prescriptions and these people were not telling their other practitioners that they were in fact doing this type of activity. Not only did they go to multiple practitioners but in fact some of these individuals were even going to multiple emergency room and in some cases, 15 emergency rooms in a month time period. And these were the types of abuses that I was seeing and concerned about and sharing with the public health.

The most alarming incidents have been the pharmacy robberies and burglaries, which are occurring in New Hampshire and New England. We have had a number of night break-ins, armed robberies, unarmed robberies, and strong-arm robberies which Oxycontin had been demanded. The people who are abusing these drugs are willing to risk committing more serious crimes because nothing else matters but getting those drugs. Oxycontin is selling on the street for approximately \$1.00 a milliliter, a milligram. Oxycontin is being sold and traded on the street for money or other elicit drugs.

Oxycontin is the drug being sold and traded, is it the only one being sold and traded; no, but it seems to be the drug of choice of a lot of drug abusers. To my knowledge at this time since January of 2002, we have had 5 armed

robberies in the state of New Hampshire involving Oxycontin. I contacted DEA in Boston and learned that Massachusetts as of 200 has had approximately 60 of these types of crimes since January of 2002. I can tell you from my experiences, the trend of drug in Massachusetts today is our problem tomorrow. Are there any questions?

Senator Russell E. Prescott, D. 19: Thank you very much for your testimony.

Nancy Wiggins: Thank you.

Senator Russell E. Prescott, D. 19: Anyone else wish to come and testify?

<u>Frank Case</u>: Can I give you my feeling about the Board of Pharmacy and the other amendment?

Senator Russell E. Prescott, D. 19: Please have a seat.

Frank Case: Thank you. My name is Frank Case; I am President of the Board of Pharmacy. I would like to thank this Committee for listening to me. We came in with a canoe and now it seems as though the Queen Mary is sitting here with our little House Bill 1218, maybe it' the Titanic. I would just like the Senate to know that on March 20<sup>th</sup> when we met, we considered two possible resolutions to our ill that we knew might come in; one was Representative Millham's amendment that we did speak about and talk to, the other was an amendment that has not come in, so I won't have to bother you with that.

We had no idea of the Patten amendment coming and it is to bad because I would really be interested in how the Board would of taken a position on this; I wouldn't even dare guess, and it may be out of place for me to say that. But I would just like to leave the Committee with this; we had this little kayak that we were pushing around here, we have been working on it for over a year and it is known as House Bill 1218, and we would really like to see that get through however it can happen. We have gone through all of the processes and would appreciate whatever help you can give us. I will sit up there in that hot, old gallery if I have to, you know that. Thank you.

Senator Russell E. Prescott, D. 19: Thank you. Anyone else wish to testify? Under the circumstances of contentiousness of this bill and the amendment, I am going to recess this and if we need to we can just open it back up and close it again; I will find out the proper procedures. So, I just want everybody to understand that, the Committee may need further help in making this decision on this Bill. Thank you very much.

## Hearing Recessed at 11:36 A.M.

Hearing Re-opened on 4/10/02 at 12:18 P.M. in Room 103,LOB.

Senator Russell E. Prescott, D. 19: On line 19, Representative Patten's amendment that came to us yesterday. (See Attachment # 5). And there was given to us during the hearing that there should be more legislative oversight, more public policy oversight. So, bringing that closer to the people, is we would have this amendment that the Commissioner wouldn't just report to the Speaker of the House or the President of the Senate and the Chairman of Joint Legislative Committee, they would report to a Committee. The Committee is made up here, that is what I have requested. I haven't read through the amendment yet. But, in B it says what the purpose is, on the second page (See Attachment # 13).

Senator Robert B. Flanders, D. 7: What I have been advised is...the understanding that I have of this is that Health and Human Services went beyond where they should have in going out and implementing something without rules. And this is a scolding tacit. Senator Patten gave them a way out, if you read on her amendment from 9 to 18, she gave them an out to cut to pass this; it would of given them out to go back and make rules and they testified that they did not want any part of that, they wanted the second part.

So, Representative Patten has told me that we ought to ITL her amendment and go back to the original Millham amendment and pass that and let it go. And, then this will be a message to JLCAR that we do not approve, that the Senate does not approve of what Health and Human Services has done and now go right your rules. That is my understanding, I hope someone else understands it exactly as I do.

<u>Senator Lou D'Allesandro, D. 20</u>: Well, I haven't heard from Representative Patten.

Senator Robert B. Flanders, D. 7: Well, unfortunately she has gone to lunch.

Senator Sylvia B. Larsen, D. 15: But her process makes sense to pass 1218. That hearing was enough of a scolding for any Commissioner.

Senator Robert B. Flanders, D. 7: I would think so.

Senator Lou D'Allesandro, D. 20: Right.

Senator Sylvia B. Larsen, D. 15: And they got the message. And yet, we also heard that in passing, lines 9 through 18, we are going to be in legal battle. This state is going to have to pay megabucks for legal battles far into the future. We will not have the kind of savings, 7 million dollars. And, for those of us who like to save money for the state and to haul in and rain in the spread of prescription drug costs. It makes sense not to put us in legal battles for something that we know needs to be done.

So, I think a fiscal conservative as well as those of us who want to see have access to prescription drugs continue in a way that is affordable for everyone. We need to not put us into litigation. If anything, I say pass 1218 as is. If anything on an amendment, we pass the reporting mechanism, lines 19 and on.

<u>Senator Russell E. Prescott, D. 19</u>: I see it as just the opposite. I see it as just as opposite because if we do not pass Representative Patten's amendment, which is with my isolated amendment to tail on the back end, if we don't say that we as a legislative believe the lock-in program, that we believe in the prior authorization program, we will get sued because the Commissioner had no authority to do what he did.

Senator Sylvia B. Larsen, D. 15: He sighted RSA 126.

Senator Lou D'Allesandro, D. 20: I think quite the contrary. By passing this what you are saying is that he didn't have the authority. It is opening the door for litigation.

Senator Sylvia B. Larsen, D. 15: He has told us that it means that you have to go back to the drawing board and rewrite them starting with the passage of this law.

<u>Senator Robert B. Flanders, D. 7</u>: But the only two that he would have to write would be just those two. He is in JLCAR under that we just recessed it.

Senator Lou D'Allesandro, D. 20: Right.

Senator Robert B. Flanders, D. 7: I yield to you when we were discussing it with him and we were having a great deal difficulty with him and you just recesses.

<u>Senator Sylvia B. Larsen, D. 15</u>: You have lawsuits and you don't have the savings, so you have a double whammy to the budget and it makes no sense to pass, to do that to...

<u>Senator Russell E. Prescott, D. 19</u>: Obviously we don't have the savings because the prior authorization has not been implemented for the lock-in because he himself testified that that is only .4 % and there is no savings yet.

Senator Gary R. Francoeur, D. 14: I think they have already implemented it.

Senator Lou D'Allesandro, D. 20: They have implemented it.

<u>Senator Robert B. Flanders, D. 7</u>: We are scolding him for implementing without rules.

Senator Russell E. Prescott, D. 19: Then why would he tell me, that everybody here, that we are not saving 300 thousand dollars a month, only .4% of it.

Senator Gary R. Francoeur, D. 14: The program is huge.

Senator Russell E. Prescott, D. 19: The public testimony was that the prior authorization and the lock-in program is only .4%, it's nothing.

Senator Gary R. Francoeur, D. 14: Where did the 2 million dollars come from?

Senator Russell E. Prescott, D. 19: I don't know.

Senator Sylvia B. Larsen, D. 15: It's 7 million in a year, I am assuming...

Senator Robert B. Flanders, D. 7: That is right.

Senator Russell E. Prescott, D. 19: So, all of those programs are existing and ongoing and this has nothing to do with it.

Senator Sylvia B. Larsen, D. 15: No, not true.

Senator Gary R. Francoeur, D. 14: No, (inaudible).

Senator Russell E. Prescott, D. 19: Then you are not losing 300 thousand a month, you are losing .4%.

Senator Gary R. Francoeur, D. 14: I think the whole program overall is, my understanding was a couple of million dollars.

Senator Russell E. Prescott, D. 19: Overall?

Senator Gary R. Francoeur, D. 14: It was 7 million a year, Shumway says 7 million, others say 2 million on up. I think that...I'll tell you what, it was a provider that said 2 million; Shumway said 7, the provider said 2. But there is savings and then you have to shut it all down and have to start everything back up and that is what we are really doing (inaudible).

Senator Lou D'Allesandro, D. 20: Right.

Senator Robert B. Flanders, D. 7: You have to realize that this is my first year on JLCAR and that is not something you learn in one year.

Senator Gary R. Francoeur, D. 14: Well, Bob has been there plenty of years.

Senator Robert B. Flanders, D. 7: But he hasn't talked to Patten this morning.

Rep. Bob Mercer: Can't hear you, I'm sorry.

<u>Senator Robert B. Flanders, D. 7</u>: You haven't talked to Representative Patten this morning?

Rep. Bob Mercer: No I have not.

Hearing Closed at 12:20 P.M.

Respectfully Submitted,

Amy Lynn Reczko Committee Secretary.

Attachment # 1 A

Rep. Millham, Belk. 4 March 12, 2002 2002-2928h 10/04

# Amendment to HB 1218

1	Amena me mie	of the but by replacing it with the following:
2		
3 4 5	AN ACT	relative to the regulation of pharmacists and prescription drug orders and relative to the use of non-original containers to organize prescription and nonprescription drugs.
6	•	arags.
7	Amend the bill	by inserting after section 6 the following and renumbering the original section 7 to
8	read as 9:	
9		
10	7 New Para	graph; Pharmacy; Dealing in or Possessing Prescription Drugs. Amend RSA 318:42
11	by inserting afte	r paragraph XII the following new paragraph:
12	XIII. A	nurse licensed under RSA 326-B, who is an employee of a home health care or
13	hospice agency	licensed pursuant to RSA 151:2 and is acting in the course of employment, from
14	organizing the I	prescription and nonprescription drugs of clients into containers designed to aid
15	clients in carryir	ng out a prescriber's directions, provided that the organizing of drugs is documented
16	in the client's n	ursing record and that the original prescription containers remain in the client's
17	possession.	$\cdot$
18	8 New Subp	paragraph; Controlled Drug Act; Non-original Containers. Amend RSA 318-B:14, II
19	by inserting afte	r subparagraph (b) the following new subparagraph:
20	(c) A	A person may possess a controlled drug other than in the original container if the
21	non-original con	tainer is a medication organizer designed to aid the person in carrying out the
22	prescriber's dire	ctions and the non-original container was organized by a nurse licensed under
23	RSA 326-B who	is an employee of a home health care or hospice agency licensed pursuant to
24	RSA 151:2, and	who is acting in the course of employment, provided the original prescription
25	containers remai	n in the person's possession.

# Amendment to HB 1218 - Page 2 -

2002-2928h

# 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, and the filling of prescriptions by automated pharmacy systems.

This bill also allows home health care or hospice agency nurses to organize a client's prescription and nonprescription drugs into non-original containers.

Attachment# 1B

#### **HB 1218**

# Senate Hearing 4/9/02

# **Testimony**

Intro: I have two agendas with this bill today.

HB 1218 was introduced by me to the House ED&A Committee at the request of the Board of Pharmacy. The intent of the bill is to make several changes in the Pharmacy Practice Act. These changes include:

- 1. authority for the Board of Pharmacy to regulate the temporary absence of pharmacists from the pharmacy.
- 2. Clarifying the labeling of drug containers when a prescription is filled using a centralized prescription processing system.

The representatives from the Board of Pharmacy will be able to answer any questions much more effectively than me.

I cannot underscore strongly enough the importance of this amendment. If this problem is not fixed it will cause an enormous problem for visiting nurses and for the patients who rely on the nurse to help them keep their medications carefully organized.

Both the original intent of the bill and this amendment are extremely important. The House ED&A committee has assured me that they will go along with amendment when the fill returns for concurrence.

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(603) 225-5597 (800) 639-1949 Fax (603) 225-5817 Eight Green Street, #2 Concord New Hampshire 03301-4012

April 9, 2002 Senate Executive Departments and Administration Committee

Testimony of
Margaret Franckhauser, Executive Director
Community Health & Hospice, Laconia, NH
Representing Granite State Home Health Association

HB 1218, an act relative to the regulation of pharmacists and prescription drug orders

My name is Margaret Franckhauser and I am Executive Director of Community Health & Hospice, a licensed home health agency located in Laconia. I am here today representing Granite State Home Health Association, an affiliate of the Home Care Association of New Hampshire, which represents licensed home health agencies providing in-home care and supportive services to New Hampshire residents. Our membership includes all of the VNAs and hospital-affiliated agencies in the state, as well as other licensed home care providers.

Our interest in HB 1218 relates to the amendment submitted to you today by Rep. Millham pertaining to the use of pill planners and like devices by home health and hospice nurses. The filling of pill planners, like drawing up insulin in a syringe, is a common nursing activity performed for disabled and impaired individuals living at home. The intent of this practice is to assist an individual to take medications as prescribed.

In revising health facility rules, DHHS proposes to prohibit the use of pill planners, a long-standing practice in the home. Their decision was endorsed by the Attorney General's office who stated the following: "Until either the legislature or the courts further define the limits on the prohibition on the transfer of prescription and controlled drugs into unlabeled containers, it is our advice that State regulations should continue to prohibit the use of pill planners that are not filled and labeled by a licensed pharmacist."

The filling of pill planners by a home health or hospice nurse serves the interest of public health and safety by allowing the preparation of a week's worth of medications in a single visit and promoting compliance with physician orders. Otherwise, some patients would require a daily visit or more by a nurse, which is neither cost effective nor a good use of scarce resources.

The amendment before you addresses this matter in a very narrow way. It creates an exemption in the Pharmacy Act for home health and hospice nurses to be able to fill pill planners. There are likely other situations in which pill planners can be used, but such an evaluation would require more time and research. Hence, we are asking that you incorporate this exception now for home care and hospice nurses, so that they can assist their clients with the safe and appropriate use of pill planners in their own homes.

Thank you for the opportunity to share our views on this matter.

Affectment # 3

# **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 SENATE

presented by

Frank G. Case, R.Ph.
President of the Board of Pharmacy
on
April 9, 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.

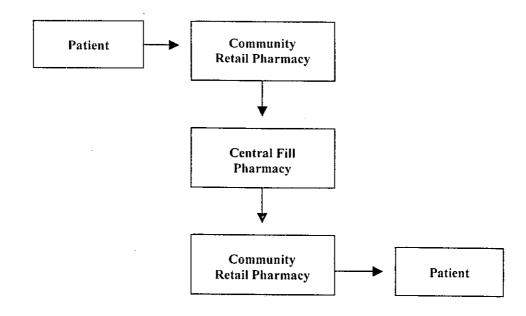
# Turning to HB 1218:

• 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".



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.

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. Currently, most prescriptions are called in to the pharmacy or carried there on handwritten blanks. Over a third of these prescriptions require some re-work because of illegible handwriting, eligibility problems or clinical problems.

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 and overall improve patient safety and the quality of healthcare.

Further, 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 emergency room or operating room), and perhaps even adapted for health care facilities (such as a nursing home for the initial administration of 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.

With regard to the amendment, submitted by Representative Millham, relative to the use of "pill planners" ("medication organizers") by certain nurses licensed as employees of a home health care or hospice agency, and as a service to the patient or client, the Board supports and encourages the inclusion of this amendment as part of HB 1218.



# STATE OF NEW HAMPSHIRE A Hachment & NEW HAMPSHIRE BOARD OF NURSING

78 REGIONAL DRIVE, BLDG. B PO BOX 3898 CONCORD NH 03302-3898

Webpage: http://www.state.nh.us/nursing

TDD Access: Relay NH 1-800-735-2964

Nursing

603-271-2323

Nurse Asst. 603-271-6282

MEMO TO: Senate E D & A Committee

DATE

April 8, 2002

FROM:

New Hampshire Board of Nursing

The Board of Nursing encourages the Board of Pharmacy and the Senate Executive Department and Administration Committee to carefully consider relaxing the Rules surrounding dispensation of medications. It is the belief of the Board of Nursing that this function has become unnecessarily highly scrutinized and legally problematic for licensed nurses but more importantly to the receiver of the care. The Board of Nursing would encourage wording that expands to clients in "Community Based Care", not just home health care or hospice patients. This would allow the licensed nurse "who is acting in the course of his or her employment, from organizing the prescription drugs on clients into containers designed to aid a client in carrying out their prescribes' directions, provided such organization is documented in a a client's record and the original prescription container(s) remain in the clients' possession."

Simply put, there are school nurses who are reluctant to move medications into containers for field trips for fear they will be accused of acting outside their scope of practice as far as dispensing. Sometimes this means children can not accompany their class on trips outside of the school environment. Also, there are home health and hospice nurses who are far more cognizant and skilled than many of their patients in organizing the medications for a week or more at a time. There are clients who live in assisted living facilities, not able to stay in their own homes but not yet ready for nursing homes who cannot see well or open their containers but who could stay out of an institution with "just a little help". Finally, as an example, there are many, many people, elderly who are cared for by their offspring but must attend day care so that their caretakers may work to pay for their care. These clients require medication during their day care stay but currently filling medi-planners and dispensing the medications is legal problematic and worrisome for the nurses assigned to their care.

It is our belief that, in an age where mobility and consumer directed care is the correct course of action, we are all restricting those clients unnecessarily and potentially jeopardizing their practical, low cost care. Please allow nurses to care for these clients in community based care in the manner they know best and do not demean the profession by suggesting they are not capable of simply moving pills from one container to another in these settings. Surely, if a nurse can care for a ventilator dependent patient, with multiple intravenous lines, pulmonary wedge readings, central lines, life and death situations and actions, certainly they can perform these simple tasks.

Attachment # 5

Rep. Patten, Carr. 9 April 8, 2002 2002-3280h 10/01

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#### Amendment to HB 1218

1	Amend the title o	f the bill by replacing it with the following:
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3 4 5 6	AN ACT	relative to the regulation of pharmacists and prescription drug orders and granting rulemaking authority for managing certain plan benefits under Medicaid.
7 8	Amend the bill by	replacing all after section 6 with the following:
9	7 New Parag	raphs; Commissioner of Health and Human Services; Rulemaking Added; Report.
10	Amend RSA 126-A	A:5 by inserting after paragraph XII the following new paragraphs:
11	XIII. The	commissioner, in order to manage plan benefits under Medicaid, shall adopt rules
12	under RSA 541-A	relative to:
13	(a) A	medical pharmacy lock-in program to prevent recipients from obtaining excessive
14	quantities of, or fr	om inappropriately using, prescription drugs through multiple pharmacies; and
15	(b)	A prior authorization process in which a prescriber seeks approval by the
16	department, thro	igh its designated agent, to make payment for drugs which are considered to have
17	a high potential f	or misuse or abuse, are high cost, or should be monitored for correct adherence to
18	clinical protocols.	
19	XIV. The	commissioner shall report to the speaker of the house, the president of the senate,
20	the governor, an	d the chairman of the joint legislative committee on administrative rules by
21	November 1 of e	ach year with respect to the Medicaid prescription drug benefits management
22	programs, includi	•
23	(a) T	he cost savings to the state that have been realized during the current budget
24		e institution of a prior authorization program;
25	(b) Th	e unintended costs in other Medicaid healthcare services programs, including long-
26		ions, hospital admissions, emergency room visits and physician visits during the
27		ennium from the institution of a prior authorization program;

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

required to comply with under the terms of the pharmacy benefits management contract;

average call waiting time and other issues that the state's pharmacy benefits administrator is

(e) Recommendations for other opportunities to improve the management of pharmacy

(c) A report on the volume of prior authorizations as a percentage of total claims,

# Amendment to HB 1218 - Page 2 -

- 1 services or to expand pharmacy benefits to additional populations.
- 2 8 Effective Date.
- 3 I. Section 7 of this act shall take effect upon its passage.
- 4 II. The remainder of this act shall take effect 60 days after its passage.

# Amendment to HB 1218 - Page 3 -

2002-3280h

#### 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, and the filling of prescriptions by automated pharmacy systems.

This bill also grants the commissioner of health and human services the rulemaking authority, concerning managing plan benefits under Medicaid, for a medical pharmacy lock-in program and a prior authorization process and requires the commissioner to report annually on the savings, cost, effectiveness, and recommendations for such Medicaid programs.

We also must determine if the rule violates Part I, Article 28-a —"Unfunded Mandates". If all the criteria are met, we are bound to approve a proposed rule. If some criteria are not met, we object on that specific criteria, but the department may still adopt the rule. However, if there are any rules that JLCAR concludes DO NOT MEET the criteria we have a statutory procedure and time table to file a JOINT RESOLUTION to both bodies of the Legislature and the department CANNOT implement that rule.

The reason I come before you today is to ask you to decide if the definitions of "Prior Authorization" and "Medical Pharmacy Lock-In" which are included in my proposed amendment No. 3280h, are appropriate policies for the Department of Health and Human Services to follow. THIS is how the process should work – a legislative committee determines the policy, giving specific rulemaking authority to an executive department and then that department promulgating the rules.

AS I SEE IT, the rulemaking process used in the Pharmaceutical Services

Rules – Chapter HE-W500 MEDICAL ASSISTANCE Part He-W 570 – was
almost totally reversed. The DHHS notified the public of the hearing and

procedure on October 25, 2001 and implemented the rules on November 2, 2001.

Also along with every proposed rule a cross reference section is submitted, showing the rule number, its title and a reference to either Federal or State laws that govern the rule. In the Cross Reference Section for "PRIOR AUTHORIZATION" AND "MEDICAL PHARMACY LOCK-IN" are ONLY reference by Federal Regulations—

NO NEW HAMPSHIRE RSAs are cross-referenced.

Federal Regulation 42 USC 1396 r-8(d) states:

\* \_

- 1) A State MAY subject ...
- 2) A State MAY exclude . . .
- 3) The following drugs . . MAY be excluded
- 4) A State MAY establish . . .
- 5) A State plan MAY require . . .
- 6) A State MAY impose . . .

In my understanding of the word: STATE" and in my interpretation of the New Hampshire Legislature's use of the word "MAY" IT IS THE LEGISLATURE THAN MAKES POLICY FOR THE EXECUTIVE DEPARTMENTS TO IMPLEMENT – NOT THE OTHER WAY AROUND.

~ ,5 - **\$**}~

As you determine what policy is or is not appropriate please let JLCAR know as soon as possible. Our statutory deadline for proposing a JOINT RESOLUTION is April 23 and our next scheduled meeting is April 19.

This process called RULEMAKING is the public's opportunity to voice their concerns and issues and to be HEARD.

REMEMBER RULES HAVE THE FORCE AND EFFECT OF LAW.

The policy question is yours to decide –the rulemaking process is JLCARs to enforce and I feel strongly that the process has been overridden by DHHS.

Mr. Chairman, thank you for the opportunity you gave me to present this amendment to your committee.

4/15/02.
This is the testimony that was submitted in the hearing.

Attachment + 7



Donald L. Shumway Commissioner

Kathleen A. Dunn Director

# STATE OF NEW HAMPSHIRE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF COMMUNITY AND PUBLIC HEALTH

6 HAZEN DRIVE, CONCORD, NH 03301-6527 603-271-4352 1-800-852-3345, Ext.4352 TDD Access: 1-800-735-2964

June 27, 2001

Her Excellency, Governor Jeanne Shaheen and the Honorable Executive Council State House Concord, New Hampshire 03301

REQUESTED ACTION

APPROVED BY 6+C

DATE 1/5/6/
PAGE 1/-/6

Authorize the Office of Community and Public Health to enter into an agreement with the First Health Services Corporation of 4300 Cox Road, Glen Allen, Virginia 23030, Vendor Number (tba), for the purpose of managing pharmacy benefits under Medicaid in the amount of \$7,596,246 for the period from July 1, 2001, or date of Governor and Council approval, whichever is later, through June 30, 2005. Funds are available and should be allocated in the following account, Medical Grants-Provider Payments, according to state fiscal year with authority to adjust amounts through the Comptroller, if needed and justified, between state fiscal years:

Үеаг	Account Number	Amount .
SFY 2002	010-090-6147-090-0112	\$1,259,824
SFY 2003	010-090-6147-090-0112	\$1,920,126
SFY 2004	010-090-6147-090-0112	\$2,187,118
SFY 2005	010-090-6147-090-0112	<b>\$</b> 2,229,178
Total		\$7,596,246

#### **EXPLANATION**

Pharmacy expenditures incurred by the New Hampshire Medicaid Program have increased at an average rate of eighteen (18%) percent annually over the past four years, mirroring increases observed in other states. Governor Shaheen, Governor Dean (Vermont) and Governor King (Maine) met in Concord at Governor Shaheen's invitation to discuss this common health care concern. The Tri-State Coalition, created as a result of the meeting, worked to create a single Request For Proposal (RFP) for Pharmacy Benefit Management (PBM) Services, the purpose being to leverage the three states' buying power by increasing the size of the population covered and gaining greater discounts through volume purchasing. The Coalition worked together in evaluating proposals from bidders and choosing a vendor, but each State will have its own contract with the vendor due to differing State contract requirements.

The DHHS Office of Community & Public Health (OCPH) issued the Tri-State Coalition RFP for Pharmacy Benefit Management Services on October 23, 2000. Proposals were due on

Her Excellency, Governor Jeanne Shaheen and the Honorable Executive Council June 27, 2001 Page 2

January 9, 2001. Bids were received from eight (8) Pharmacy Benefit Management (PBM) vendors. First Health Services Corporation was chosen as the successful bidder for the following reasons: First Health received the highest overall score, delivered the best on-site presentation, offered the lowest overall cost proposal, demonstrated quality management, and provided the best analysis of our claims history. They have experience with reducing pharmacy expenditures while increasing the quality of care through management of clinically appropriate drug therapy. First Health Services Corporation administration has the potential of reducing our pharmacy expenditures by ten to fifteen percent (10-15%) from projected levels without a PBM.

This contract will enable the First Health Services Corporation to provide Pharmacy Benefit Management services to the NH Department of Health and Human Services in administration of the Medicaid pharmacy program. Services provided will enable the State to improve the quality of health care while at the same time controlling the high cost of pharmaceuticals. First Health Services Corporation shall take the lead in all phases of the PBM project, subject to review by the NH Department of Health and Human Services, including all prior authorization, step therapy, disease state management, Maximum Allowable Cost (MAC) pricing, and development of criteria and clinical documentation for such initiatives.

This contract is necessary because our current pharmacy claims Point of Sale (POS) system does not have the capability to perform the cost saving functions that the First Health POS system can provide. With our current POS system, most prospective drug utilization review alerts are informational only. First Health's system will allow us to deny payment on a claim with a prospective drug utilization review alert unless the pharmacist takes specific actions.

Another concern with our current POS system is that we do not have the capability to prior authorize drugs. First Health's POS system is capable of processing claims for drugs that require prior authorization and they will provide us with the clinical staff to process prior authorization requests. First Health's clinical staff has experience with administering prior authorization programs for other State Medicaid agencies. In addition to prior authorization, First Health's clinical staff will recommend clinically appropriate drug therapy for specific diseases (Disease State Management). Disease state management programs are not only cost effective, but also will improve the quality of care to our recipients. First Health will provide DHHS with their MAC pricing list, which will be used as the basis for the State MAC pricing list. Currently we use the Federal Upper Limit (FUL). States are allowed to expand this list by creating their own State MAC.

Representatives from the OCPH met with members of the New Hampshire Pharmacists Association (NHPA) and the National Association of Chain Drug Stores (NACDS) on February 20, 2001. The purpose of the meeting was to solicit feedback about the eight (8) vendors bidding on the contract and discuss concerns that the Associations had regarding the Tri-State PBM Initiative. The OCPH shared the scoring tool with the Associations. At the close of the meeting the members were advised to e-mail the department directly with any additional feedback. No feedback was received. The OCPH also advised the Associations that there would be meetings

Her Excellency, Governor Jeanne Shaheen and the Honorable Executive Council June 27, 2001 Page 3

held before and during implementation of the PBM to give them an opportunity to address any concerns associated with the new system. These meetings will occur once this contract is approved.

The contract includes a provision that guarantees savings at least equal to the administrative cost of the contract so long as OCPH implements each of the initiatives by the date set in the contract and maintains each initiative for the contract period. The Contractor is obligated to refund to OCPH an amount equal to any excess of administrative fees paid or payable to the Contractor in excess of the demonstrated savings for the same period.

Services will be Statewide.

The cost of these services will be matched by seventy-five (75) percent federal funds with the remainder general funds.

Respectfully submitted,

Kathleen A. Dunn, Director (1)

Office of Community & Public Health

Approved

Donald L. Shumway

Commissioner

#### **Tri-State Coalition Bid Process**

The Tri-State Coalition was formed in February of 2000 after the Governors from Maine, Vermont and New Hampshire met to discuss common health care concerns. As a result of that meeting, the Tri-State Coalition worked with Health Management Associates (HMA) to issue a Request for Proposal (RFP) for a Pharmacy Benefit Manager (PBM). A legal notice for the RFP ran in the Nashua Telegraph and the Manchester Union Leader October 20, 21 & 22, 2000. The RFP was issued on October 23, 2000. The Bidders Conference was held November 14, 2000 and proposals were due at HMA's office on January 9, 2001. Proposals were received from eight (8) vendors; First Health Services, Consultec, Express Scripts, Gould Health Systems, Medimpact Healthcare Systems, NPA, Script Pharmacy Solutions and Wellpoint Pharmacy Management. All three States were involved in the evaluation and selection of the successful bidder. The Tri-State Coalition recommended First Health Service to the three Governors. The Governors made the announcement May 24, 2001 that First Health Services was selected as the successful bidder.

Why was First Health chosen as the successful bidder? First Health met all of the absolute requirements in the three step review process set forth in the RFP.

Step One - Mandatory Requirements: First Health successfully demonstrated that they could meet the minimum requirements set forth in the RFP for:

- Capacity to successfully manage the number of lives;
- Experience managing similar programs;
- Program Requirements, POS System with requirements listed in RFP; and,
- System that can interface with the State.

Step Two - Merits of the Bidder: First Health scored the highest on merits from the RFP review team. The review included:

- Bidder capability, qualifications and experience;
- Qualified personnel and location;
- Approach and methodology for implementation and continued operations; and,
- Aptness and brevity of response.

Step Three - Price Analysis: First Health scored the highest on cost proposal because they offered the lowest overall price.

Summary: First Health

- Received the highest overall score;
- Delivered the best on-site presentation;
- Supplied excellent references;
- Demonstrated quality management;
- Offered the best lowest cost proposal; and,
- Best analysis of our claims history.

PBM Bidders List					
Bidder	Address 1	Address 2	City	State	Zip Code
Consultec	9040 Roswell Road	Suite 700	Atlanta	GA	30350
Express Scripts	6625 West 78th Street		Bloomington	MN	55439
First Health Services Corporation	4300 Cox Road		Glen Allen	VA	23060
Gould Health Services	P.O. Box 1090		Augusta	ME	04332-1090
Medimpact Healthcare Systems	10680 Treena Street	5th Floor	San Diego	CA	92131
National Prescription Administrators	711 Ridgedale Avenue		East Hanover	NJ	07936
Scrip Pharmacy Solutions	100 Clearbrook Road		Elmsford	NY	10523
Wellpoint Pharmacy Management	4553 LaTienda Dr		Thousand Oaks		91362

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1	CATEGORY	SCORE		CONSULTEC	FIRS	T HEALTH
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1	FECHNICAL PROPOSAL SCORE	<del></del>				
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10	QUALITY OF BIDDER	10		5,00		9.50
	INANCIAL STATEMENT REVIEW	5		4.00		5.00
	CLAIMS PROCESSING AND SYSTEMS	20		19.86		20.00
	NETWORK REQUIREMENTS	10		10.00		10.00
	JNINSURED	20		10.00	<u> </u>	11.70
6 1	MEDICAID DRUG BENEFIT MANAGEMENT	20		15.00		20.00
	MEDICAID (OBRA90) REBATES	20		15.00		20.00
	STATE EMPLOYEES AND OTHER NETWORK	20		17.13		18.19
	AUDIT REQUIREMENTS	20		12.76		13.45
10 A	ANALYSIS AND REPORTING	15		10.00		14.50
11 F	HARMACEUTICAL MANUFACTURER LIAISON	20		11.56		15.00
F	ORMULARY AND REBATES FOR STATE		33.2133 33.2133	<del> </del>		
12 E	MPLOYEES AND UNINSURED	20		13.85		9.23
13 L	OUR SYSTEM	5		4.60		4.19
14 L	JTILIZATION MANAGEMENT	5		3.43		3.93
15 C	DISEASE MANAGEMENT	5		4.94		5.00
16 F	PRIOR AUTHORIZATION	10	100 miles 100 miles	8.62		8.46
E	BENEFICIARY AND PROVIDER TELEPHONE					
17 S	SUPPORT	10		10.00		10.00
	D CARDS AND MEMBER MATERIALS	5		5.00		5.00
19 C	OTHER	25		13.75		20.00
	TOTAL	265		194.48		223.15
F	PERCENTAGE			73%		84%
			700000 100000			
C	OST PROPOSAL - MONTHLY					
			70220200 70220702			
्री	PRICING	· · · · · · · · · · · · · · · · · · ·		\$ 310,780	\$	657,682
	SAVINGS			\$ (2,730,291)		(6,414,097)
	FUNDED CLAIMS			\$ 844,896		825,912
	TOTAL (SAVINGS)/COST			\$ (1,574,616)		(4,930,504)
						(3,553,653,7
P	PCT			47%		100%
A	GGREGATE (25% FOR COST PROPOSAL)			67%		88%
					··	

# AGREEMENT

The State of New Hampshire and the Contractor hereby mutually agree as follows:

#### **GENERAL PROVISIONS**

	Identification and Definitio	ns.					Y		
1.1	State Agency Name		1.2	Sta	te Agency Addre	ess			
_	Department of Health and Human Services			6 Hazen Drive					
•	Office of Community an	id Public Health	1		Concord, NH	03301			•
1.3	Contractor Name		1.4		tractor Address	;			
1	First Health Services Co	orporation	ŀ		0 Cox Road				
4 5	A	T-1			n Allen, VA 230				
1.5	Account No.	1.6 Completion Date	1.7		lit Date	1.8	Price Limitat		
	010-090-6147-090	6/30/2005		n/a		1	\$7,596,24	6	
1.9	Contracting Officer for 6	State Account 4.40		•	. = 1	<u> </u>	<del></del>		
1.3	Contracting Officer for S Kathleen A. Dunn, M.		State A		y Telephone Nu	mber			
	Radileeli A. Dullii, W.	PH bilector		603	-271-4501				
1.11	Contractor Signature			Nan	ne & Title of Cor	ntenotor	Ciones		
	TOUT OF	Press K	1.12				=		
1	June 1.	concer	James	G.	Council,	Vice	President	and	Corporat
1.13	Acknowledgment: State	of VA County of Henrico	·			-	· · · · · · · · · · · · · · · · · · ·		Counsel
العراه	glor "	•							
Ougl'	before the undersigned of	officer, personally appeared the person	n identified	in bloc	k 1.12., or satis	factorily	proven to be the	oerso	n whose name
is signed	d in block 1.11., and ackno	owledged that s/he executed this docu	ment in the	capa	city indicated in	block 1.	.12.	Poloo	ii wilooc name
	•			•	-				
1.13.1	Signature of Notary Pub	olic or Justice of the Peace							
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1.13.2	Name 9 Title of Name	CHUMAN 11. X	reples	MA.			.v.=u		•
1.13.2	Name & Title of Notary								4-
	Christine K:	Stevens, (lotary							
1.14	State Agency Signature		1445	Mari	- Citte - 6 Ot-1-	<u> </u>	· · · · · · · · · · · · · · · · · · ·		<del> v </del>
1.17	Otate Agency Signature	(2)	1.15 Signor/		ne/Title of State	Agency	'		
•	$\gamma \leq A \wedge A$	k.00 ~	Signor(		leen A. Dunn, N	ADU Die			**
		(5)			e of Community				
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1.16	Approval by Department	t of Personnel (Rate of Compensation	for Individu	al Cor	nsultants)				
•		,			,				
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1.17	Approval by Attorney Ge	eneral (Form, Substance and Executio	n)						
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1.18	Approval by the Governo	ne and Council					***		
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2. EMF	PLOYMENT OF CONTRA	CTOR/SERVICES TO BE PERFORM	ED. The S	tate of	New Hampshir	e actino	through the see	novid.	antified in bloo
1.1 ("the	State"), engages contract	or identified in block 1.3 ("the Contrac	tor") to perf	om a	and the Contract	o, acuit Ior shall	nerform that was	rk or er	enuneu in biod
both, ide	ntified and more particular	rly described in EXHIBIT A incorporate	ed herein ("	the Se	rvices").	011011	portoriii, atat WOI	n UI 30	aic oi goods, o
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3. EFF	ECTIVE DATE: COMPLE	TION OF SERVICES.							
3.1 Thi	is agreement, and all oblig	pations of the parties hereunder, shall	become eff	ective	on the date the	Govern	or and Council of	the Si	tate of New
riampsni	ire approve this agreemen	it, ("the Effective Date").							
3.2 If th	he date for commenceme	nt in Exhibit A precedes the Effective (	Date all sen	vices p	performed by Co	ontracto	r between the cor	nmend	ement date
and the t	Effective Date shall be per	formed at the sole risk of the contract	or and in th	e ever	nt that this Agree	ement d	oes not become	effectiv	ve, the State

shall be under no obligation to pay the contractor for any costs incurred or services performed; however that if this Agreement becomes effective all costs incurred prior to the effective date shall be paid under the terms of this Agreement. All services must be completed by the date specified in block 1.6.

4. CONDITIONAL NATURE OF AGREEMENT. Notwithstanding anything in this agreement to the contrary, all obligations of the State hereunder,

4. CONDITIONAL NATURE OF AGREEMENT. Notwithstanding anything in this agreement to the contrary, all obligations of the State hereunder, including, without limitation, the continuance of payments hereunder, are contingent upon the availability and continued appropriation of funds, and in no event shall the State be liable for any payments hereunder in excess of such available appropriated funds. In the event of a reduction or termination of those funds, the State shall have the right to withhold payment until such funds become available, if ever, and shall have the right to terminate this agreement immediately upon giving the Contractor notice of such termination. The State shall not be required to transfer funds from any other account to the account identified in block 1.5 in the event funds in that account are reduced or unavailable.

- 5. CONTRACT PRICE: LIMITATION ON PRICE: PAYMENT.
- 5.1 The contract price, method of payment, and terms of payment are identified and more particularly described in Exhibit B, incorporated herein.
- 5.2 The payment by the State of the contract price shall be the only, and the complete, reimbursement to the Contractor for all expenses, of whatever nature, incurred by the Contractor in the performance hereof, and shall be the only and

incurred by the Contractor in the performance hereof, and shall be the only and the complete compensation to the Contractor for the Services. The State shall have no liability to the Contractor other than the contract price.

- 5.3 The State reserves the right to offset from any amounts otherwise payable to the Contractor under this Agreement those liquidated amounts required or permitted by RSA 80.7 through 7-C or any other provision of law.
- 5.4 Notwithstanding anything in this Agreement to the contrary, and notwithstanding unexpected circumstances, in no event shall the total of all payments authorized, or actually made, hereunder exceed the price limitation set forth in block 1.8 of these general provisions.
- 6. COMPLIANCE BY CONTRACTOR WITH LAWS AND REGULATIONS: EQUAL EMPLOYMENT OPPORTUNITY.
- 6.1 In connection with the performance of the Services, the Contractor shall comply with all statutes, laws, regulations, and orders of federal, state, county or municipal authorities which impose any obligation or duty upon the Contractor, including, but not limited to civil rights and equal opportunity laws.
- 6.2 During the term of this Agreement, the Contractor shall not discriminate against employees or applicants for employment because of race, color, religion, creed, age, sex, handicap or national origin and will take affirmative action to prevent such discrimination.
- 6.3 If this agreement is funded in any part by monies of the United States, the Contractor shall comply with all the provisions of Executive Order No. 11246 ("Equal Employment Opportunity"), as supplemented by the regulations of the United States Department of Labor (41C.F.R. Part 60), and with any rules, regulations and guidelines as the State of New Hampshire or the United States issue to implement these regulations. The Contractor further agrees to permit the State or United States, access to any of the Contractor's books, records and accounts for the purpose of ascertaining compliance with all rules, regulations and orders, and the covenants and conditions of this Agreement.
  7. PERSONNEL
- 7.1 The performance of the Services shall be carried out by employees of the Contractor. The Contractor shall at its own expense, provide all personnel necessary to perform the Services. The Contractor warrants that all personnel engaged in the Services shall be qualified to perform the Services, and shall be properly licensed and otherwise authorized to do so under all applicable laws.
  7.2 The Contractor shall not hire, and shall permit no subcontractor or other person, firm or corporation with whom it is engaged in a combined effort to perform the Services, to hire any person who has a contractual relationship with the State, or who is a State officer or employee, elected or appointed.
- 7.3 The Contracting Officer specified in block 1.9, or his or her successor, shall be the State's representative. In the event of any dispute concerning the interpretation of this Agreement, the Contracting Officer's decision shall be final.

  8. EVENT OF DEFAULT, REMEDIES.
- 8.1 Any one or more of the following acts or omissions of the Contractor shall constitute an event of default hereunder ("Events of Default"):
- 8.1.1 failure to perform the Services satisfactorily or on schedule; or
- 8.1.2 failure to submit any report required hereunder, or
- 8.1.3 failure to perform any other covenant or condition of this Agreement.
- 8.2 Upon the occurrence of any Event of Default, the State may take any one, or more, or all, of the following actions:
- 8.2.1 give the Contractor a written notice specifying the Event of Default and requiring it to be remedied within, in the absence of a greater or lesser specification of time, thirty (30) days from the date of the notice; and if the Event of Default is not timely remedied, terminate this agreement, effective two-ten (102) days after giving the Contractor notice of termination; and
- 8.2.2 give the Contractor a written notice specifying the Event of Default and suspending all payments to be made under this Agreement and ordering that the portion of the Contract price which would otherwise accrue to the Contractor during the period from the date of such notice until such time as the State determines that the Contractor has cured the Event of Default shall never-be paid to the Contractor of the Event of Default is cured to the satisfaction of the Department; and
- 8.2.3 set off against any other obligations the State may owe to the Contractor any damages the State suffers by reason of any Event of Default; and 8.2.4 treat the agreement as breached and pursue any of its remedies at law or in
- 8.2.4 treat the agreement as breached and pursue any of its remedies a equity, or both.9. DATA: ACCESS; CONFIDENTIALITY; PRESERVATION.
- 9.1 As used in this Agreement, the word "data" shall mean all information and things developed or obtained during the performance of, or acquired or developed by reason of, this Agreement, including, but not limited to, all studies, reports, flies, formulae, surveys, maps, charts, sound recordings, video recordings, pictorial reproductions, drawings, analyses, graphic representations, computer programs, computer printouts, notes, letters, memoranda, papers, and documents, all whether finished or unfinished.

- 9.2 On and after the Effective Date, all data and any property which has been received from the State or purchased with funds provided for that purpose under this Agreement, shall be the property of the State, and shall be returned to the State upon demand or upon termination of this Agreement for any reason.
  9.3 Confidentiality of data shall be governed by RSA 91-A or other existing law. Disclosure pursuant to a right to know request shall require prior written approval of the State.
- 10. TERMINATION. In the event of an early termination of this Agreement for any reason other than the completion to the Services, the Contractor shall deliver to the Contracting Officer, not later than fifteen (15) days after the date of termination, a report ("the Termination Report") describing in detail all Services performed, and the Contract Price earned, to and including the date of termination. To the extent possible, the form, subject matter, content, and number of copies of the Termination Report shall be identical to those of any Final Report described in EXHIBIT A.
- 11. CONTRACTOR'S RELATION TO THE STATE. In the performance of this agreement the Contractor is in all respects an independent contractor, and is neither an agent nor an employee of the State. Neither the Contractor nor any of its officers, employees, agents or members shall have authority to bind the State or receive any benefits, worker's compensation or other emoluments provided by the State to its employees.
- 12. ASSIGNMENT, DELEGATION AND SUBCONTRACTS. The Contractor shall not assign, or otherwise transfer any interest in this Agreement without the prior written consent of the State. None of the Services shall be delegated or subcontracted by the Contractor without the prior written consent of the State.
- 13. INDEMNIFICATION. The Contractor shall defend, indemnify and hold harmless the State, its officers and employees, from and against any and all losses suffered by the State, its officers and employees, and any and all claims, liabilities or penalties asserted against the State, its officers and employees, by or on behalf of any person, on account of, based or resulting from, arising out of (or which may be claimed to arise out of) the acts or omissions of the Contractor. Notwithstanding the foregoing, nothing herein contained shall be deemed to constitute a waiver of the sovereign immunity of the State, which immunity is hereby reserved to the State. This covenant shall survive the termination of this Agreement.
- 14. INSURANCE AND BOND.
- 14.1 The Contractor shall, at its sole expense, obtain and maintain in force, and shall require any subcontractor or assignee to obtain and maintain in force, both for the benefit of the State, the following insurance:
- 14.1.1 comprehensive general liability insurance against all claims of bodily injury, death or properly damage, in amounts of not less than \$250,000 per claim and \$2,000,000 per incident; and
- 14.1.2 fire and extended coverage insurance covering all property subject to subparagraph 9.2 of these general provisions, in an amount not less than 80% of the whole replacement value of the property.
- 14.2 The policies described in subparagraph 14.1 of this paragraph shall be the standard form employed in the State of New Hampshire, issued by underwriters acceptable to the State, and authorized to do business in the State of New Hampshire. Each policy shall contain a clause prohibiting cancellation or modifications of the policy earlier than 10 days after written notice thereof has been received by the State.
- 15. WAIVER OF BREACH. No failure by the State to enforce any provisions hereof after any Event of Default shall be deemed a waiver of its rights with regard to that event, or any subsequent Event. No express failure of any Event of Default shall be deemed a waiver of the right of the State to enforce each and all of the provisions hereof upon any further or other default on the part of the Contractor.
- 16. NOTICE. Any notice by a party hereto to the other party shall be deemed to have been duly delivered or given at the time of mailing by certified mail, postage prepaid, in a United States Post Office addressed to the parties at the addresses given in blocks 1.2 and 1.4, above.
- 17. AMENDMENT. This agreement may be amended, waived or discharged only by an instrument in writing signed by the parties hereto and only after approval of such amendment, waiver or discharge by the Governor and Council of the State of New Hampshire.
- 18. CONSTRUCTION OF AGREEMENT AND TERMS. This Agreement shall be construed in accordance with the laws of the State of New Hampshire, and is binding upon and Inures to the benefit of the parties and their respective successors and assigns.
- 19. THIRD PARTIES. The parties hereto do not intend to benefit any third parties and this agreement shall not be construed to confer any such benefit. 20. SPECIAL PROVISIONS. The additional provisions set forth in EXHIBIT C hereto are incorporated as part of this Agreement.
- 21. ENTIRE AGREEMENT. This agreement, which may be executed in a number of counterparts, each of which shall be deemed an original, constitutes the entire agreement and understanding between the parties, and supersedes all prior agreements and understandings.



# CERTIFICATE

(Corporation with Seal)

I, James G. Council, Assistant Secretary of First Health Services Corporation, do hereby certify that: (1) I am the duly elected and acting Assistant Secretary of First Health Services Corporation, a Virginia corporation (the "Corporation"); (2) I maintain and have custody of and am familiar with the Seal and minute books of the Corporation; (3) I am duly authorized to issue certificates; (4) that by unanimous written consent in lieu of a duly convened meeting, the Board of Directors of the Corporation has granted Teresa R. DiMarco, President of the Corporation, the right, power, and authority to enter into contracts on behalf of the Corporation and thereby legally bind the Corporation, and the right, power, and authority to delegate the aforementioned right, power, and authority to other officers of the Corporation; and, (5) Teresa R. DiMarco, by Delegation of Authority dated June 18, 2001, did authorize James G. Council, Vice President, Corporate Counsel and Assistant Secretary to execute on behalf of the Corporation all contracts, leases, and other business agreements (and related Documents) during Teresa R. DiMarco's absence until June 25, 2001.

	IN WITNESS WHEREOF, I have hereunto set my hand as the Assistant Secretary of the Corporation this 19 <sup>th</sup> day of June, 2001.  Assistant Secretary
	(Seal)
-	On this the 19 day of June ,, 2001, before me, Chrotine 151 evens (), the undersigned Officer, personally appeared James 6. Lounce 1 , who acknowledged her himself to be the Plast Secretary of First Health Services Corporation, and that she he as such VP Asst Secretary being authorized to do so, executed the foregoing instrument for the purposes therein contained, as  IN WITNESS WHEREOF I hereunto set my hand and official seal.
	Christian Stenent, Actam Notary Public/Justice of the Peace
	My Commission expires: April 30.2004

# **Exhibit A**

# **SCOPE OF SERVICES**

DATE: June 18, 2001

CONTRACT PERIOD: July 1, 2001 to June 30, 2005

CONTRACTOR: First Health Services Corporation

ADDRESS: 4300 Cox Road
Glen Allen, VA 23060

TELEPHONE: (804) 965-7555

Marketing & Account Peter Quinn Manager:

This agreement is to provide pharmacy benefit management services to the NH Medicaid population for the purpose of improving the quality of pharmaceutical health care and controlling pharmacy costs through clinically appropriate drug therapy.

In addition to the scope of services to be provided by First Health Services Corporation (hereinafter, "Contactor") to the New Hampshire Department of Health and Human Services (hereinafter, "Department") as set forth in the following pages of Exhibit A, attached and incorporated by reference as Exhibit A1 is the Department's RFP issued October 23, 2000. Also attached and incorporated by reference as Exhibit A2 is the Contractor's proposal to provide Pharmacy Benefit Management Services issued January 9, 2001. All documents that make up this Agreement, and the order of precedence of the documents that constitute the Agreement are set forth in Exhibit C.

# 3. Implementation

- 3.1 Implementation will occur within 120 days of contract signing
  - The Contractor shall be responsible for implementation of all aspects of the system interfaces to support Pharmacy Benefit Management (PBM) and New Hampshire Advanced Information Management (NHAIM) processing as well as the design and build of the Benefit Plan. The Contractor is responsible for all aspects of the Contractor's side of the interface. The Department shall be responsible for the NHAIM side of the interfaces.
- 3.2 Project Initiations and Management
  - The Contractor shall be responsible for project initiation which shall include a kick-off meeting where Contractor and Department staff are introduced and the initial planning completed. The plan shall include a schedule of all work to be completed through two

months of post-implementation as well as ongoing operations. During this phase the Contractor shall establish issue tracking and prepare for the Department weekly status reports.

# 3.3 Requirements Analysis

Requirements Analysis shall include both system and benefit plan requirements. The requirements analysis shall be the first activity to be performed under the plan. The Contractor shall make sufficient system and benefit plan staff available in Concord during the requirements analysis phase. Within five (5) days of completion of the Requirements Analysis sessions, the Contractor shall produce a written requirements document which shall include both the system interface and benefit plan. The requirements documents shall be signed off by the Department.

# 3.4 Design, Code and Test

The Contractor shall design, document the design, code, and unit test the system interfaces and benefit plan components. The system interface design and unit testing shall be coordinated with the Department. Design sign-off shall be required from the Department.

# 3.5 User Acceptance Testing

Three forms of acceptance testing shall occur. The Medicaid Management Information System (MMIS) vendor shall conduct their own acceptance testing, the Contractor shall conduct its own acceptance testing and the Department shall conduct its own system acceptance testing. The Contractor shall run the test scripts for the Department. Interfaces and benefit plans can be tested together. System test or acceptance test results conducted by the Contractor shall be provided to the Department.

# 3.6 Users and Provider Training

The Contractor shall provide User and Provider training necessary to work with the Contractor on the reporting and other relevant modules. The Contractor shall provide training/reference documents that are acceptable to the Department.

# 3.7 Conversion of Data and File Loads

Part of acceptance testing shall be a mock exchange of conversion data between the Contractor and NHAIM. The actual conversion of data shall occur prior to implementation as described in the final plan.

# 3.8 Operational Readiness Review

Prior to full implementation and migration of PBM from a test to a live environment the Department and the Contractor shall develop a readiness checklist. The parties shall review status prior to full implementation of PBM. The Department shall make the final decision on actual implementation date.

# 3.9 Implementation Support

The Contractor shall provide sufficient staff as on site implementation support for the first full thirty (30) days of processing for both system and clinical issues.

# 3.10 Post Implementation Review

The Contractor and the Department shall conduct a Post Implementation review meeting at the end of the second month of operation. The Contractor shall provide a full status report at that meeting.

# 4. Claims Processing and System

- 4.1 The Contractor shall provide Point of Sale (POS) on-line real time 24/7 claims processing system for adjudication and reversal of pharmacy claims.
- 4.2 The Contractor shall support paper or batch (electronic tape/disk/Bulletin Board System {BBS}) claims processing.
- 4.3 Contractor shall achieve Health Insurance Portability & Accountability Act (HIPAA) compliance within the time frame established by the published final rule.
- 4.4 Contractor shall support the transition to National Council for Prescription Drug Programs (NCPDP) version 5.1 prior to HIPAA compliance date.
- 4.5 The Contractor shall support conversion of NCPDP version 3.2 to version 5.1 for the first year for providers using version 3.2.
- 4.6 The POS processing system (First SX) shall ensure that a transaction is subject to all syntax editing (e.g., number-only fields are all numeric) and that the transaction is subject to all relational editing (e.g., member number is on file).

The Contractor shall be responsible for ensuring that the system shall support pricing methodology based on:

- 4.7 Brand vs. Generic (typically indicators from First Data Bank (FDB) are used to determine brand vs. generic; however, the proposed system shall allow for Department determination of a drug's brand/generic status when applicable).
- 4.8 Federal Upper Limit (FUL) or State Maximum Allowable Cost (MAC) (FH to provide its' MAC price list & update regularly. Could be used as either the actual MAC, or as a basis for setting the NHFUL)
- 4.9 Department Pricing
- 4.10 Standard vs. Non-standard package size
- 4.11 Dispensing Fee allowing variable fees
- 4.12 Other Insurance price reductions using Coordination of Benefits
- 4.13 Patient responsibility price reductions (Copays)
- 4.14 Variable benefit limit; monthly, quarterly, annually, lifetime
- 4.15 Lesser of logic; U&C, Gross Amt, Department Pricing, FDB pricing
- 4.16 Variable dispensing fee logic (i.e., Clozaril, Unit Dose Meds)
- 4.17 POS System must calculate price for compounded prescription and infusion claims when the NCPDP 5.1 transaction standard is being utilized.
- 4.18 Contractor shall accept compound prescriptions claims using NCPDP format when NCPDP version 5.1 is available

4.19 Contractor shall support the process for handling compounds with a dummy National Drug Code (NDC), or most expensive/prevalent ingredient until version 5.1 of the NCPDP transaction standard is implemented.

The system must provide lock-in functions to lock Recipients into one Pharmacy or Physician

4.20 First SX<sup>TM</sup> shall provide the ability to perform multiple lock-in functions. The Department shall be able to lock a recipient into a specific pharmacy (ies), physician(s), or combinations of pharmacy and physician(s).

# 5. The system must support TPL Cost Avoidance

- 5.1 The claims processing system shall allow for provider-submitted TPL overrides to identify claim adjudication status. A provider override is allowed under those situations where benefits are exhausted or partially exhausted. The system shall retrieve override variables from applicable historical transactions that shall be used in conjunction with the current transaction to ensure that all carrier/plan combinations have been overridden for adjudication to be completed. The carrier/plan name, client identifier, and member information shall be communicated to the provider using messaging information in the NCPDP response record. Multiple carrier/plan data shall be provided to the pharmacist as part of the cost avoidance override process.
- 5.2 The Contractor shall verify eligibility prior to pricing claims.
- 5.3 Contractor shall interface with NHAIM System for daily eligibility file uploads.
- 5.4 Contractor shall interface with NHAIM System for daily provider file updates
- 5.5 The Contractor shall provide a desktop pricing model for reimbursements in cases of retroactive eligibility.
- 5.6 Contractor shall maintain system interface with NHAIM for transfer of information.
- 5.7 The Contractor shall send claims information including all adjustments to NHAIM for Health Care Financing Administration (HCFA) reporting to be carried out the Department or it's MMIS vendor. The Contractor is responsible to ensure that the information is in a format suitable to the department or its MMIS vendor.
- 5.8 The Contractor shall receive Medical claims data to carry out Drug Utilization Review (DUR) and Disease State Management functions
- 5.9 The Contractor shall receive daily eligibility, third party liability and provider files.
- 5.10 The Contractor shall work with the Department's Medicaid Decision Support System (MDSS) Contractor during MDSS system development.
- 5.11 The Contractor shall send bi-weekly warrant tapes to the Treasurer, State of New Hampshire for provider payments.

5.12 The Contractor shall receive the provider payments from the Treasurer, match with the remittance advice and mail them to the providers.

# 6. Provider Network

- 6.1 During development Contractor staff shall conduct provider training
- The Contractor shall provide education to providers on claim filing and program specifics. The Contractor shall respond to provider billing questions/problems received by telephone within twenty-four (24) hours. All written inquires will b responded to within 5 days of receipt.
- 6.3 The Contractor shall issue biannual provider manuals to every pharmacy in Medicaid network and keep updated manual posted on website
- 6.4 The Contractor shall provide education and training to all providers
- 6.5 The Contractor shall coordinate transition of pharmacy providers billing software so that services are not interrupted.

# 7. Auditing

- 7.1 The Contractor shall provide a complete and comprehensive audit program at the direction of the Department and as set forth in this section.
- 7.2 All prescription claims shall be reviewed and analyzed during the detection phase. The Contractor shall focus on duplicate claims, Average Wholesale Price (AWP) pricing errors, Usual & Customary pricing and incorrect discounting, and shall also review claims from excluded drug category prescriptions that were dispensed.
- 7.3 The Contractor shall establish high dollar thresholds that will trigger desk audits.

The Contractor shall work with Department staff in the following manner:

- 7.4 Determine the criteria for special audit selection procedures and directives.
- 7.5 Define a threshold for certain "high-cost" compound pharmacy claims by May 1, 2002
- 7.6 Keep Department informed about specific audit concerns.
- 7.7 Provide quarterly reports to Department to summarize and detail audits performed.

# 8. On-site Audit Percentage

- 8.1 The Contractor shall work with the Department to identify outlier criteria from the review in order to determine the number of on-site reviews.
- 8.2 The Contractor shall conduct audits on at least 10 percent of the outliers identified through desktop audits on an annual basis.
- The Contractor shall conduct complete and comprehensive audit program that shall include both desk and on-site audits.
- 8.4 The Contractor shall detect duplication of claims.
- 8.5 The Contractor shall detect potential fraud, abuse and misuse of prescription drug benefit.

- 8.6 The Contractor shall initiate all necessary recovery reports.
- 8.7 The Contractor shall conduct a maximum of fifteen (15) on-site audits per year. The Department shall determine the actual number of on-site audits per year.
- 8.8 The Contractor shall select pharmacy providers for audit using provider profiling reports. The Contractor approach to pharmacy audits shall include:
  - 8.8(a) Reviewing Medicaid and other Department policy documents to verify that patterns identified are not due to intricacies of payment methods or practices
  - 8.8(b) Collaborating with Department staff on a regularly scheduled basis to identify data reporting/capturing that is State specific that maybe responsible for erroneous fraud, waste and abuse detection
  - 8.8(c) Identify and analyze statistically valid sample of claims performing desk audits and reviewing original documents on site
  - 8.8(d) Interviewing providers, beneficiaries, and related persons
  - 8.8(e) Reviewing cases with Medical consultants
  - 8.8(f) Referring appropriate cases to State Surveillance & Utilization Review (SURS) units
  - 8.8(g) Keeping qualitative and quantitative statistics on substantiated cases and compile reports to be submitted to the Department on a quarterly basis
  - 8.9(h) Maintain documentation of findings and recoveries to be submitted to the Department on a quarterly basis
  - 8.10(i) The Contractor shall upon completion of an audit, generate and mail a final report 30 days to appropriate pharmacy or third party administrator.
- 8.9 The Contractor shall provide sufficient audit department-staff with expertise in;

# 9. Medicaid policy

- 9.1 Healthcare over payment identification and recovery
- 9.2 Caseload management and reporting
- 9.3 System development and integration in data warehousing and fraud control applications
- 9.4 The Contractor shall develop audit criteria for on-site and desk audits. The criteria shall be reviewed and approved by the Department prior to use.
- 9.5 The Contractor shall identify providers that deviate from other providers by 20% or more from average claim statistics such as number of claims per beneficiary, total payment per beneficiary, number of brand certifications.

- 10. All on-site audits shall be performed by a licensed pharmacist(s) employed by the Contractor beginning May 1, 2002.
- 11. The Contractor shall conduct two types of on-site audits, which shall include the following components:
  - Usual and Customary audits to detect problems relating to abuse of usual and customary charges of processed claims.
  - 11.2 Full on-site pharmacy abuse compliance audit, all claims selected for review shall be checked against the hard copy of the prescription on-site for;
    - 11.2(a) Verification of patient name and eligibility
    - 11.2(b) Drug information per authorized prescription
    - 11.2(c) Dispense as written code
    - 11.2(d) Quantity authorized to dispense and refill limitations
    - 11.2(e) Brand / Generic substitution
    - 11.2(f) Day supply
    - 11.2(g) Co-payment collection
    - 11.2(h) DEA compliance
    - 11.2(i) Dispensing accuracy
    - 11.2(j) Signature log
    - 11.2(k) Unfilled prescription policy and procedures
    - 11.2(1) Telephone order authorization
    - 11.2(m) Reversal of unclaimed prescriptions
    - 11.2(n) Invoices of a sufficient number of purchases on target drugs to support the dispensing history
- 12. Analysis and Reporting
  - 12.1 The Contractor shall provide standard reports which shall include:
    - 12.1(a) number of recipients
    - 12.1(b) number of prescriptions and cost per prescription
    - 12.1(c) cost per recipient
    - 12.1(d) total cost both per month and year to date by State Fiscal Year.
  - 12.2 The Contractor shall provide the following standard reports on a monthly basis:
    - 12.2(a) Denied claims analysis
    - 12.2(b) Cost and Utilization reports
    - 12.2(c) Summarization of claims reports
    - 12.2(d) Drug ranking
    - 12.2(e) Generic analysis reporting
    - 12.2(f) Monthly summary
    - 12.2(g) Balancing report
    - 12.2(h) Recipient summary
    - 12.2(i) Therapeutic class analysis
    - 12.2(j) Twelve month summary
    - 12.2(k) Drug utilization analysis

- 12.2(l) Distribution report
- 12.2(m) New drug listing report
- 12.3 The Contractor shall provide interfaces that will ensure that MARS/SURS Federal Reports can be produced by the Department or its MMIS vendor.
- 12.4 The Contractor shall provide personal computer software for Ad-hoc (First IQ) to the Department for 28 users, additional client licenses may be acquired at a per seat price.
- 12.5 The Contractor shall provide hands-on five (5) day training for First IQ at the Contractors' headquarters.
- 12.6 The Contractor shall provide eight (8) hours per month of consultation to determine the best ways to access data.
- 12.7 The Contractor shall provide customized reports, which shall be developed during implementation and approved by the Department. The reports shall include but not be limited to:
  - 12.7(a) Any standard report that is modified for the Department
  - 12.7(b) Any Department specific report that is created
  - 12.7(c) Any reports created in the ad-hoc report manager
- 12.8 The Contractor shall provide templates for:
  - 12.8(a) Claims summary report
  - 12.8(b) Per member/per month (PMPM) report
  - 12.8(c) Claims detail report
  - 12.8(d) Top X ranking report
  - 12.8(e) Top X prescribers
  - 12.8(f) Co-pay Analysis
  - 12.8(g) Monthly listing of claims with excess dollars
  - 12.8(h) Patient claim history report
  - 12.8(i) Prescribing provider ranking by region
  - 12.8(j) Dispensing provider ranking by region
  - 12.8(k) Drug search
  - 12.8(1) Top 20 Prior authorized Drugs
- 12.9 The Contractor shall provide Power play reports (drug trends and utilization)

# 13. Pharmaceutical Liaison

- 13.1 The Contractor shall develop and maintain working relations with pharmaceutical manufacturers.
- 13.2 The Contractor shall develop working relations with professional pharmacy associations such as New Hampshire Pharmacist Association (NHPA) and National Association of Chain Drug Stores (NACDS)
- 13.3 The Contractor shall develop working relations with the Department's Fiscal Agent

# 14. Medicaid Drug Coverage Management

14.1 The Contractor shall implement drug coverage parameters as set by the Department

- 14.2 The Contractor shall duplicate Department's current reimbursement methodology
- 14.3 The Contractor shall assign a full-time clinical manager (RPh or PharmD) for daily oversight of the Department's clinical program

# 14.4 The Contractor's clinical manager shall:

- 14.4(a) Recommend drugs for prior authorization and step therapy to the Department's P&T Committee at regularly scheduled meetings.
- 14.4(b) Provide periodic written report to the Department's P&T Committee
- 14.4(c) Attend all P&T Committee meetings
- 14.4(d) Be available to the Department for consultation and oversight activities related to the management of the Department's formulary(s) on a daily basis.
- 14.4(e) Gather and review information as requested by the P&T Committee in order to facilitate and support formulary management. This function is also typically used to determine a course of action with newly introduced drugs into the market.
- 14.4(f) At each P&T Committee meeting provide written summary information on each Department's pharmacy claims for the previous quarter. Based on this information, the Clinical Manager shall also provide recommendations for additions or changes in the programs and provide educational materials including supportive clinical research, protocols, and financial analysis for newly approved therapies and indications.
- 14.5 The Contractor shall update drug prices weekly using FDB
- 14.6 Written and electronic report provided weekly to identify changes made to the drug file
- 14.7 Provide the State with subscriptions to; Price Alert, Medispan and Redbook
- 14.8 The Contractor shall update FUL weekly using FDB
- 14.9 Contractor's MAC shall be updated monthly by the Contractor
- 14.10 The Contractor shall integrate drug coverage design with eligibility system by utilizing eligibility, drug, and benefit systems to adjudicate claims for appropriate coverage. Batch, POS, and paper claims shall be adjudicated through the same adjudication model.

# 15. Medicaid OBRA '90 Rebates

- 15.1 The Contractor shall manage all Medicaid drug rebate and dispute resolution from July 1, 1994 and ongoing
- 15.2 The Contractor shall implement accounting functions of drug rebate
- 15.3 The Contractor shall maintain quarterly unit rebate amount data
- 15.4 The Contractor shall maintain accounting procedure for prior period adjustments
- 15.5 The Contractor shall calculate interest due on overdue payments
- 15.6 The Contractor shall provide online message indicating obsolete NDC's

- 15.7 The Contractor shall provide data on claims reversed post invoicing
- 15.8 The Contractor shall perform quarterly posting of reconciliation invoice
- 15.9 The Contractor shall perform posting of prior quarter adjustment statements
- 15.10 The Contractor shall provide reporting to HCFA for required rebate reports
- 15.11 The Contractor shall implement dispute resolution functions
- 15.12 The Contractor shall respond to HCFA changes

### 16. Drug Utilization Review

- 16.1 The Contractor shall perform Drug Utilization Review as defined by the RFP, includes ProDUR, Concurrent DUR, RetroDUR, and educational programs.
- 16.2 The Contractor shall provide a full-time clinical manager (RPh or PharmD) to coordinate with State DUR Boards.
- 16.3 The Contractor shall present annual DUR plan to the Department and DUR board.
- 16.4 The Contractor shall prepare annual DUR report for both the Department and HCFA as mandated by HCFA.
- 16.5 The Contractor shall attend each DUR Board meeting and present a report to the DUR board.
- 16.6 The Contractor shall recruit clinical pharmacists educators from local pharmacies to perform face-to-face clinical detailing to targeted providers.
- 16.7 The Contractor shall develop policy and procedures for a clinical detailing program, which shall be reviewed and approved by the Department prior to use.
- 16.8 The Contractor shall provide orientation and training of clinical pharmacist educators as approved by the Department.
- 16.9 The Contractor shall identify target drug therapies by November 1, 2001.
- 16.10 The Contractor shall develop educational materials by November 1, 2001, which shall be used by the Contractor for their clinical detailing program.
- 16.11 The Contractor shall have the capacity to identify targeted prescribers by November 1, 2001 using the following criteria:
  - 16.12(a) Over treatment/ under treatment
  - 16.12(b) Treatment failure
  - 16.12(c) Drug to drug interactions
  - 16.12(d) Iatrogenic effects / adverse reactions
  - 16.12(e) Therapeutic duplication
  - 16.12(f) Drugs with diagnosis / drugs without diagnosis
  - 16.12(g) Drugs without procedure
- 16.13 The Contractor shall present analysis, education materials and list of targeted prescribers with specific profiles to DUR Board for approval on a quarterly basis.
- 16.14 The Contractor shall provide face to face clinical detailing beginning May 1, 2002 to the top ten percent of all providers that are identified by

- physician profiling on a quarterly basis not to exceed one hundred and twenty (120) interventions per year.
- 16.15 The Contractor shall provide clinical pharmacist educators with profiles to perform face to face interventions with targeted providers.
- 16.16 The Contractor shall comply with all OBRA '90 and PL 104 191 requirements.
- 16.17 The Contractor shall perform prospective and Concurrent DUR on line real time 24/7.
- 16.18 The Contractor shall perform retrospective DUR through analysis of claims history and present quarterly reports to the Department and DUR Board.
- 16.19 The Contractor shall provide educational programs and materials to the targeted providers.

### 17. Utilization Management

- 17.1 The Contractor shall provide integrated clinical programs which best preserve both clinical and fiscal resources of the State of New Hampshire.
- 17.2 The Contractor shall present annual utilization plans which control/reduce pharmacy utilization.
- 17.3 The Contractor shall analyze claims and present recommendations for utilization management programs to the Department on a monthly basis.
- 17.4 The Contractor shall provide a report of the top 100 utilizing recipients to the Department on a monthly basis.
- 17.5 The Contractor shall provide First IQ for utilization management screenings by the Department.
- 17.6 The Contractor shall provide face to face interventions between the Contractor's clinical staff and the top ten (10) percent of targeted and prescribing and dispensing providers not to exceed one hundred and twenty (120) interventions per year.
- 17.7 The Contractor shall provide utilization management reminders containing specific information and suggested changes in prescribing and dispensing practices to targeted providers on a monthly basis.
- 17.8 The Contractor shall analyze utilization patterns on a monthly basis for recipients/pharmacies/prescribers using the following criteria:
  - 17.8(a) Large number of prescriptions per month
  - 17.8(b) High cost of prescriptions
  - 17.8(c) Prescriptions from multiple pharmacies or prescribers
  - 17.8(d) Disproportionate dispensing patterns
  - 17.8(e) Low generic substitution
  - 17.8(f) High dispense as written rate
  - 17.8(g) High number of DUR overrides
- 17.9 The Contractor shall provide First IQ fraud and abuse model to perform fraud and abuse analysis using standard algorithms to support the Department's fraud and abuse detection effort.

### 18. Disease Management

- 18.1 The Contractor shall provide a Disease Management program to promote appropriate medical and pharmaceutical utilization.
- 18.2 The Contractor shall identify and manage troublesome therapies for the following:
  - 18.2(a) Diabetes
  - 18.2(b) Asthma
  - 18.2(c) Congestive Heart Failure
  - 18.2(d) Coronary Artery Disease
  - 18.2(e) Chronic Obstructive Pulmonary Disease
  - 18.2(f) Peptic Ulcer Disease
  - 18.2(g) Arthritis
- 18.3 The Contractor shall provide a disease state management process to:
  - 18.3(a) Develop algorithms through predictive modeling
  - 18.3(b) Rank patients' risk of preventable adverse therapeutic outcomes
  - 18.3(c) Provide interventions and education
- 18.4 The Contractor shall provide a disease management overview to:
  - 18.4(a) Implement broad based clinical programs
  - 18.4(b) Educate prescribers about matters of clinical practice
  - 18.4(c) Influence patient behavior to take an active role in their own care
- 18.5 The Contractor shall provide a written clinical and financial outcome assessment to the Department on a monthly basis

### 19. Prior Authorization

- 19.1 The Contractor shall establish a prior authorization program, which shall be fully automated and an integral part of the POS/ProDUR system.
- 19.2 Any medication requiring prior authorization shall be reject by an on-line adjudication process.
- 19.3 This rejection shall include messaging describing the reason for the denial and the Contractor's toll-free telephone number for the pharmacist or the prescriber.
- 19.4 The retail pharmacist or the prescriber may initiate a prior authorization request.
- 19.5 The prescriber or his/her agent may call the Clinical Support Center to request the approval.
- 19.6 The caller first speaks to a certified pharmacy technician who collects the information from him/her based on the criteria for that medication or class of medications.
- 19.7 If the information furnished by the physician satisfies the criteria, the technician may grant an approval.
- 19.8 If the retail pharmacist initiates the call the certified pharmacy technician shall call the prescriber and collect the information from him/her based on the criteria for that medication or class of medications.

- 19.9 If the information furnished by the physician satisfies the criteria, the technician may grant an approval.
- 19.10 If there is any doubt that the criteria have been met, the telephone call is escalated to a licensed clinical pharmacist who will discuss the patient specifics with the prescriber.
- 19.11 The Contractor shall assist the prescriber in changing to a more appropriate therapy rather than simply denying the initial request.
- 19.12 If the prescriber is unwilling to switch the patient to an acceptable therapy, the pharmacist will issue a denial.
- 19.13 The Contractor shall recommend drugs for Prior Authorization to the Department by September 1,2001.
- 19.14 The Contractor shall describe prior authorization process and develop clinical guidelines by September 1, 2001. The Department shall review and approve the process prior to use.
- 19.15 The Contractor shall provide prior authorization tracking process so that providers do not have to submit claim with PA number by November 1, 2001.
- 19.16 The Contractor shall develop an appeals process in accordance with Department procedures by September 1, 2001. The Department shall review and approve the process prior to use.
- 19.17 The Contractor shall provide regular reporting to the Department to summarize Prior Authorization activity on a monthly basis.
- 19.18 The Contractor shall provide a clinical manager to review medical necessity on all prior authorization requests.
- 19.19 The Contractor shall match prior authorizations to the audit process, identifying any drugs restricted to PA that were dispensed without such authorization on a monthly basis.

### 20. Beneficiary and Provider Telephone Support

- 20.1 The Contractor shall provide telephone support for both providers and recipients as follows:
  - 20.1(a) Must be toll free
  - 20.1(b) Available 24 hours per day, 7 days per week;
  - 20.1(c) Sufficient telecommunications capacity;
  - 20.1(d) Assist beneficiaries in locating participating pharmacies;
  - 20.1(e) Telephone support for providers seeking prior authorization;
  - 20.1(f) Must offer translation services.

### 21. Staffing Requirements

- 21.1 The Contractor shall provide an account manager with a business degree, pharmacy related experience and knowledgeable in State Government affairs located in Concord, New Hampshire.
- 21.2 The Contractor shall provide a clinical manager (RPh or PharmD) located in Concord, New Hampshire.
- 21.3 The Contractor shall recruit clinical pharmacist educators from local pharmacies

- 21.4 The Contractor shall provide access to clinical and technical staff at the Contractors home office.
- 21.5 The Contractor shall solicit feedback from the Department on candidates for the Account Manager and Clinical Manager.

### 22. Disaster Recovery

22.1 In the event of a natural disaster there must be a system in place for processing claims so that recipients are not denied access to prescriptions. The disaster recovery system shall be reviewed and approved by the Department if it is deemed to be adequate by the Department.

### 23. Post Implementation

- 23.1 The Contractor shall be responsible for routine system maintenance, including any changes necessary to maintain interface.
- 23.2 The Contractor shall make available system modification hours at an agreed upon hourly rate.

### 24. System Monitoring

- 24.1 The Contractor shall put a process in place to monitor the system interface for:
  - 24.1(a) Error tracking
  - 24.1(b) Error identification
  - 24.1(c) Error correction
- 24.2 The Department shall review and approve the process if the process is deemed to be adequate by the Department.

June 5, 2001

#### Exhibit B

### Methods and Conditions Precedent to Payment

### I) Terms of Payment

Subject to the Contractor's compliance with the terms and conditions of the agreement and for services provided, the Department shall reimburse the Contractor at .2730 cents per adjudicated Medicaid claim. The Coalition intends to add additional groups under the individual States' contracts up to a total volume of claims of 6,000,000 annually by the Coalition. The additional group's claims will be the product of the total Coalition's claims including other groups such as State Employees, the Uninsured or Seniors' currently enrolled in the discount program. If the Coalition claims count exceeds 6,000,000 annually for the excess claim count the Contractor will be reimbursed .019 cents per claim for the next 125,000 claims, 0.005 cents per claim for the next 125,000 claims and above. The Department as a member of the Coalition, anticipating the minimum claims volume threshold may not be achieved within 6 months of the last Coalition commencement date, agrees to extend the contract length from 2 to 4 years.

#### **Coalition Claims Volume based Rates**

			<u>From</u>					
		Up to	Fr	om 6m to	6	.125m to	Fro	om 6.25m
Coalition Groups	<u>6</u>	000,000	6	,125,000	6	,250,000	8	higher
NH-Medicaid Regular	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
NH-Medicaid Senior Waiver	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
NH State Employees	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
NH Uninsured	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
VT Medicaid Regular	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
VT Medicaid ABD	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
VT VAHP Uninsured	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
VT VAHP Pharmacy	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
VT Vscript	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
VT Vscript Expanded	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
Misc other groups	\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031

An adjudicated claim is defined as a "Paid" or "Denied" claim. Multiple submissions of up to 4 claim lines per transaction shall be counted by claim line rather than by transaction.

The Department shall reimburse the Contractor for the following additional items at the rates quoted in accordance with the services defined in the Contractor's cost proposal as outlined below:

- 1) Utilization management \$0.0763 cents x Per Member Per Month (pmpm)
- 2) Medicaid Disease management (8 modules) \$0.14 x pmpm
- 3) Auditing Up to 15 audits annually at \$1,400 per audit

- 4) Drug coverage management \$0.1445 x pmpm
- 5) Obra 90 Rebate management \$0.2511 x pmpm
- 6) Telephone support \$0.0596 x pmpm
- 7) Prior authorizations \$11 per approval by Pharmacy Tech & \$19.50 per approval by RPh Pharmacist
- 8) Disease state profiling \$0.0272 x pmpm
- 9) Provider profiling \$0.0272 x pmpm
- 10) Clinical detailing \$300 per detail session x up to 120 clinics

Also, in accordance with the Contractor's cost proposal, the Contractor agrees to further volume level discounts as each 100,000 aggregate members per month are added for those items defined as per member per month in the Coalition proposal.

The contractor shall be reimbursed for Postage, Printing, ID Cards, Provider Manuals and Telephone toll free numbers (Call Center Usage) at cost to the Contractor plus 12 percent Administration expense under the Contract. This amount shall be included in the Maximum Total Payment.

The Contractor's prices to the Department for Provider Profiling and Disease State Profiling as defined in the cost proposal shall occur not withstanding the Contractor's arrangements with the other members of the Coalition.

### II) MAXIMUM PAYMENT & DURATION OF AGREEMENT

The Maximum Total Amount of this contract shall not exceed \$7,596,246 for the period from July 1, 2001 through June 30, 2005. For the period from July 1, 2001 through completion of the Design and Development (approximately 120 days) to the date of going operational no payments will be made. From start of operations estimated to be

- o November 1, 2001 through June 30, 2002, payments shall not exceed \$1,259,824,
- o For the period from July 1, 2002 through June 30, 2003, payments shall not exceed \$1,920,126,
- o For the period from July 1, 2003 through June 30, 2004, payments shall not exceed \$2,187,118,
- o For the period from July 1, 2004, through June 30, 2005, payments shall not exceed \$2,229,178.

Unexpended funds in any given State Fiscal Year shall be carried forward into the next year so long as the Maximum Total Amount for the length of the contract does not exceed \$7,596,246. In the event of increases in volume, caseload or costs the Department and the Contractor shall by mutual agreement and subject to approval by Governor and Council increase the Maximum Total Amount.

### III) CONTRACTOR GUARANTEE

The Contractor guarantees upon the following terms that the Department, by implementation of the program initiatives listed below, will realize savings at least equal to the total Administrative Fee payable to the Contractor under Section I above:

- 1. Savings will be computed over a twelve-month period (except for the final contract year which may only consist of eight (8) months) (the "Savings Period"), commencing with the date the Contractor commences processing pharmacy claims for the Department.
- 2. Calculated savings will be compared against the Administrative Fee paid or payable by the Department to the Contractor over the same Savings Period.
- 3. The Contractor will be obligated to refund to the Department an amount equal to any excess (less any applicable withholds owed by the Department to the Contractor) of Administrative Fees paid or payable to the Contractor over demonstrated savings for the same period.
- 4. The parties agree that they anticipate savings from the program initiatives set forth in this Paragraph 4. In the event the Department elects not to implement each of the initiatives by the date set opposite each of them or terminates any program before the end of the contract, the savings guarantee by Contractor for that Savings Period in which any of the programs were not implemented or for which any program is terminated becomes null and void. Further, the guarantee is conditioned upon the Department implementing the following Contractor recommendations and criteria within the date specified, provided they are consistent with clinical best practice guidelines.
- Point of Service (POS) device with First Health Maximum Allowable Cost (MAC) pricing

November 1, 2001

Prospective Drug Utilization Review

November 1, 2001

- Early refill edits
- Therapeutic Duplication edits
- Utilization Management
- Disease Management
- Auditing
- Medicaid Drug Coverage Management
- OBRA 90 Rebate Management
- Prior Authorization Programs
  - Gastrointestinal Drugs
  - Arthritis Drugs

February 1, 2002

May 1, 2002

May 1, 2002

November 1, 2001

November 1, 2001

November 1, 2001

• Narcotic Analgesic Utilization

Selective Seratonin Reuptake Inhibitors

Disease State Profiling
 Provider Profiling
 Clinical Detailing
 May 1, 2002
 May 1, 2002
 May 1, 2002

- 5. The criteria, benchmarks, and formulae for measuring savings shall be mutually agreed to by the parties in writing no later than the date the contract for services is executed. The Department acknowledges that the criteria used by the Contractor is proprietary and that the methodologies for calculating savings, which includes the criteria, will not be subject to public disclosure.
- 6. The savings for each program will be calculated in the following manner. The year prior to the contract will always be used as the "base year" against which future savings will be measured in each contract year. Changes in the "base year" due, but not limited, to: new drugs, changes in drug status, population growth, changes in clinical practices, Consumer Price Index (CPI) adjustments, etc. will be agreed to by both the Department and the Contractor within 90 days of each Savings Period.

### 7. POS with First Health MAC pricing/Medicaid Drug Coverage Management

The annual cost savings will be equal to the difference between Average Wholesale Price - 12% (lacking a Federal Upper Limit (FUL) or Health Care Financing Administration (HCFA) FUL and First Health MAC pricing for all paid claims for each drug with a First Health MAC price. For example, where the Average Wholesale Price of a drug minus 12% (\$64.15 - \$7.70) equals \$56.45, and the Contractor's Maximum Allowable Cost is \$50.00, the difference of \$6.45 is the annual savings.

### <u>Prospective Drug Utilization Review Professional Review Organization Drug</u> <u>Utilization Review (ProDUR)</u>

The annual savings for "soft" (informational) ProDUR edits will be calculated by subtracting the dollar amount of all "soft" edited claims reversed by the pharmacy and not resubmitted within thirty (30) days from the original claim submission

The annual savings for "hard" (denied) Therapeutic Duplication ProDUR edits will be calculated by adding the "allowable" (amount that would have been allowed for an eligible prescription per the reimbursement formula) cost of all claims denied annually and subtracting those claims that are prior authorized and paid. The value of a denied claim will be prorated to an annual cost savings for all claims not receive for at least 90 days after being initially denied.

The annual savings for "hard" Early Refill claims will be calculated by comparing the annualized refill frequency of denied claims and annualized frequency of paid claims

with the same GCN Sequence number. The savings will be the "allowable" cost of the claims not filled.

### **Utilization Management**

The annual savings will be calculated by subtracting the allowed cost of all drugs in a Specific Therapeutic Class which were identified by Retroactive DUR and interventions for those patients profiled for six months after the intervention from the allowed cost of the drugs of the Specific Therapeutic Class before the intervention.

### **Auditing**

The annual savings will be the amount that is identified by the Contractor auditors as being an overpayment for any reason, including but not limited to claims involving fraud, abuse, up-coding, etc. Savings will not be determined by the amount the Department ultimately collects from providers, but the amount identified.

### **OBRA 90 Rebate Management**

The annual savings will be calculated by comparing rebate collection percentage in the "base year" to the rebate collection percentage in each subsequent year of the contract.

### **Prior Authorization Programs**

The annual savings for all Prior Authorization programs will be calculated by adding the allowed cost of all claims which are denied annually and subtracting the allowed costs of those claims that are prior authorized. The value of a denied claim will be prorated to an annual cost savings for all claims for the recipient who has not had a claim received for at least 90 days after being denied.

### **Disease State Profiling**

The annual savings will be calculated by subtracting the allowed cost of all drugs associated with the treatment of the profiled disease state that were intervened on for those patients profiled for six months after the intervention from the allowed cost of the drugs six months before the intervention. The calculations will be normalized to a PUPM (Per Unit Per Month).

### **Provider Profiling**

The annual savings will be calculated by subtracting the allowed cost of all drugs in a Specific Therapeutic Class which was intervened on for those providers profiled for six months after the intervention from the allowed cost of the drugs of the Specific Therapeutic Class six months before the intervention. The calculations will be normalized to a PUPM.

### **Clinical Detailing**

The annual savings will be calculated by subtracting the allowed cost of all drugs in a Specific Therapeutic Class which was intervened on for those providers detailed for six months after the intervention from the allowed cost of the drugs of the Specific Therapeutic Class six months before the interventions The calculations will be normalized to a PUPM (utilizing member month).

Negative savings will not be included in calculation of guaranteed cost savings however they will be reported to the Department.

8. Any overrides or reversals by the Department or otherwise of prescription denials made by the Contractor in accordance with agreed upon criteria in part 4 of this exhibit shall nevertheless be credited as a savings for purposes of calculating savings hereunder.

### IV) SCHEDULE OF PAYMENT:

The Provider shall bill the Department on a monthly basis for the claims handled during the previous month. Invoices shall calculate the service payment in detail including the units, volume and price by service for each group under the contract as well as report the transactions volumes by month and year to date for the Coalition. The reports shall include numbers of users, number of prescriptions and cost per user and prescription as well as total cost both per month and year to date by State Fiscal Year. The invoice shall be sent to the Office of Community and Public Health at the address below in order to receive payment. All invoices shall be sent to the Department within 12 months of the date of service.

John Fransway, Budget Officer Medicaid Administration Bureau Office of Community and Public Health Department of Health and Human Services 6 Hazen Drive, Concord, NH 03301

# EXHIBIT C TO THE CONTRACT BETWEEN FIRST HEALTH SERVICES CORP. AND

### THE STATE OF NEW HAMPSHIRE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **SPECIAL PROVISIONS**

#### **DEFINITIONS**

AGREEMENT: Shall mean the contract executed between First Health Services Corporation ("Contractor") and the Department of Health and Human Services ("Department") including the standard forms contract (Form p-37) and all exhibits A, A1, A2 through G.

COSTS: Shall mean those direct and indirect items of expense determined by the Department to be allowable and reimbursable in accordance with cost and accounting principles established in accordance with state and federal laws, regulations, rules and orders.

**PROPOSAL:** Shall mean the document submitted by the Contractor on January 9, 2001 as the Contractor's response to the request for proposal for pharmacy benefit management services issued by the Department on October 23, 2000. This document is also referred to as Exhibit A2.

TRANSACTION (or CLAIM): A transaction as defined by the NCPDP Transaction Code, that is received, processed, and responded to by the Contractor. A transaction can be received in multiple media as: (1) POS - a transaction received electronically via telephone lines from the Providers' Point of Service (2) Electronic Media - A batch of transactions received by the Contractor in electronic media (tape, diskette or electronic bulletin board) and submitted to Contractor System for processing, and (3) Paper - a transaction received on paper and data entered by the Contractor and submitted to the Contractor System for processing.

UNIT: As specified in Exhibit B of the Agreement.

FEDERAL/STATE LAW: Wherever federal or state laws, regulations, rules orders and policies, etc. are referred to in the Agreement, the said reference shall be deemed to mean all such laws, regulations, etc as they may be amended or revised from time to time.

1. Contractor Obligations: The Contractor agrees that all funds received by the Contractor under the Agreement shall be used only as payment to the Contractor for services provided to eligible individual and Contractor hereby further agrees as follows:

- 2. Fair Hearings: The Contractor understands that all applicants for services hereunder, as well as individuals declared ineligible have a right to a fair hearing regarding that determination. The Contractor hereby agrees that all applicants for services shall be informed of his/her right to a fair hearing in accordance with Department regulations. The Contractor further agrees to provide the Department with all information generated regarding adverse determinations and as necessary provides expert pharmaceutical fair hearing testimony.
- 3. Maintenance of Records: In addition to the eligibility records the Contractor agrees to maintain the following records during the term of the Agreement.
- 3.1 Fiscal records: Books, records documents and other data evidencing and reflecting all costs and other expenses incurred by the Contractor in the performance of the Agreement and all income received or collected by the Contractor during the term of the contract, said records to be maintained in accordance with accounting procedures and practices which sufficiently and properly reflect all such costs and expenses and which are acceptable to the Department and to include, without limitation, all ledgers, books, records and original evidence of costs such as purchase requisitions and orders, vouchers requisitions for materials, inventories, valuations of in-kind contributions labor time cards, payrolls and other records requested or required by the Department
- 3.2 Statistical records: Program statistical and enrollment attendance or visit records for each recipient of services during the contract term which records shall include all records of application and eligibility records regarding the provision of services and all invoices submitted to the Department to obtain payment for such services.
- 3.3 Medical records: Where appropriate and as prescribed by the Department regulations the Contractor shall retain medical records on each patient/recipient of services.
- 4. Audit and Review: During the term of this Agreement and the period for retention, the Department, the United States Department of Health and Human Services and any of their designated representatives shall have access to all reports and records maintained pursuant to the Agreement for purposes of audit, examination excerpts and transcripts.
- 5. Audit Liabilities: In addition to and not in any way in limitation of obligations of the Agreement, it is understood and agreed by the Contractor that the Contractor shall be held liable for any state or federal audit exceptions and shall return to the Department all payments made under the Agreement to which exception has been taken or which have been disallowed because of such an exception.
- 6. Confidentiality of Records: All information, reports and records maintained in connection with this Agreement, or collected in connection with the performance of the services and the Agreement shall be confidential and shall not be disclosed by the Contractor provided, however that pursuant to state laws and the regulations of the Department regarding the use and disclosure of such information, disclosure may be made to public officials requiring such information in connection with their official duties

and for purposes directly connected to the administration of the services and Agreement; and provided further, that the use or disclosure by any party of any information concerning a New Hampshire Medicaid recipient or any other person served under the terms of this contract for any purpose not directly connected with the administration of the Department or the Contractor's responsibilities with respect to purchased services hereunder is prohibited except on appropriate written consent. Notwithstanding anything to the contrary contained herein the conditions contained this paragraph 6 shall survive the termination of the Agreement for any reason whatsoever.

- 7. Reports: Fiscal and Statistical: In addition to reports required pursuant to Exhibit A of this Agreement, the Contractor agrees to submit the following reports at the following times if requested by the Department:
- 7.1 Interim Financial Reports: Written interim financial reports containing a detailed description of all costs and non-allowable expenses incurred by the Contractor to the date of the report and containing such other information as shall be deemed satisfactory by the Department to justify the rate of payment. Such financial reports shall be submitted on the form designated by the Department or deemed satisfactory by the Department
- 7.2 Final Report: A final report shall be submitted within ninety (90) days after the end of the term of this Agreement. The final report shall be in a form satisfactory to the Department and shall contain a summary statement of progress toward goals and objectives stated in the Contractor proposal and other information required by the Department
- 8. Completion of services: Disallowance of Costs: Upon the purchase by the Department of the maximum number of units provided for in the Agreement and upon payment of the price limitation hereunder, the Agreement and all the obligations of the parties hereunder (except such obligations as by the terms of the Agreement are to be performed after the end of the term of this Agreement and or survive the termination of the Agreement) shall terminate; provided however, that if, upon review of the final expenditure report the Department shall allow any expenses claimed by the Contractor as costs hereunder the Department shall retain the right, at its discretion to deduct the amount of such expenses as are disallowed or to recover such sums from the Contractor.
- 9. Credits: All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services or the Agreement shall not be sent without prior approval by the Department and shall include the following statement:

The preparation of this (report, document etc.) was financed under an Agreement with the State of New Hampshire, Department of Health and Human Services with funds provided in part by the United States Department of Health and Human Services.

10. Operation of facilities: Compliance with Laws and Regulations: In the operation of any facilities for providing services, the Contractor shall comply with all laws orders

and regulations of federal, state, county and municipal authorities and with any direction of any public officer or officers pursuant to laws which shall impose an order or duty upon the Contractor with respect to the operation of the facility or the provision of the services at such facility, if any governmental license or permit shall be required for the operation of the said facility or the performance of the said services, the Contractor will procure said license or permit, and will at all times comply with the terms and conditions of each such license or permit. In connection with the foregoing requirements, the Contractor hereby covenants and agrees that, during the term of this agreement the facilities shall comply with all rules, orders, regulations and requirements of the State Office of the Fire Marshal and the local fire protection agency, and shall be in conformance with local building and zoning codes, by laws and regulations.

- 11. Dispute resolution: Order of Precedence: In the event that any provisions of this Agreement conflict and there is dispute among the parties regarding resolution of the dispute. The parties agree that the order of precedence for resolution of disputes shall be to look first to the language of the standard signed contract labeled Form Number P-37, second to the language of Exhibit B, third, to the language of Exhibit A, fourth, to the language of Exhibit A1 and then fifth to Exhibit A2. In the event that the parties are unable to informally settle any dispute arising under the Agreement, the Contractor further agrees and submits to the jurisdiction of the courts of the State of New Hampshire and agrees that venue for any legal proceeding against the State shall be filed in the Merrimack County Superior Court, Court Street, Concord, New Hampshire. The provisions of this paragraph shall not in any way be considered a waiver of sovereign immunity by the State of New Hampshire.
- 11.1 In the event that either party deems it necessary to take legal action to enforce any provision of the Agreement, each party shall bear its own costs associated with the litigation, including attorney fees. Any action against the State, including, but not limited to, actions for either breach of contract or for enforcement of its provisions, or both, shall commence within three (3) years from the date of completion specified in this Agreement. All defenses in law or equity shall be preserved to the State, including sovereign immunity.
- 12. Entire Agreement: This Agreement represents the entire agreement between the parties on the subject matter. All prior agreements, representations, statements, negotiations and understandings shall have no effect.
- 13. Applicable Law: This Agreement shall be governed by the laws of the State of New Hampshire.
- 14. Gratuities or Kickbacks: The Contractor agrees that it is a breach of this Agreement to accept or make a payment, gratuity or offer of employment on behalf of the Contractor, any Sub-Contractor or the State in order to influence the performance of the Scope of Services detailed in Exhibit A of this Agreement. The state may terminate this Agreement and any sub-contract or sub-agreement if the State determines that payments,

gratuities or offers of employment of any kind were offered or received by any officials, officers, employees or agents of the Contractor or Sub-Contractor.

- 15. Retroactive payments-Individual Services: Notwithstanding anything to the contrary contained in this Agreement or in any other document, agreement or understanding, it is expressly understood and agreed by the parties that no payments will be made to reimburse the Contractor for any services provided to any individual prior to the Effective date of this Agreement and no payments shall be made for expenses incurred by the Contractor for any services provided prior to the date on which the individual applies for services or (except as otherwise provided by the federal regulations) prior to a determination that the individual is eligible for such services.
- 16. Retroactive Payments Contractor Services: Notwithstanding anything to the contrary contained in this Agreement or in any other document, agreement or understanding, it is expressly understood and agreed by the parties that no payments will be made to reimburse the Contractor for any costs incurred for any purposes prior to the Effective date of the Agreement.
- 17. Debarment, Suspension and Other Responsibility Matters: If this Agreement is funded in any part by monies of the United States, the Contractor shall comply with the provisions of Section 319 of the Public Law 101-121, Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions; with the provisions of the Executive Order 12549 and 45 CFR Subpart A, B,C,D, and E Section 76 regarding Debarment, Suspension and Other Responsibility Matters, and shall complete and submit to the State the appropriate certificates of compliance upon approval of the Agreement by the Governor and Council.
- 18. No Third Party Benefits: Nothing in this Agreement, express or implied, is intended to confer upon any other entity or person (including without limitation any Member or health care provider) any rights or remedies under or by reason of this Agreement.
- 19. Compliance with Laws: The Contractor and the Department shall each be solely responsible for compliance with all laws, rules and regulations that are now or hereafter applicable to each of them and their own performance under this Agreement. The Contractor and the Department agree to inform each other of any and all special federal, state or local laws, rules or regulations and revisions there to that either party becomes aware of which impact the manner in which the Contractor processes claims required by the agreement.
- 20. HIPAA Compliance: Contractor represents that its operations and First SX POS shall comply with the requirements of HIPAA as such requirements currently exist. Notwithstanding the above, the Department acknowledges that the First SX POS will initially contain NCPDP 3.2 Version but be converted to NCPDP Version 5.1 prior to the HIPAA compliance date, currently proposed as October 16, 2002. The Department

further acknowledges that the Conversion/Implementation Fee assumes no significant changes in HIPAA requirements between the date of this Amendment and actual implementation. In the event of revisions to HIPAA requirements, either before or after implementation, modifications to First SX necessitated by such changes shall be billed in accordance with the Systems Maintenance Rates. Prior to undertaking such modifications the Department and Contractor shall agree upon the fixed price for the modifications or Contractor shall provide an estimate of the cost of the systems work.

- 21. Eligibility Lists: The Department acknowledges and agrees that the Contractor shall approve or deny benefits to Members in complete reliance upon the eligibility lists provided by the Department. In the event of any retroactive termination of Members, the Department shall be liable for all Claims approved for such Members prior to loading of the eligibility data deleting such Members.
- 22. Overpayments to Providers: In the event any overpayments are made to Providers, whether through the fault of the Contractor or otherwise, the Contractor may, in addition to any other rights or remedies it may have at law or in equity, recover such overpayments within Contractor System through offset against subsequent payments otherwise due to such Providers. Notwithstanding the recovery mechanism provided above, the Contractor shall not be liable for any overpayments unless such overpayments are solely the fault of the Contractor. If any network of pharmacies other than that of the Contractor is to be used under this Agreement, the Department shall assure that all agreements with pharmacies provide for such offset by the pharmacies.
- 23. Software Ownership: The parties mutually acknowledge that each respectively has no ownership in any of the software developed or owned by the other party and used in connection with services rendered pursuant to this Agreement. The Department specifically acknowledges and agrees that it acquires no right, title, interest, or license to FIRSTSX AND FIRSTIQ by virtue of this Agreement.

In the event the Department is granted possession of, or access to, any of the Contractor's proprietary software products, the Department shall execute in advance thereof a Software License Agreement.

### NH Department of Health and Human Services

#### STANDARD EXHIBIT D

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq.), and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

### CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS ALTERNATIVE I - FOR GRANTEES OTHER THAN INDIVIDUALS

US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS
US DEPARTMENT OF EDUCATION - CONTRACTORS
US DEPARTMENT OF AGRICULTURE - CONTRACTORS

This certification is required by the regulations implementing Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq.). The January 31, 1989 regulations were amended and published as Part II of the May 25, 1990 Federal Register (pages 21681-21691), and require certification by grantees (and by inference, sub-grantees and sub-contractors), prior to award, that they will maintain a drug-free workplace. Section 3017.630° of the regulation provides that a grantee (and by inference, sub-grantees and sub-contractors) that is a State may elect to make one certification to the Department in each federal fiscal year in lieu of certificates for each grant during the federal fiscal year covered by the certification. The certificate set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government wide suspension or debarment. Contractors using this form should send it to:

Commissioner, NH Department of Health and Human Services, 6 Hazen Drive, Concord, NH 03301-6505.

- (A) The grantee certifies that it will or will continue to provide a drug-free workplace by:
  - (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
  - (b) Establishing an ongoing drug-free awareness program to inform employees about—

### CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS ALTERNATIVE I - FOR GRANTEES OTHER THAN INDIVIDUALS, cont'd

## US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS US DEPARTMENT OF EDUCATION - CONTRACTORS US DEPARTMENT OF AGRICULTURE - CONTRACTORS

- (1) The dangers of drug abuse in the workplace;
- (2) The grantee's policy of maintaining a drug-free workplace;
- (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
- (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—
  - (1) Abide by the terms of the statement; and
  - (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
- (e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
- (f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—
  - (1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or
  - (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

### CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS ALTERNATIVE I - FOR GRANTEES OTHER THAN INDIVIDUALS, cont'd

## US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS US DEPARTMENT OF EDUCATION - CONTRACTORS US DEPARTMENT OF AGRICULTURE - CONTRACTORS

- (g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (e) and (f).
- B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant.

Place of Performance (street address, city, county, State, zip code) (list each location)								
4300 Cox Road								
Glen Allen, VA 23060								
Tri-State Office not yet determined								
Check if there are workplaces on file that are not identified here.								
First_Health Services Corporation From:								
Contractor Name	Period Covered by this Certification							
James G. Council, Vice President and Co	orporate Counsel							
Name and Title of Authorized Contractor Represer	ntative							
Tours Of The State	i liela							
HAMIY CALLERY								
Contractor Representative Signature	Daté							

JPF: AMENDFORM 8-10 (DHS 09/05/91) (CRTCATION 20-22)

### NH Department of Health and Human Services

#### STANDARD EXHIBIT E

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Section 319 of Public Law 101-121, Government wide Guidance for New Restrictions on Lobbying, and 31 U.S.C. 1352, and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

#### CERTIFICATION REGARDING LOBBYING

## US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS US DEPARTMENT OF EDUCATION - CONTRACTORS US DEPARTMENT OF AGRICULTURE - CONTRACTORS

Programs (indicate applicable program covered):

Aid to Families with Dependent Children Program under Title IV-A Child Support Enforcement Program under Title IV-D Job Opportunities and Basic Skills (JOBS) Program under Title IV-F Medicaid Program under Title XIX Social Services Block Grant Program under Title XX The Food Stamp Program under Title VII

Contract Period:

7/1/01\_ through 6/30/05\_

The undersigned certifies, to the best of his or her knowledge and belief, that:

- (1) No Federal appropriated funds have been paid or will be paid by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement (and by specific mention sub-grantee or sub-contractor).
- (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement (and by specific mention sub-grantee or sub-contractor), the undersigned shall complete and submit Standard Form LLL, "Disclosure Form to Report Lobbying, in accordance with its instructions, attached and identified as Standard Exhibit E-I.
- (3) The undersigned shall require that the language of this certification be included in the award document for sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS
US DEPARTMENT OF EDUCATION - CONTRACTORS
US DEPARTMENT OF AGRICULTURE - CONTRACTORS

### CERTIFICATION REGARDING LOBBYING, cont'd

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Vice President and Corporate Counsel

Contractor's Representative Title

First Health Services Corporation

Contractor Name

Date

JPF: AMENDFORM 11-12 (DHS 09/05/91) (CRTCATION 26-27)

### NH Department of Health and Human Services

#### STANDARD EXHIBIT F

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Executive Office of the President, Executive Order 12529 and 45 CFR Part 76 regarding Debarment, Suspension, and Other Responsibility Matters, and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions executive the following Certification:

### CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS - PRIMARY COVERED TRANSACTIONS

#### Instructions for Certification

- 1. By signing and submitting this proposal (contract), the prospective primary participant is providing the certification set out below.
- 2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the NH Department of Health and Human Services" (DHHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.
- 3. The certification in this clause is a material representation of fact upon which reliance was placed when DHHS determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, DHHS may terminate this transaction for cause or default.
- 4. The prospective primary participant shall provide immediate written notice to the DHHS agency to whom this proposal (contract) is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
- 5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549: 45 CFR Part 76. See the attached definitions
- 6. The prospective primary participant agrees by submitting this proposal (contract) that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by DHHS.

### CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS - PRIMARY COVERED TRANSACTIONS, cont'd

- 7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lower Tier Covered Transaction," provided by DHHS, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
- 8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or involuntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List (of excluded parties).
- 9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
- 10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, DHHS may terminate this transaction for cause or default.

### Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions

- 1. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:
  - a. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
  - b, have not within a three-year period preceding this proposal (contract) been convicted or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or a contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
  - are not presently indicted for otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph 1 b of this certification; and
  - have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

### CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS - PRIMARY COVERED TRANSACTIONS, cont'd

Where the prospective primary participant is unable to certify to any of the statements in this
certification, such prospective participant shall attach an explanation to this proposal
(contract).

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions
(To Be Supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal (contract), the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

- are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- b. where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal (contract).

The prospective lower tier participant further agrees by submitting this proposal (contract) that it will include this clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion - Lower Tier Covered Transactions," without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Contractor Signature

Vice President and Corporate Counsel

Contractor's Representative Title

First Health Services Corporation

Contractor Name

vate

JPF: AMENDFORM 13-15 (DHS 09/05/91)

(CRTCATION pg. 30-32)

#### NH Department of Health and Human Services

#### STANDARD EXHIBIT G

### CERTIFICATION REGARDING THE AMERICANS WITH DISABILITIES ACT COMPLIANCE

The Contractor identified in Section 1.3 of the General Provisions agrees by signature of the Contractor's representative as identified in Sections 1.11 and 1.12 of the General Provisions, to execute the following certification:

1. By signing and submitting this proposal (contract) the Contractor agrees to make reasonable efforts to comply with all applicable provisions of the Americans with Disabilities Act of 1990.

Contractor Signature

Vice President and Corporate Counsel

Contractor's Representative Title

First Health Services Corporation

Contractor Name

JPF: AMENDFORM 16 (DHS 02-25-93) (06/08/93)

### **Directors of First Health Services:**

Joseph E. Whitters Vice President of Finance and Chief Financial Officer First Health Group Corp. 3200 Highland Avenue Downers Grove, IL 60515

Edward L. Wristen
Executive Vice President and Chief Operating Officer
First Health Group Corp.
3200 Highland Avenue
Downers Grove, IL 60515

Teresa R. DiMarco
President
First Health Services Corporation
4300 Cox Road
Glen Allen, VA 23060

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,	c/o First Health Group, Inc.		-	INSURER C:		
	3200 Highland Downers Grove, IL 60515	·		INSURER D:		
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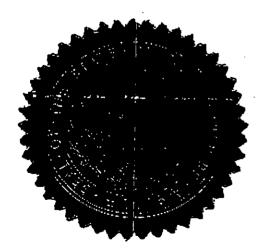
### STATE OF NEW HAMPSHIRE MEDICAID ADMINISTRATION BUREAU

FACSIMIL	E TRANSMITTAL SHEET
то: Jim Fredyma	FROM: Liz Brown
COMPANY: DHHS Commissioner's Office	DATE: 6/28/01
FAX NUMBER: 271-4912	TOTAL NO. OF PAGES INCLUDING COVER:
Phone number:	SENDER'S REFERENCE NUMBER:
RE: First Health Services Corporation	YOUR REFERENCE NUMBER
□ URGENT □ FOR REVIEW □ PLE	ASE COMMENT   PLEASE REPLY     PLEASE RECYCLE
NOTES/COMMENTS:	
Good morning Jim,	
John Fransway asked that I forward a cop have any questions. John is out on leave	y of this over to you for your records. Please call me if you today and will be in tomorrow.
Thanks, I iz	

### State of New Hampshire Department of State

#### CERTIFICATE OF AUTHORIZATION

I, William M. Gardner, Secretary of State of the State of New Hampshire, do hereby certify that a certificate of authority to do business in this state was issued to FIRST HEALTH SERVICES CORPORATION, a(n) VIRGINIA corporation, on June 27, 2001. I further certify that all fees required by the Secretary of State's office have been paid.



IN TESTIMONY WHEREOF, I hereto set my hand and cause to be affixed the Seal of the State of New Hampshire, this 27th day of June, A.D. 2001

William M. Gardner Secretary of State

### HEALTH MANAGEMENT ASSOCIATES

216

State Northwest in Hwy See S Farming to S Hues, Michigan is (248) 539-9701 - Fax (248) 5,965 (248) Web Site www.hilthmote.com

## Tri-State Coalition of Maine, New Hampshire and Vermont Project Executive Summary

May 14, 2001

We are pleased to present this summary of the timelines and major events associated with the Tri-State Coalition's efforts to explore the feasibility of aggregating pharmaceutical purchasing. We suggest that, once you have reviewed it, it will be shared senior state officials to recommend a finalist, provide a summary of the project activities undertaken over the past year and suggest the appropriate next steps.

As explained below, the Coalition, after a series of careful and deliberate processes has determined that First Health Services Corporation is the bidder best suited to meet the needs of the Coalition.

Health Management Associates (HMA) assisted the Coalition with these activities, and HMA staff members believe that all major events stayed within the expected timelines and the expectations of the Coalition members. HMA staff members also believe this project should be considered a success by both the Coalition and policy makers in other states across the nation who are looking at the efforts of the Tri-State Coalition as a model to complete their own purchasing alliances and bid processes.

The process is nearing completion in that a final vendor will be announced very shortly, in accord with the timeline described in the RFP. The following table provides an overview of the project timeline and major events.

### Overview of Timeline and Major Events

Date	Event
Early 2000	Governors of Maine, New Hampshire and Vermont met to discuss pharmacy benefits issues common among three states. Appointed a work group to explore options of aggregating purchasing to achieve cost savings.
Spring 2000	Work group concluded that the most effective strategy to accomplish the goals of the collective states was to implement a multi-state purchasing alliance to recruit a pharmacy benefits manager for Medicaid, State Employees and their dependents, and those without prescription insurance.
Summer 2000	The Coalition released a request for information to PBMs. Its purpose was to help state officials understand the capabilities of PBMs to help control drug costs.
	<ul> <li>The Coalition requested 3 PBMs to present PBM capabilities to Coalition. PBMs presented.</li> </ul>
·	The Coalition had a series of meetings to discuss what was to be included in the RFP, draft the RFP, and discuss timelines for RFP release and review.
October 23, 2000	The Coalition released an RFP for a PBM .
November 2000	Bidder conference, and question and answer process. More than twelve PBMs attended the Bidders Conference
January 9, 2001	Proposal due date. Eight proposals received.
January 2001	Review of proposals against scoring tool. HMA collected Medicaid claims information from states in order to provide to potential vendors for claims analysis.
February 7, 2001	Coalition met and reviewed the eight proposals submitted. Two of the eight proposals did not meet minimum RFP requirements. Four proposals were recommended to proceed to a second-level review. (As they exceeded 70% on the technical score Since the other four proposals fell

Date	Event
	below a 70% technical score, the Coalition decided that further efforts should not be expended on the other four bidders, and they were no longer considered in the process.
February 2001	A second tier of the review of the four proposals included: claims analysis by the potential vendors, clarification of proposals by the potential vendors based on follow-up questions from the Coalition, and reference checks on the remaining potential vendors.
March 12, 2001	Coalition met. Determined to continue reviewing only 2 of the 4 proposals submitted. Express Scripts and NPA were not considered for further review because neither demonstrated enough expertise in processing the Medicaid claims provided by the Coalition. Additionally, neither had significant Medicaid experience as documented through the reference check and the additional clarification information provided by the two vendors. Technical scores were adjusted to reflect these additional findings, and Consultec and First Health had the top two technical scores.  Consultec and First Health were then invited to present to the Coalition on March 19th and 20th. The Coalition mailed, in advance, issues for the potential vendors to address during the site visit.
March 19, 20, 2001	Consultec and First Health presented additional information to the Coalition. At the end of the two days, the Coalition concluded that First Health emerged as the stronger of the two potential vendors due to their demo, superior capacity to report claims, vast Medicaid experience and OBRA90 rebate experience.  During these presentations Coalition members had the opportunity to think through the logistical issues associated with dual processing and concluded that the PBM will be able to process drug claims and achieve the goals of the RFP while allowing for all necessary reporting to continue.
End of March 2000	Cost and savings analysis completed for the three states, using First Health data and the services that each state presently plans to use. Since each state indicated that the funding for the PBM must come from savings, it was critical to the project that such savings be clearly evident. It is extremely gratifying that, overall, the ratio of savings to expenses is calculated to be 6:1.
April 20, 2001	Meeting with First Health to further clarify their proposal & for interaction with officials from the three states

Date	Event
	interaction with officials from the three states
May, 2001	New Hampshire and Vermont are committed to contracting for Medicaid Pharmacy Benefits managementwith First Health as soon as possible. The probable time frame is autumn, 2001. Maine is not planning to do so at this time. Maine is comfortable with their current Rx Medicaid processing environment. They may be interested, however, in buying disease state management services from First Health.  As part of the decision-making process, Maine provided a current claims file for analysis by First Health on May 8,2001. HMA will forward the claims to First Health. The claims will be for the first quarter of 2001, and will therefore reflect the recent changes implemented by Maine. Maine will continue to explore purchasing options with First Health while Vermont and New Hampshire proceed to contract.
May, 2001	Next Steps: Review scope of services, plan for contracting Determine when to announce final vendor Determine schedule and process for contracting Develop timetable for implementation

HMA is pleased to be involved in this project and we look forward to its' successful conclusion.

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given by a lobbyist
who said that
what was harded
in as testimony
was not in its
entirety. This is
the whole testimony
that was not
submitted as
testimony.



Donald L. Shumway Commissioner

Kathleen A. Dunn Director

# STATE OF NEW HAMPSHIRE DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF COMMUNITY AND PUBLIC HEALTH

6 HAZEN DRIVE, CONCORD, NH 03301-6527 603-271-4352 1-800-852-3345, Ext.4352 TDD Access: 1-800-735-2964

June 27, 2001

Her Excellency, Governor Jeanne Shaheen and the Honorable Executive Council State House Concord, New Hampshire 03301

#### REQUESTED ACTION

Authorize the Office of Community and Public Health to enter into an agreement with the First Health Services Corporation of 4300 Cox Road, Glen Allen, Virginia 23030, Vendor Number (tba), for the purpose of managing pharmacy benefits under Medicaid in the amount of \$7,596,246 for the period from July 1, 2001, or date of Governor and Council approval, whichever is later, through June 30, 2005. Funds are available and should be allocated in the following account, Medical Grants-Provider Payments, according to state fiscal year with authority to adjust amounts through the Comptroller, if needed and justified, between state fiscal years:

Year	Account Number	Amount
SFY 2002	010-090-6147-090-0112	\$1,259,824
SFY 2003	010-090-6147-090-0112	\$1,920,126
SFY 2004	010-090-6147-090-0112	\$2,187,118
SFY 2005	010-090-6147-090-0112	\$2,229,178
Total		\$7,596,246

#### EXPLANATION

Pharmacy expenditures incurred by the New Hampshire Medicaid Program have increased at an average rate of eighteen (18%) percent annually over the past four years, mirroring increases observed in other states. Governor Shaheen, Governor Dean (Vermont) and Governor King (Maine) met in Concord at Governor Shaheen's invitation to discuss this common health care concern. The Tri-State Coalition, created as a result of the meeting, worked to create a single Request For Proposal (RFP) for Pharmacy Benefit Management (PBM) Services, the purpose being to leverage the three states' buying power by increasing the size of the population covered and gaining greater discounts through volume purchasing. The Coalition worked together in evaluating proposals from bidders and choosing a vendor, but each State will have its own contract with the vendor due to differing State contract requirements.

The DHHS Office of Community & Public Health (OCPH) issued the Tri-State Coalition RFP for Pharmacy Benefit Management Services on October 23, 2000. Proposals were due on

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Her Excellency, Governor Jeanne Shaheen and the Honorable Executive Council June 27, 2001 Page 2

January 9, 2001. Bids were received from eight (8) Pharmacy Benefit Management (PBM) vendors. First Health Services Corporation was chosen as the successful bidder for the following reasons: First Health received the highest overall score, delivered the best on-site presentation, offered the lowest overall cost proposal, demonstrated quality management, and provided the best analysis of our claims history. They have experience with reducing pharmacy expenditures while increasing the quality of care through management of clinically appropriate drug therapy. First Health Services Corporation administration has the potential of reducing our pharmacy expenditures by ten to fifteen percent (10-15%) from projected levels without a PBM.

This contract will enable the First Health Services Corporation to provide Pharmacy Benefit Management services to the NH Department of Health and Human Services in administration of the Medicaid pharmacy program. Services provided will enable the State to improve the quality of health care while at the same time controlling the high cost of pharmaceuticals. First Health Services Corporation shall take the lead in all phases of the PBM project, subject to review by the NH Department of Health and Human Services, including all prior authorization, step therapy, disease state management, Maximum Allowable Cost (MAC) pricing, and development of criteria and clinical documentation for such initiatives.

This contract is necessary because our current pharmacy claims Point of Sale (POS) system does not have the capability to perform the cost saving functions that the First Health POS system can provide. With our current POS system, most prospective drug utilization review alerts are informational only. First Health's system will allow us to deny payment on a claim with a prospective drug utilization review alert unless the pharmacist takes specific actions.

Another concern with our current POS system is that we do not have the capability to prior authorize drugs. First Health's POS system is capable of processing claims for drugs that require prior authorization and they will provide us with the clinical staff to process prior authorization requests. First Health's clinical staff has experience with administering prior authorization programs for other State Medicaid agencies. In addition to prior authorization, First Health's clinical staff will recommend clinically appropriate drug therapy for specific diseases (Disease State Management). Disease state management programs are not only cost effective, but also will improve the quality of care to our recipients. First Health will provide DHHS with their MAC pricing list, which will be used as the basis for the State MAC pricing list. Currently we use the Federal Upper Limit (FUL). States are allowed to expand this list by creating their own State MAC.

Representatives from the OCPH met with members of the New Hampshire Pharmacists Association (NHPA) and the National Association of Chain Drug Stores (NACDS) on February 20, 2001. The purpose of the meeting was to solicit feedback about the eight (8) vendors bidding on the contract and discuss concerns that the Associations had regarding the Tri-State PBM Initiative. The OCPH shared the scoring tool with the Associations. At the close of the meeting the members were advised to e-mail the department directly with any additional feedback. No feedback was received. The OCPH also advised the Associations that there would be meetings

Her Excellency, Governor Jeanne Shaheen and the Honorable Executive Council June 27, 2001 Page 3

held before and during implementation of the PBM to give them an opportunity to address any concerns associated with the new system. These meetings will occur once this contract is approved.

The contract includes a provision that guarantees savings at least equal to the administrative cost of the contract so long as OCPH implements each of the initiatives by the date set in the contract and maintains each initiative for the contract period. The Contractor is obligated to refund to OCPH an amount equal to any excess of administrative fees paid or payable to the Contractor in excess of the demonstrated savings for the same period.

Services will be Statewide.

The cost of these services will be matched by seventy-five (75) percent federal funds with the remainder general funds.

Respectfully submitted,

(Athleen A. Dunn, Director (Co.)

Office of Community & Public Health

Approved b

Donald L. Shumway

Commissioner

#### **Tri-State Coalition Bid Process**

The Tri-State Coalition was formed in February of 2000 after the Governors from Maine, Vermont and New Hampshire met to discuss common health care concerns. As a result of that meeting, the Tri-State Coalition worked with Health Management Associates (HMA) to issue a Request for Proposal (RFP) for a Pharmacy Benefit Manager (PBM). A legal notice for the RFP ran in the Nashua Telegraph and the Manchester Union Leader October 20, 21 & 22, 2000. The RFP was issued on October 23, 2000. The Bidders Conference was held November 14, 2000 and proposals were due at HMA's office on January 9, 2001. Proposals were received from eight (8) vendors; First Health Services, Consultec, Express Scripts, Gould Health Systems, Medimpact Healthcare Systems, NPA, Script Pharmacy Solutions and Wellpoint Pharmacy Management. All three States were involved in the evaluation and selection of the successful bidder. The Tri-State Coalition recommended First Health Service to the three Governors. The Governors made the announcement May 24, 2001 that First Health Services was selected as the successful bidder.

Why was First Health chosen as the successful bidder? First Health met all of the absolute requirements in the three step review process set forth in the RFP.

**Step One - Mandatory Requirements:** First Health successfully demonstrated that they could meet the minimum requirements set forth in the RFP for:

- Capacity to successfully manage the number of lives;
- Experience managing similar programs;
- Program Requirements, POS System with requirements listed in RFP; and,
- System that can interface with the State.

Step Two - Merits of the Bidder: First Health scored the highest on merits from the RFP review team. The review included:

- Bidder capability, qualifications and experience;
- Qualified personnel and location;
- Approach and methodology for implementation and continued operations; and,
- Aptness and brevity of response.

**Step Three - Price Analysis:** First Health scored the highest on cost proposal because they offered the lowest overall price.

Summary: First Health

- Received the highest overall score;
- Delivered the best on-site presentation;
- Supplied excellent references;
- Demonstrated quality management;
- Offered the best lowest cost proposal; and,
- Best analysis of our claims history.

PBM Bidders List				1	
Bidder	Address 1	Address 2	City	State	Zip Code
Consultec	9040 Roswell Road	Suite 700	Atlanta	GA	30350
Express Scripts	6625 West 78th Street		Bloomington	MN	55439
First Health Services Corporation	4300 Cox Road		Glen Allen	VA	23060
Gould Health Services	P.O. Box 1090		Augusta	ME	04332-1090
Medimpact Healthcare Systems	10680 Treena Street	5th Floor	San Diego	CA	92131
National Prescription Administrators	711 Ridgedale Avenue		East Hanover	NJ	07936
Scrip Pharmacy Solutions	100 Clearbrook Road		Elmsford	NY	10523
Wellpoint Pharmacy Management	4553 LaTienda Dr		Thousand Oaks	CA	91362

	-			
CATEGORY	SCORE		CONSULTEC	FIRST HEALTH
		200 mars 200 mars		
MANDATORY REQUIREMENTS	PASS/FAIL			
TECHNICAL PROPOSAL SCORE		199399 1993		
		****		<u>,</u>
1 QUALITY OF BIDDER	10	(81116) 881.88	5.00	9.50
2 FINANCIAL STATEMENT REVIEW	5		4.00	5.00
3 CLAIMS PROCESSING AND SYSTEMS	20	950000	19.86	20.00
4 NETWORK REQUIREMENTS	10		10.00	10.00
5 UNINSURED	20		10.00	11.70
6 MEDICAID DRUG BENEFIT MANAGEMENT	20		15.00	20.00
7 MEDICAID (OBRA90) REBATES	20		15.00	20.00
8 STATE EMPLOYEES AND OTHER NETWORK	20		17.13	18.19
9 AUDIT REQUIREMENTS	20		12.76	13.45
10 ANALYSIS AND REPORTING	15		10.00	14.50
11 PHARMACEUTICAL MANUFACTURER LIAISON	20		11.56	15.00
FORMULARY AND REBATES FOR STATE		180,000		10.00
12 EMPLOYEES AND UNINSURED	20		13.85	9.23
13 DUR SYSTEM	5		4.60	4.19
14 UTILIZATION MANAGEMENT	5		3.43	3.93
15 DISEASE MANAGEMENT	5		4.94	5.00
16 PRIOR AUTHORIZATION	10		8.62	8.46
BENEFICIARY AND PROVIDER TELEPHONE	10		0.02	0,40
17 SUPPORT	/ 10		10.00	10.00
18 ID CARDS AND MEMBER MATERIALS	/ 5		5.00	5.00
19 OTHER	/ 25	1000000	13.75	
TOTAL	265		194.48	L
PERCENTAGE	200		73%	
PERGENTAGE			13%	84%
OCCUPANCE HOUTHY				
COST PROPOSAL - MONTHLY				
PRICING			\$ 310,780	
SAVINGS			\$ (2,730,291)	
FUNDED CLAIMS			\$ 844,896	
TOTAL (SAVINGS)/COST			\$ (1,574,616)	\$ (4,930,504)
PCT			47%	100%
AGGREGATE (25% FOR COST PROPOSAL)			67%	88%

### HEALTH MANAGEMENT ASSOCIATES

30000 NORTHWESTERN
HWY, SCHE 210
FARMINGTON HILLS MICHIGAN 18334
(248) 530-0701 FAX (248) 539-9705
Web Site www.hltmig) com

### Tri-State Coalition of Maine, New Hampshire and Vermont

### **Project Executive Summary**

### May 14, 2001

We are pleased to present this summary of the timelines and major events associated with the Tri-State Coalition's efforts to explore the feasibility of aggregating pharmaceutical purchasing. We suggest that, once you have reviewed it, it will be shared senior state officials to recommend a finalist, provide a summary of the project activities undertaken over the past year and suggest the appropriate next steps.

As explained below, the Coalition, after a serie's of careful and deliberate processes has determined that First Health Services Corporation is the bidder best suited to meet the needs of the Coalition.

Health Management Associates (HMA) assisted the Coalition with these activities, and HMA staff members believe that all major events stayed within the expected timelines and the expectations of the Coalition members. HMA staff members also believe this project should be considered a success by both the Coalition and policy makers in other states across the nation who are looking at the efforts of the Tri-State Coalition as a model to complete their own purchasing alliances and bid processes.

The process is nearing completion in that a final vendor will be announced very shortly, in accord with the timeline described in the RFP. The following table provides an overview of the project timeline and major events.

### Overview of Timeline and Major Events

Date	Event
Early 2000	Governors of Maine, New Hampshire and Vermont met to discuss pharmacy benefits issues common among three states. Appointed a work group to explore options of aggregating purchasing to achieve cost savings.
Spring 2000	Work group concluded that the most effective strategy to accomplish the goals of the collective states was to implement a multi-state purchasing alliance to recruit a pharmacy benefits manager for Medicaid, State Employees and their dependents, and those without prescription insurance.
Summer 2000	<ul> <li>The Coalition released a request for information to PBMs. Its purpose was to help state officials understand the capabilities of PBMs to help control drug costs.</li> </ul>
	<ul> <li>The Coalition requested 3 PBMs to present PBM capabilities to Coalition. PBMs presented.</li> </ul>
	<ul> <li>The Coalition had a series of meetings to discuss what was to be included in the RFP, draft the RFP, and discuss timelines for RFP release and review.</li> </ul>
October 23, 2000	The Coalition released an RFP for a PBM .
November 2000	Bidder conference, and question and answer process. More than twelve PBMs attended the Bidders Conference
January 9, 2001	Proposal due date. Eight proposals received.
January 2001	Review of proposals against scoring tool. HMA collected Medicaid claims information from states in order to provide to potential vendors for claims analysis.
February 7, 2001	Coalition met and reviewed the eight proposals submitted. Two of the eight proposals did not meet minimum RFP requirements. Four proposals were recommended to proceed to a second-level review. (As they exceeded 70% on the technical score Since the other four proposals fell

Date	Event
	below a 70% technical score, the Coalition decided that further efforts should not be expended on the other four bidders, and they were no longer considered in the process.
February 2001	A second tier of the review of the four proposals included: claims analysis by the potential vendors, clarification of proposals by the potential vendors based on follow-up questions from the Coalition, and reference checks on the remaining potential vendors.
March 12, 2001	Coalition met. Determined to continue reviewing only 2 of the 4 proposals submitted. Express Scripts and NPA were not considered for further review because neither demonstrated enough expertise in processing the Medicaid claims provided by the Coalition. Additionally, neither had significant Medicaid experience as documented through the reference check and the additional clarification information provided by the two vendors. Technical scores were adjusted to reflect these additional findings, and Consultec and First Health had the top two technical scores.  Consultec and First Health were then invited to present to the Coalition on March 19th and 20th. The Coalition mailed, in advance, issues for the potential vendors to address during the site visit.
March 19, 20, 2001	Consultec and First Health presented additional information to the Coalition. At the end of the two days, the Coalition concluded that First Health emerged as the stronger of the two potential vendors due to their demo, superior capacity to report claims, vast Medicaid experience and OBRA90 rebate experience.  During these presentations Coalition members had the opportunity to think through the logistical issues associated with dual processing and concluded that the PBM will be able to process drug claims and achieve the goals of the RFP while allowing for all necessary reporting to continue.
End of March 2000	Cost and savings analysis completed for the three states, using First Health data and the services that each state presently plans to use. Since each state indicated that the funding for the PBM must come from savings, it was critical to the project that such savings be clearly evident. It is extremely gratifying that, overall, the ratio of savings to expenses is calculated to be 6:1.
April 20, 2001	Meeting with First Health to further clarify their proposal & for interaction with officials from the three states

Date	Event
	interaction with officials from the three states
May, 2001	New Hampshire and Vermont are committed to contracting for Medicaid Pharmacy Benefits managementwith First Health as soon as possible. The probable time frame is autumn, 2001. Maine is not planning to do so at this time. Maine is comfortable with their current Rx Medicaid processing environment. They may be interested, however, in buying disease state management services from First Health.  As part of the decision-making process, Maine provided a current claims file for analysis by First Health on May 8,2001. HMA will forward the claims to First Health. The claims will be for the first quarter of 2001, and will therefore reflect the recent changes implemented by Maine. Maine will continue to explore purchasing options with First Health while Vermont and New Hampshire proceed to contract.
May, 2001	Next Steps: Review scope of services, plan for contracting Determine when to announce final vendor Determine schedule and process for contracting Develop timetable for implementation

HMA is pleased to be involved in this project and we look forward to its' successful conclusion.

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				BIDDERS					,	
801 BONIS	CATEGORY	SCORE	CONSULTEC	EXPRESS	FIRST HEALTH	GHS	MEDIMPACT	NPA	SCRIP	WELLPOINT
Step 1										<u> </u>
	MANDATORY REQUIREMENTS	PASS/FAIL				Failed	8		Falled	
	Min requirements such as capacity not met									
C1 0			ļ				Fälled			Failed
Step 2	TEOLINIO AND DOCUMENT OF THE OWNER.	Below 70%		· · · · · · · · · · · · · · · · · · ·		200.000.000.000	er Generalisas <b>m</b> eralisas (1990)	L		(20,2222 <u>m201</u> 22220
	TECHNICAL PROPOSAL SCORE	Delow 70%					Failed	:		Failed
<u> </u>	Next lowest 2 scores cut			ļ				·		
<b> </b>	TOTAL		194.48		1 223.15			196.19	124,63	163.69
<u> </u>	PERCENTAGE		73%	80%	84%	47%	62%	74%	47%	62%
Step 3			<del>-</del>				62%	<del>}</del>		
	MEDICAID EXPERIENCE MINIMAL	>=60 below 70%		Failed	2			Failed		Yiki Nelwala katika
	Next 2 bidders cut for failure to demonstrate									
	enough expertise in processing a sample of	1							1,6,000,000,000	
İ	Medicaid claims					an and an				
				4.40.00.000		w, nervistins,				
Step 4			Falled					]		
1	With oral presentations from 2 finalists, First		- (15) 101 (16) (20) (8)							
	Health demonstrated greater experience and		1 1210110 11 0001000000000							
	capacity surrounding Medicald, Obra 90 Rebetes					]				
	and cost savings potential.		\$ (2,730,291)		\$ (6,414,097)					
	AGGREGATE 25% FOR COST PROPOSAL		47%		100%					
	FINAL SCORE		67%		88%			-		

#### **AGREEMENT**

The State of New Hampshire and the Contractor hereby mutually agree as follows:

#### GENERAL PROVISIONS

1. i	dentification and Definitions.						
1.1	State Agency Name Department of Health and Human Services Office of Community and Public Health	1.2 State Agency Address 6 Hazen Drive Concord, NH 03301					
1.3	Contractor Name First Health Services Corporation	1.4	Contractor Address 4300 Cox Road Glen Allen, VA 23	-			
1.5	Account No. 1.6 Completion Date 6/30/2005	1.7	Audit Date n/a	1.8	Price Limitat \$7,596,24		4,44 = 4,
1.9	Contracting Officer for State Agency 1.10 Kathleen A. Dunn, MPH Director	State A	gency Telephone No 603-271-4501	umber			
1.11	Contractor Signature	1.12 James	Name & Title of Co G. Council,		-	and	
	Acknowledgment: State of VACounty of Penric O  Plos  Defore the undersigned officer, personally appeared the person in block 1.11., and acknowledged that s/he executed this documents.					e perso	Counsel n whose name
1.13.1 [Seal]	Signature of Notary Public or Justice of the Peace  (Surfere 7. )	Vene.	rs				
1.13.2	Name & Title of Notary or Justice of the Peace Christine R. Stevens, action		<u>′</u>				
) 1.14 -	State Agency Signature(s)  The Depute (C)	1.15 Signore	Name/Title of States) / Kathleen A. Dunn, Office of Communi	MPH Di	rector		
1.16	Approval by Department of Personnel (Rate of Compensation for	or Individu	al Consultants)				
Ву:	NIA		Di	rector, O	n:		
1.17 By:	Approval by Attorney General (Form, Substance and Execution)  Assistant		General, On:	122	101	·	
1.18	Approval by the Governor and Council						
Ву:					On:		
2. EMF	PLOYMENT OF CONTRACTOR/SERVICES TO BE PERFORME	D. The S	tate of New Hampsh	ire, actin	g through the ag	ency id	entified in block

- the State"), engages contractor identified in block 1.3 ("the Contractor") to perform, and the Contractor shall perform, that work or sale of goods, or both, identified and more particularly described in EXHIBIT A incorporated herein ("the Services").
- 3. EFFECTIVE DATE: COMPLETION OF SERVICES.
- 3.1 This agreement, and all obligations of the parties hereunder, shall become effective on the date the Governor and Council of the State of New Hampshire approve this agreement, ("the Effective Date").
- 3.2 If the date for commencement in Exhibit A precedes the Effective Date all services performed by Contractor between the commencement date and the Effective Date shall be performed at the sole risk of the contractor and in the event that this Agreement does not become effective, the State shall be under no obligation to pay the contractor for any costs incurred or services performed; however that if this Agreement becomes effective all costs incurred prior to the effective date shall be paid under the terms of this Agreement. All services must be completed by the date specified in block
- 4. CONDITIONAL NATURE OF AGREEMENT. Notwithstanding anything in this agreement to the contrary, all obligations of the State hereunder, including, without limitation, the continuance of payments hereunder, are contingent upon the availability and continued appropriation of funds, and in no event shall the State be liable for any payments hereunder in excess of such available appropriated funds. In the event of a reduction or termination of those funds, the State shall have the right to withhold payment until such funds become available, if ever, and shall have the right to terminate this agreement immediately upon giving the Contractor notice of such termination. The State shall not be required to transfer funds from any other account to the account identified in block 1.5 in the event funds in that account are reduced or unavailable.

- 5. CONTRACT PRICE: LIMITATION ON PRICE: PAYMENT.
- 5.1 The contract price, method of payment, and terms of payment are identified and more particularly described in Exhibit B, incorporated herein.
- 5.2 The payment by the State of the contract price shall be the only, and the complete, reimbursement to the Contractor for all expenses, of whatever nature, incurred by the Contractor in the performance hereof, and shall be the only and the complete compensation to the Contractor for the Services. The State shall have no liability to the Contractor other than the contract price.
- 5.3 The State reserves the right to offset from any amounts otherwise payable to the Contractor under this Agreement those liquidated amounts required or permitted by RSA 80:7 through 7-C or any other provision of law.
- 5.4 Notwithstanding anything in this Agreement to the contrary, and notwithstanding unexpected circumstances, in no event shall the total of all payments authorized, or actually made, hereunder exceed the price limitation set forth in block 1.8 of these general provisions.
- 6. COMPLIANCE BY CONTRACTOR WITH LAWS AND REGULATIONS: EQUAL EMPLOYMENT OPPORTUNITY.
- 6.1 In connection with the performance of the Services, the Contractor shall comply with all statutes, laws, regulations, and orders of federal, state, county or municipal authorities which impose any obligation or duty upon the Contractor, including, but not limited to civil rights and equal opportunity laws.
- 6.2 During the term of this Agreement, the Contractor shall not discriminate against employees or applicants for employment because of race, color, religion, creed, age, sex, handicap or national origin and will take affirmative action to prevent such discrimination.
- 6.3 If this agreement is funded in any part by monies of the United States, the Contractor shall comply with all the provisions of Executive Order No. 11246 ("Equal Employment Opportunity"), as supplemented by the regulations of the United States Department of Labor (41C.F.R. Part 60), and with any rules, regulations and guidelines as the State of New Hampshire or the United States issue to implement these regulations. The Contractor further agrees to permit the State or United States, access to any of the Contractor's books, records and accounts for the purpose of ascertaining compliance with all rules, regulations and orders, and the covenants and conditions of this Agreement.
  7. PERSONNEL
- 7.1 The performance of the Services shall be carried out by employees of the Contractor. The Contractor shall at its own expense, provide all personnel necessary to perform the Services. The Contractor warrants that all personnel engaged in the Services shall be qualified to perform the Services, and shall be properly licensed and otherwise authorized to do so under all applicable laws. 7.2 The Contractor shall not hire, and shall permit no subcontractor or other person, firm or corporation with whom it is engaged in a combined effort to perform the Services, to hire any person who has a contractual relationship with the State, or who is a State officer or employee, elected or appointed.
- 7.3 The Contracting Officer specified in block 1.9, or his or her successor, shall be the State's representative. In the event of any dispute concerning the interpretation of this Agreement, the Contracting Officer's decision shall be final.

  8. EVENT OF DEFAULT, REMEDIES.
- 8.1 Any one or more of the following acts or omissions of the Contractor shall constitute an event of default hereunder ("Events of Default"):
- 8.1.1 failure to perform the Services satisfactority or on schedule; or
- 8.1.2 failure to submit any report required hereunder; or
- 8.1.3 failure to perform any other covenant or condition of this Agreement.
- 8.2 Upon the occurrence of any Event of Default, the State may take any one, or more, or all, of the following actions:
- 8.2.1 give the Contractor a written notice specifying the Event of Default and requiring it to be remedied within, in the absence of a greater or lesser specification of time, thirty (30) days from the date of the notice; and if the Event of Default is not timely remedied, terminate this agreement, effective two-ten (102) days after giving the Contractor notice of termination; and
- 8.2.2 give the Contractor a written notice specifying the Event of Default and suspending all payments to be made under this Agreement and ordering that the portion of the Contract price which would otherwise accrue to the Contractor during the period from the date of such notice until such time as the State determines that the Contractor has cured the Event of Default shall never-be paid to the Contractor until the Event of Default is cured to the satisfaction of the Department; and
- 8.2.3 set off against any other obligations the State may owe to the Contractor any damages the State suffers by reason of any Event of Default; and 8.2.4 treat the agreement as breached and pursue any of its remedies at law or in equity, or both.
- 9. DATA: ACCESS; CONFIDENTIALITY; PRESERVATION.
- 9.1 As used in this Agreement, the word "data" shall mean all information and things developed or obtained during the performance of, or acquired or developed by reason of, this Agreement, including, but not limited to, all studies, reports, files, formulae, surveys, maps, charts, sound recordings, video recordings, pictorial reproductions, drawings, analyses, graphic representations, computer programs, computer printouts, notes, letters, memoranda, papers, and documents, all whether finished or unfinished.

- 9.2 On and after the Effective Date, all data and any property which has been received from the State or purchased with funds provided for that purpose under this Agreement, shall be the property of the State, and shall be returned to the State upon demand or upon termination of this Agreement for any reason.
  9.3 Confidentiality of data shall be governed by RSA 91-A or other existing law. Disclosure pursuant to a right to know request shall require prior written approval of the State.
- 10. TERMINATION. In the event of an early termination of this Agreement for any reason other than the completion to the Services, the Contractor shall deliver to the Contracting Officer, not later than fifteen (15) days after the date of termination, a report ("the Termination Report") describing in detail all Services performed, and the Contract Price earned, to and including the date of termination. To the extent possible, the form, subject matter, content, and number of copies of the Termination Report shall be identical to those of any Final Report described in EXHIBIT A.
- 11. CONTRACTOR'S RELATION TO THE STATE. In the performance of this agreement the Contractor is in all respects an independent contractor, and is neither an agent nor an employee of the State. Neither the Contractor nor any of its officers, employees, agents or members shall have authority to bind the State or receive any benefits, worker's compensation or other emoluments provided by the State to its employees.
- 12. ASSIGNMENT, DELEGATION AND SUBCONTRACTS. The Contractor shall not assign, or otherwise transfer any interest in this Agreement without the prior written consent of the State. None of the Services shall be delegated or subcontracted by the Contractor without the prior written consent of the State.
- 13. INDEMNIFICATION. The Contractor shall defend, indemnify and hold harmless the State, its officers and employees, from and against any and all losses suffered by the State, its officers and employees, and any and all claims, itabilities or penalties asserted against the State, its officers and employees, by or on behalf of any person, on account of, based or resulting from, arising out of (or which may be claimed to arise out of) the acts or omissions of the Contractor. Notwithstanding the foregoing, nothing herein contained shall be deemed to constitute a waiver of the sovereign immunity of the State, which immunity is hereby reserved to the State. This covenant shall survive the termination of this Agreement.
- 14. INSURANCE AND BOND.
- 14.1 The Contractor shall, at its sole expense, obtain and maintain in force, and shall require any subcontractor or assignee to obtain and maintain in force, both for the benefit of the State, the following insurance:
- 14.1.1 comprehensive general liability insurance against all claims of bodily injury, death or property damage, in amounts of not less than \$250,000 per claim and \$2,000,000 per incident; and
- 14.1/2 fire and extended coverage insurance covering all property subject to subparagraph 9.2 of these general provisions, in an amount not less than 80% of the whole replacement value of the property.
- 14.2 The policies described in subparagraph 14.1 of this paragraph shall be the standard form employed in the State of New Hampshire, issued by underwriters acceptable to the State, and authorized to do business in the State of New Hampshire. Each policy shall contain a clause prohibiting cancellation or modifications of the policy earlier than 10 days after written notice thereof has been received by the State.
  15. WAIVER OF BREACH. No failure by the State to enforce any provisions
- 15. WAIVER OF BREACH. No failure by the State to enforce any provisions hereof after any Event of Default shall be deemed a waiver of its rights with regard to that event, or any subsequent Event. No express failure of any Event of Default shall be deemed a waiver of the right of the State to enforce each and all of the provisions hereof upon any further or other default on the part of the Contractor.
- 16. NOTICE. Any notice by a party hereto to the other party shall be deemed to have been duly delivered or given at the time of mailing by certified mail, postage prepaid, in a United States Post Office addressed to the parties at the addresses given in blocks 1.2 and 1.4, above.
- 17. AMENDMENT. This agreement may be amended, waived or discharged only by an instrument in writing signed by the parties hereto and only after approval of such amendment, waiver or discharge by the Governor and Council of the State of New Hampshire.
- 18. CONSTRUCTION OF AGREEMENT AND TERMS. This Agreement shall be construed in accordance with the laws of the State of New Hampshire, and is binding upon and inures to the benefit of the parties and their respective successors and assigns.
- 19. THIRD PARTIES. The parties hereto do not intend to benefit any third parties and this agreement shall not be construed to confer any such benefit.
  20. SPECIAL PROVISIONS. The additional provisions set forth in EXHIBIT C hereto are incorporated as part of this Agreement.
- 21. ENTIRE AGREEMENT. This agreement, which may be executed in a number of counterparts, each of which shall be deemed an original, constitutes the entire agreement and understanding between the parties, and supersedes all prior agreements and understandings.



#### CERTIFICATE

(Corporation with Seal)

I, James G. Council, Assistant Secretary of First Health Services Corporation, do hereby certify that: (1) I am the duly elected and acting Assistant Secretary of First Health Services Corporation, a Virginia corporation (the "Corporation"); (2) I maintain and have custody of and am familiar with the Seal and minute books of the Corporation; (3) I am duly authorized to issue certificates; (4) that by unanimous written consent in lieu of a duly convened meeting, the Board of Directors of the Corporation has granted Teresa R. DiMarco, President of the Corporation, the right, power, and authority to/enter into contracts on behalf of the Corporation and thereby legally bind the Corporation, and the right, power, and authority to delegate the aforementioned right, power, and authority to other officers of the Corporation; and, (5) Teresa R. DiMarco, by Delegation of Authority dated June 18, 2001, did authorize James G. Council, Vice President, Corporate Counsel and Assistant Secretary to execute on behalf of the Corporation all contracts, leases, and other business agreements (and related Documents) during Teresa R. DiMarco's absence until June 25, 2001.

IN WITNESS WHEREOF, I have hereunto set my hand as the Assistant
Secretary of the Corporation this 19 <sup>th</sup> day of June, 2001.  Assistant Secretary
(Seal)
STATE OF Virginia
COUNTY OF Nenvico
On this the 19 day of
IN WITNESS WHEREOF I hereunto set my hand and official seal.
Christian Stenens Actam Notary Public/Justice of the Peace
My Commission expires: April 30, 2004

#### **Exhibit A**

#### **SCOPE OF SERVICES**

DATE:

June 18, 2001

CONTRACT PERIOD:

July 1, 2001 to June 30, 2005

CONTRACTOR:

NAME:

First Health Services Corporation

ADDRESS:

4300 Cox Road

Glen Allen, VA 23060

TELEPHONE:

(804) 965-7555

Marketing & Account Manager:

This agreement is to provide pharmacy benefit management services to the NH Medicaid population for the purpose of improving the quality of pharmaceutical health care and controlling pharmacy costs through clinically appropriate drug therapy.

In addition to the scope of services to be provided by First Health Services Corporation (hereinafter, "Contactor") to the New Hampshire Department of Health and Human Services (hereinafter, "Department") as set forth in the following pages of Exhibit A, attached and incorporated by reference as Exhibit A1 is the Department's RFP issued October 23, 2000. Also attached and incorporated by reference as Exhibit A2 is the Contractor's proposal to provide Pharmacy Benefit Management Services issued January 9, 2001. All documents that make up this Agreement, and the order of precedence of the documents that constitute the Agreement are set forth in Exhibit C.

#### 3. Implementation

- 3.1 Implementation will occur within 120 days of contract signing
  - The Contractor shall be responsible for implementation of all aspects of the system interfaces to support Pharmacy Benefit Management (PBM) and New Hampshire Advanced Information Management (NHAIM) processing as well as the design and build of the Benefit Plan. The Contractor is responsible for all aspects of the Contractor's side of the interface. The Department shall be responsible for the NHAIM side of the interfaces.
- 3.2 Project Initiations and Management
  - The Contractor shall be responsible for project initiation which shall include a kick-off meeting where Contractor and Department staff are introduced and the initial planning completed. The plan shall include a schedule of all work to be completed through two

months of post-implementation as well as ongoing operations. During this phase the Contractor shall establish issue tracking and prepare for the Department weekly status reports.

#### 3.3 Requirements Analysis

Requirements Analysis shall include both system and benefit plan requirements. The requirements analysis shall be the first activity to be performed under the plan. The Contractor shall make sufficient system and benefit plan staff available in Concord during the requirements analysis phase. Within five (5) days of completion of the Requirements Analysis sessions, the Contractor shall produce a written requirements document which shall include both the system interface and benefit plan. The requirements documents shall be signed off by the Department.

#### 3.4 Design, Code and Test

The Contractor shall design, document the design, code, and unit test the system interfaces and benefit plan components. The system interface design and unit testing shall be coordinated with the Department. Design sign-off shall be required from the Department.

#### 3.5 User Acceptance Testing

Three forms of acceptance testing shall occur. The Medicaid Management Information System (MMIS) vendor shall conduct their own acceptance testing, the Contractor shall conduct its own acceptance testing and the Department shall conduct its own system acceptance testing. The Contractor shall run the test scripts for the Department. Interfaces and benefit plans can be tested together. System test or acceptance test results conducted by the Contractor shall be provided to the Department.

#### 3.6 Users and Provider Training

The Contractor shall provide User and Provider training necessary to work with the Contractor on the reporting and other relevant modules. The Contractor shall provide training/reference documents that are acceptable to the Department.

#### 3.7 Conversion of Data and File Loads

 Part of acceptance testing shall be a mock exchange of conversion data between the Contractor and NHAIM. The actual conversion of data shall occur prior to implementation as described in the final plan.

#### 3.8 Operational Readiness Review

Prior to full implementation and migration of PBM from a test to a live environment the Department and the Contractor shall develop a readiness checklist. The parties shall review status prior to full implementation of PBM. The Department shall make the final decision on actual implementation date.

#### 3.9 Implementation Support

The Contractor shall provide sufficient staff as on site implementation support for the first full thirty (30) days of processing for both system and clinical issues.

#### 3.10 Post Implementation Review

• The Contractor and the Department shall conduct a Post Implementation review meeting at the end of the second month of operation. The Contractor shall provide a full status report at that meeting.

#### 4. Claims Processing and System

- 4.1 The Contractor shall provide Point of Sale (POS) on-line real time 24/7 claims processing system for adjudication and reversal of pharmacy claims.
- 4.2 The Contractor shall support paper or batch (electronic tape/disk/Bulletin Board System {BBS}) claims processing.
- 4.3 Contractor shall achieve Health Insurance Portability & Accountability Act (HIPAA) compliance within the time frame established by the published final rule.
- 4.4 Contractor shall support the transition to National Council for Prescription Drug Programs (NCPDP) version 5.1 prior to HIPAA compliance date.
- 4.5 The Contractor shall support conversion of NCPDP version 3.2 to version 5.1 for the first year for providers using version 3.2.
- 4.6 The POS processing system (First SX) shall ensure that a transaction is subject to all syntax editing (e.g., number-only fields are all numeric) and that the transaction is subject to all relational editing (e.g., member number is on file).

The Contractor shall be responsible for ensuring that the system shall support pricing methodology based on:

- 4.7 Brand vs. Generic (typically indicators from First Data Bank (FDB) are used to determine brand vs. generic; however, the proposed system shall allow for Department determination of a drug's brand/generic status when applicable).
- 4.8 Federal Upper Limit (FUL) or State Maximum Allowable Cost (MAC) (FH to provide its' MAC price list & update regularly. Could be used as either the actual MAC, or as a basis for setting the NHFUL)
- 4.9 Department Pricing
- 4.10 Standard vs. Non-standard package size
- 4.11 Dispensing Fee allowing variable fees
- 4.12 Other Insurance price reductions using Coordination of Benefits
- 4.13 Patient responsibility price reductions (Copays)
- 4.14 Variable benefit limit; monthly, quarterly, annually, lifetime
- 4.15 Lesser of logic; U&C, Gross Amt, Department Pricing, FDB pricing
  - 4.16 Variable dispensing fee logic (i.e., Clozaril, Unit Dose Meds)
  - 4.17 POS System must calculate price for compounded prescription and infusion claims when the NCPDP 5.1 transaction standard is being utilized.
  - 4.18 Contractor shall accept compound prescriptions claims using NCPDP format when NCPDP version 5.1 is available

4.19 Contractor shall support the process for handling compounds with a dummy National Drug Code (NDC), or most expensive/prevalent ingredient until version 5.1 of the NCPDP transaction standard is implemented.

The system must provide lock-in functions to lock Recipients into one Pharmacy or Physician

4.20 First SX<sup>TM</sup> shall provide the ability to perform multiple lock-in functions. The Department shall be able to lock a recipient into a specific pharmacy (ies), physician(s), or combinations of pharmacy and physician(s).

### 5. The system must support TPL Cost Avoidance

- 5.1 The claims processing system shall allow for provider-submitted TPL overrides to identify claim adjudication status. A provider override is allowed under those situations where benefits are exhausted or partially exhausted. The system shall retrieve override variables from applicable historical transactions that shall be used in conjunction with the current transaction to ensure that all carrier/plan combinations have been overridden for adjudication to be completed. The carrier/plan name, client identifier, and member information shall be communicated to the provider using messaging information in the NCPDP response record. Multiple carrier/plan data shall be provided to the pharmacist as part of the cost avoidance override process.
- 5.2 The Contractor shall verify eligibility prior to pricing claims.
- 5.3 Contractor shall interface with NHAIM System for daily eligibility file uploads.
- 5.4 Contractor shall interface with NHAIM System for daily provider file updates
- 5.5 The Contractor shall provide a desktop pricing model for reimbursements in cases of retroactive eligibility.
- 5.6 Contractor shall maintain system interface with NHAIM for transfer of information.
- 5.7 The Contractor shall send claims information including all adjustments to NHAIM for Health Care Financing Administration (HCFA) reporting to be carried out the Department or it's MMIS vendor. The Contractor is responsible to ensure that the information is in a format suitable to the department or its MMIS vendor.
- 5.8 The Contractor shall receive Medical claims data to carry out Drug Utilization Review (DUR) and Disease State Management functions
- 5.9 The Contractor shall receive daily eligibility, third party liability and provider files.
- 5.10 The Contractor shall work with the Department's Medicaid Decision Support System (MDSS) Contractor during MDSS system development.
- 5.11 The Contractor shall send bi-weekly warrant tapes to the Treasurer, State of New Hampshire for provider payments.

5.12 The Contractor shall receive the provider payments from the Treasurer, match with the remittance advice and mail them to the providers.

#### 6. Provider Network

- 6.1 During development Contractor staff shall conduct provider training
- 6.2 The Contractor shall provide education to providers on claim filing and program specifics. The Contractor shall respond to provider billing questions/problems received by telephone within twenty-four (24) hours. All written inquires will b responded to within 5 days of receipt.
- 6.3 The Contractor shall issue biannual provider manuals to every pharmacy in Medicaid network and keep updated manual posted on website
- 6.4 The Contractor shall provide education and training to all providers
- 6.5 The Contractor shall coordinate transition of pharmacy providers billing software so that services are not interrupted.

### 7. Auditing

- 7.1 The Contractor shall provide a complete and comprehensive audit program at the direction of the Department and as set forth in this section.
- 7.2 All prescription claims shall be reviewed and analyzed during the detection phase. The Contractor shall focus on duplicate claims, Average Wholesale Price (AWP) pricing errors, Usual & Customary pricing and incorrect discounting, and shall also review claims from excluded drug category prescriptions that were dispensed.
- 7.3 The Contractor shall establish high dollar thresholds that will trigger desk audits.

The Contractor shall work with Department staff in the following manner:

- 7.4 Determine the criteria for special audit selection procedures and directives.
- 7.5 Define a threshold for certain "high-cost" compound pharmacy claims by May 1, 2002
- 7.6 Keep Department informed about specific audit concerns.
- 7.7 Provide quarterly reports to Department to summarize and detail audits performed.

### 8. On-site Audit Percentage

- 8.1 The Contractor shall work with the Department to identify outlier criteria from the review in order to determine the number of on-site reviews.
- The Contractor shall conduct audits on at least 10 percent of the outliers identified through desktop audits on an annual basis.
- 8.3 The Contractor shall conduct complete and comprehensive audit program that shall include both desk and on-site audits.
- 8.4 The Contractor shall detect duplication of claims.
- 8.5 The Contractor shall detect potential fraud, abuse and misuse of prescription drug benefit.

- 8.6 The Contractor shall initiate all necessary recovery reports.
- 8.7 The Contractor shall conduct a maximum of fifteen (15) on-site audits per year. The Department shall determine the actual number of on-site audits per year.
- 8.8 The Contractor shall select pharmacy providers for audit using provider profiling reports. The Contractor approach to pharmacy audits shall include:
  - 8.8(a) Reviewing Medicaid and other Department policy documents to verify that patterns identified are not due to intricacies of payment methods or practices
  - 8.8(b) Collaborating with Department staff on a regularly scheduled basis to identify data reporting/capturing that is State specific that maybe responsible for erroneous fraud, waste and abuse detection
  - 8.8(c) Identify and analyze statistically valid sample of claims performing desk audits and reviewing original documents on site
  - 8.8(d) Interviewing providers, beneficiaries, and related persons
  - 8.8(e) Reviewing cases with Medical consultants
  - 8.8(f) Referring appropriate cases to State Surveillance & Utilization Review (SURS) units
  - 8.8(g) Keeping qualitative and quantitative statistics on substantiated cases and compile reports to be submitted to the Department on a quarterly basis
  - 8.9(h) Maintain documentation of findings and recoveries to be submitted to the Department on a quarterly basis
  - 8.10(i) The Contractor shall upon completion of an audit, generate and mail a final report 30 days to appropriate pharmacy or third party administrator.
- 8.9 The Contractor shall provide sufficient audit department-staff with expertise in;

### 9. Medicaid policy

- 9.1 Healthcare over payment identification and recovery
- 9.2 Caseload management and reporting
- 9.3 System development and integration in data warehousing and fraud control applications
- 9.4 The Contractor shall develop audit criteria for on-site and desk audits. The criteria shall be reviewed and approved by the Department prior to use.
- 9.5 The Contractor shall identify providers that deviate from other providers by 20% or more from average claim statistics such as number of claims per beneficiary, total payment per beneficiary, number of brand certifications.

- 10. All on-site audits shall be performed by a licensed pharmacist(s) employed by the Contractor beginning May 1, 2002.
- 11. The Contractor shall conduct two types of on-site audits, which shall include the following components:
  - 11.1 Usual and Customary audits to detect problems relating to abuse of usual and customary charges of processed claims.
  - 11.2 Full on-site pharmacy abuse compliance audit, all claims selected for review shall be checked against the hard copy of the prescription on-site for;
    - 11.2(a) Verification of patient name and eligibility
    - 11.2(b) Drug information per authorized prescription
    - 11.2(c) Dispense as written code
    - 11.2(d) Quantity authorized to dispense and refill limitations
    - 11.2(e) Brand / Generic substitution
    - 11.2(f) Day supply
    - 11.2(g) Co-payment collection
    - 11.2(h) DEA compliance
    - 11.2(i) Dispensing accuracy
    - 11.2(j) Signature log
    - 11.2(k) Unfilled prescription policy and procedures
    - 11.2(1) Telephone order authorization
    - 11.2(m) Reversal of unclaimed prescriptions
    - 11.2(n) Invoices of a sufficient number of purchases on target drugs to support the dispensing history
- 12. Analysis and Reporting
  - 12.1 The Contractor shall provide standard reports which shall include:
    - 12.1(a) number of recipients
    - 12.1(b) number of prescriptions and cost per prescription
    - 12.1(c) cost per recipient
    - 12.1(d) total cost both per month and year to date by State Fiscal Year.
  - 12.2 The Contractor shall provide the following standard reports on a monthly basis:
    - 12.2(a) Denied claims analysis
    - 12.2(b) Cost and Utilization reports
    - 12.2(c) Summarization of claims reports
    - 12.2(d) Drug ranking
    - 12.2(e) Generic analysis reporting
    - 12.2(f) Monthly summary
    - 12.2(g) Balancing report
    - 12.2(h) Recipient summary
    - 12.2(i) Therapeutic class analysis
    - 12.2(j) Twelve month summary
    - 12.2(k) Drug utilization analysis

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- 12.2(l) Distribution report
- 12.2(m) New drug listing report
- 12.3 The Contractor shall provide interfaces that will ensure that MARS/SURS Federal Reports can be produced by the Department or its MMIS vendor.
- 12.4 The Contractor shall provide personal computer software for Ad-hoc (First IQ) to the Department for 28 users, additional client licenses may be acquired at a per seat price.
- 12.5 The Contractor shall provide hands-on five (5) day training for First IQ at the Contractors' headquarters.
- 12.6 The Contractor shall provide eight (8) hours per month of consultation to determine the best ways to access data.
- 12.7 The Contractor shall provide customized reports, which shall be developed during implementation and approved by the Department. The reports shall include but not be limited to:
  - 12.7(a) Any standard report that is modified for the Department
  - 12.7(b) Any Department specific report that is created
  - 12.7(c) Any reports created in the ad-hoc report manager
- 12.8 The Contractor shall provide templates for:
  - 12.8(a) Claims summary report
  - 12.8(b) Per member/per month (PMPM) report
  - 12.8(c) Claims detail report
  - 12.8(d) Top X ranking report
  - 12.8(e) Top X prescribers
  - 12.8(f) Co-pay Analysis
  - 12.8(g) Monthly listing of claims with excess dollars
  - 12.8(h) Patient claim history report
  - 12.8(i) Prescribing provider ranking by region
  - 12.8(j) Dispensing provider ranking by region
  - 12.8(k) Drug search
  - 12.8(l) Top 20 Prior authorized Drugs
- 12.9 The Contractor shall provide Power play reports (drug trends and utilization)

#### 13. Pharmaceutical Liaison

- 13.1 The Contractor shall develop and maintain working relations with pharmaceutical manufacturers.
- 13.2 The Contractor shall develop working relations with professional pharmacy associations such as New Hampshire Pharmacist Association (NHPA) and National Association of Chain Drug Stores (NACDS)
- 13.3 The Contractor shall develop working relations with the Department's Fiscal Agent

### 14. Medicaid Drug Coverage Management

14.1 The Contractor shall implement drug coverage parameters as set by the Department

- 14.2 The Contractor shall duplicate Department's current reimbursement methodology
- 14.3 The Contractor shall assign a full-time clinical manager (RPh or PharmD) for daily oversight of the Department's clinical program
- 14.4 The Contractor's clinical manager shall:
  - 14.4(a) Recommend drugs for prior authorization and step therapy to the Department's P&T Committee at regularly scheduled meetings.
  - 14.4(b) Provide periodic written report to the Department's P&T Committee
  - 14.4(c) Attend all P&T Committee meetings
  - 14.4(d) Be available to the Department for consultation and oversight activities related to the management of the Department's formulary(s) on a daily basis.
  - 14.4(e) Gather and review information as requested by the P&T Committee in order to facilitate and support formulary management. This function is also typically used to determine a course of action with newly introduced drugs into the market.
  - 14.4(f) At each P&T Committee meeting provide written summary information on each Department's pharmacy claims for the previous quarter. Based on this information, the Clinical Manager shall also provide recommendations for additions or changes in the programs and provide educational materials including supportive clinical research, protocols, and financial analysis for newly approved therapies and indications.
- 14.5 The Contractor shall update drug prices weekly using FDB
- 14.6 Written and electronic report provided weekly to identify changes made to the drug file
- 14.7 Provide the State with subscriptions to; Price Alert, Medispan and Redbook
- 14.8 The Contractor shall update FUL weekly using FDB
- 14.9 Contractor's MAC shall be updated monthly by the Contractor
- 14.10 The Contractor shall integrate drug coverage design with eligibility system by utilizing eligibility, drug, and benefit systems to adjudicate claims for appropriate coverage. Batch, POS, and paper claims shall be adjudicated through the same adjudication model.

#### 15. Medicaid OBRA '90 Rebates

- 15.1 The Contractor shall manage all Medicaid drug rebate and dispute resolution from July 1, 1994 and ongoing
- 15.2 The Contractor shall implement accounting functions of drug rebate
- 15.3 The Contractor shall maintain quarterly unit rebate amount data
- 15.4 The Contractor shall maintain accounting procedure for prior period adjustments
- 15.5 The Contractor shall calculate interest due on overdue payments
- 15.6 The Contractor shall provide online message indicating obsolete NDC's

- 15.7 The Contractor shall provide data on claims reversed post invoicing
- 15.8 The Contractor shall perform quarterly posting of reconciliation invoice
- 15.9 The Contractor shall perform posting of prior quarter adjustment statements
- 15.10 The Contractor shall provide reporting to HCFA for required rebate reports
- 15.11 The Contractor shall implement dispute resolution functions
- 15.12 The Contractor shall respond to HCFA changes

#### 16. Drug Utilization Review

- 16.1 The Contractor shall perform Drug Utilization Review as defined by the RFP, includes ProDUR, Concurrent DUR, RetroDUR, and educational programs.
- 16.2 The Contractor shall provide a full-time clinical manager (RPh or PharmD) to coordinate with State DUR Boards.
- 16.3 The Contractor shall present annual DUR plan to the Department and DUR board.
- 16.4 The Contractor shall prepare annual DUR report for both the Department and HCFA as mandated by HCFA.
- 16.5 The Contractor shall attend each DUR Board meeting and present a report to the DUR board.
- 16.6 The Contractor shall recruit clinical pharmacists educators from local pharmacies to perform face-to-face clinical detailing to targeted providers.
- 16.7 The Contractor shall develop policy and procedures for a clinical detailing program, which shall be reviewed and approved by the Department prior to use.
- 16.8 The Contractor shall provide orientation and training of clinical pharmacist educators as approved by the Department.
- 16.9 The Contractor shall identify target drug therapies by November 1, 2001.
- 16.10 The Contractor shall develop educational materials by November 1, 2001, which shall be used by the Contractor for their clinical detailing program.
- 16.11 The Contractor shall have the capacity to identify targeted prescribers by November 1, 2001 using the following criteria:
  - 16.12(a) Over treatment/ under treatment
  - 16.12(b) Treatment failure
  - 16.12(c) Drug to drug interactions
  - 16.12(d) Iatrogenic effects / adverse reactions
  - 16.12(e) Therapeutic duplication
  - 16.12(f) Drugs with diagnosis / drugs without diagnosis
  - 16.12(g) Drugs without procedure
- 16.13 The Contractor shall present analysis, education materials and list of targeted prescribers with specific profiles to DUR Board for approval on a quarterly basis.
- 16.14 The Contractor shall provide face to face clinical detailing beginning May 1, 2002 to the top ten percent of all providers that are identified by

physician profiling on a quarterly basis not to exceed one hundred and twenty (120) interventions per year.

- 16.15 The Contractor shall provide clinical pharmacist educators with profiles to perform face to face interventions with targeted providers.
- 16.16 The Contractor shall comply with all OBRA '90 and PL 104 191 requirements.
- 16.17 The Contractor shall perform prospective and Concurrent DUR on line real time 24/7.
- 16.18 The Contractor shall perform retrospective DUR through analysis of claims history and present quarterly reports to the Department and DUR Board.
- 16.19 The Contractor shall provide educational programs and materials to the targeted providers.

### 17. Utilization Management

- 17.1 The Contractor shall provide integrated clinical programs which best preserve both clinical and fiscal resources of the State of New Hampshire.
- 17.2 The Contractor shall present annual utilization plans which control/reduce pharmacy utilization.
- 17.3 The Contractor shall analyze claims and present recommendations for utilization management programs to the Department on a monthly basis.
- 17.4 The Contractor shall provide a report of the top 100 utilizing recipients to the Department on a monthly basis.
- 17.5 The Contractor shall provide First IQ for utilization management screenings by the Department.
- 17.6 The Contractor shall provide face to face interventions between the Contractor's clinical staff and the top ten (10) percent of targeted and prescribing and dispensing providers not to exceed one hundred and twenty (120) interventions per year.
- 17.7 The Contractor shall provide utilization management reminders containing specific information and suggested changes in prescribing and dispensing practices to targeted providers on a monthly basis.
- 17.8 The Contractor shall analyze utilization patterns on a monthly basis for recipients/pharmacies/prescribers using the following criteria:
  - 17.8(a) Large number of prescriptions per month
  - 17.8(b) High cost of prescriptions
  - 17.8(c) Prescriptions from multiple pharmacies or prescribers
  - 17.8(d) Disproportionate dispensing patterns
  - 17.8(e) Low generic substitution
  - 17.8(f) High dispense as written rate
  - 17.8(g) High number of DUR overrides
- 17.9 The Contractor shall provide First IQ fraud and abuse model to perform fraud and abuse analysis using standard algorithms to support the Department's fraud and abuse detection effort.

#### 18. Disease Management



- 18.1 The Contractor shall provide a Disease Management program to promote appropriate medical and pharmaceutical utilization.
- 18.2 The Contractor shall identify and manage troublesome therapies for the following:
  - 18.2(a) Diabetes
  - 18.2(b) Asthma
  - 18.2(c) Congestive Heart Failure
  - 18.2(d) Coronary Artery Disease
  - 18.2(e) Chronic Obstructive Pulmonary Disease
  - 18.2(f) Peptic Ulcer Disease
  - 18.2(g) Arthritis
- 18.3 The Contractor shall provide a disease state management process to:
  - 18.3(a) Develop algorithms through predictive modeling
  - 18.3(b) Rank patients' risk of preventable adverse therapeutic outcomes
  - 18.3(c) Provide interventions and education
- 18.4 The Contractor shall provide a disease management overview to:
  - 18.4(a) Implement broad based clinical programs
  - 18.4(b) Educate prescribers about matters of clinical practice
  - 18.4(c) Influence patient behavior to take an active role in their own care
- 18.5 The Contractor shall provide a written clinical and financial outcome assessment to the Department on a monthly basis

### 19. Prior Authorization

- 19.1 The Contractor shall establish a prior authorization program, which shall be fully automated and an integral part of the POS/ProDUR system.
- 19.2 Any medication requiring prior authorization shall be reject by an on-line adjudication process.
- 19.3 This rejection shall include messaging describing the reason for the denial and the Contractor's toll-free telephone number for the pharmacist or the prescriber.
- 19.4 The retail pharmacist or the prescriber may initiate a prior authorization request.
- 19.5 The prescriber or his/her agent may call the Clinical Support Center to request the approval.
- The caller first speaks to a certified pharmacy technician who collects the information from him/her based on the criteria for that medication or class of medications.
  - 19.7 If the information furnished by the physician satisfies the criteria, the technician may grant an approval.
  - 19.8 If the retail pharmacist initiates the call the certified pharmacy technician shall call the prescriber and collect the information from him/her based on the criteria for that medication or class of medications.

- 19.9 If the information furnished by the physician satisfies the criteria, the technician may grant an approval.
- 19.10 If there is any doubt that the criteria have been met, the telephone call is escalated to a licensed clinical pharmacist who will discuss the patient specifics with the prescriber.
- 19.11 The Contractor shall assist the prescriber in changing to a more appropriate therapy rather than simply denying the initial request.
- 19.12 If the prescriber is unwilling to switch the patient to an acceptable therapy, the pharmacist will issue a denial.
- 19.13 The Contractor shall recommend drugs for Prior Authorization to the Department by September 1,2001.
- 19.14 The Contractor shall describe prior authorization process and develop clinical guidelines by September 1, 2001. The Department shall review and approve the process prior to use.
- 19.15 The Contractor shall provide prior authorization tracking process so that providers do not have to submit claim with PA number by November 1, 2001.
- 19.16 The Contractor shall develop an appeals process in accordance with Department procedures by September 1, 2001. The Department shall review and approve the process prior to use.
- 19.17 The Contractor shall provide regular reporting to the Department to summarize Prior Authorization activity on a monthly basis.
- 19.18 The Contractor shall provide a clinical manager to review medical necessity on all prior authorization requests.
- 19.19 The Contractor shall match prior authorizations to the audit process, identifying any drugs restricted to PA that were dispensed without such authorization on a monthly basis.

### 20. Beneficiary and Provider Telephone Support

- 20.1 The Contractor shall provide telephone support for both providers and recipients as follows:
  - 20.1(a) Must be toll free
  - 20.1(b) Available 24 hours per day, 7 days per week;
  - 20.1(c) Sufficient telecommunications capacity;
  - 20.1(d) Assist beneficiaries in locating participating pharmacies;
  - 20.1(e) Telephone support for providers seeking prior authorization;
  - 20.1(f) Must offer translation services.

### 21. Staffing Requirements

- 21.1 The Contractor shall provide an account manager with a business degree, pharmacy related experience and knowledgeable in State Government affairs located in Concord, New Hampshire.
- 21.2 The Contractor shall provide a clinical manager (RPh or PharmD) located in Concord, New Hampshire.
- 21.3 The Contractor shall recruit clinical pharmacist educators from local pharmacies

- 21.4 The Contractor shall provide access to clinical and technical staff at the Contractors home office.
- 21.5 The Contractor shall solicit feedback from the Department on candidates for the Account Manager and Clinical Manager.

#### 22. Disaster Recovery

22.1 In the event of a natural disaster there must be a system in place for processing claims so that recipients are not denied access to prescriptions. The disaster recovery system shall be reviewed and approved by the Department if it is deemed to be adequate by the Department.

#### 23. Post Implementation

- 23.1 The Contractor shall be responsible for routine system maintenance, including any changes necessary to maintain interface.
- 23.2 The Contractor shall make available system modification hours at an agreed upon hourly rate.

### 24. System Monitoring

- 24.1 The Contractor shall put a process in place to monitor the system interface for:
  - 24.1(a) Error tracking
  - 24.1(b) Error identification
  - 24.1(c) Error correction
- 24.2 The Department shall review and approve the process if the process is deemed to be adequate by the Department.

June 5, 2001

#### Exhibit B

#### Methods and Conditions Precedent to Payment

#### I) Terms of Payment

Subject to the Contractor's compliance with the terms and conditions of the agreement and for services provided, the Department shall reimburse the Contractor at .2730 cents per adjudicated Medicaid claim. The Coalition intends to add additional groups under the individual States' contracts up to a total volume of claims of 6,000,000 annually by the Coalition. The additional group's claims will be the product of the total Coalition's claims including other groups such as State Employees, the Uninsured or Seniors' currently enrolled in the discount program. If the Coalition claims count exceeds 6,000,000 annually for the excess claim count the Contractor will be reimbursed .019 cents per claim for the next 125,000 claims, 0.005 cents per claim for the next 125,000 claims and above. The Department as a member of the Coalition, anticipating the minimum claims volume threshold may not be achieved within 6 months of the last Coalition commencement date, agrees to extend the contract length from 2 to 4 years.

#### **Coalition Claims Volume based Rates**

		<u>From</u>					
	Up to	From 6m to		<u>6</u> .	125m to	Fro	m 6.25m
<u>6</u> ,	000,000	6	125,000	6	,250,000	8.	higher
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0:0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	ø.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
\$	0.2730	\$	0.0190	\$	0.0050	\$	0.0031
	***	6,000,000 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730 \$ 0.2730	6,000,000 6 \$ 0.2730 \$ \$ 0.2730 \$	6,000,000 6,125,000 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190 \$ 0.2730 \$ 0.0190	6,000,000 6,125,000 6 \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$ \$ 0.2730 \$ 0.0190 \$	Up to 6,000,000         From 6m to 6,125m to 6,250,000         6.125m to 6,250,000           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050           \$ 0.2730         \$ 0.0190         \$ 0.0050	Up to 6,000,000         From 6m to 6,125m to 6,250,000         From 6m to 6,250,000         Ero 8           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$           \$ 0.2730         \$ 0.0190         \$ 0.0050         \$

An adjudicated claim is defined as a "Paid" or "Denied" claim. Multiple submissions of up to 4 claim lines per transaction shall be counted by claim line rather than by transaction.

The Department shall reimburse the Contractor for the following additional items at the rates quoted in accordance with the services defined in the Contractor's cost proposal as outlined below:

- 1) Utilization management \$0.0763 cents x Per Member Per Month (pmpm)
- 2) Medicaid Disease management (8 modules) \$0.14 x pmpm
- 3) Auditing Up to 15 audits annually at \$1,400 per audit

- 4) Drug coverage management \$0.1445 x pmpm
- 5) Obra 90 Rebate management \$0.2511 x pmpm
- 6) Telephone support \$0.0596 x pmpm
- 7) Prior authorizations \$11 per approval by Pharmacy Tech & \$19.50 per approval by RPh Pharmacist
- 8) Disease state profiling \$0.0272 x pmpm
- 9) Provider profiling \$0.0272 x pmpm
- 10) Clinical detailing \$300 per detail session x up to 120 clinics

Also, in accordance with the Contractor's cost proposal, the Contractor agrees to further volume level discounts as each 100,000 aggregate members per month are added for those items defined as per member per month in the Coalition proposal.

The contractor shall be reimbursed for Postage, Printing, ID Cards, Provider Manuals and Telephone toll free numbers (Call Center Usage) at cost to the Contractor plus 12 percent Administration expense under the Contract. This amount shall be included in the Maximum Total Payment.

The Contractor's prices to the Department for Provider Profiling and Disease State Profiling as defined in the cost proposal shall occur not withstanding the Contractor's arrangements with the other members of the Coalition.

#### II) MAXIMUM PAYMENT & DURATION OF AGREEMENT

The Maximum Total Amount of this contract shall not exceed \$7,596,246 for the period from July 1, 2001 through June 30, 2005. For the period from July 1, 2001 through completion of the Design and Development (approximately 120 days) to the date of going operational no payments will be made. From start of operations estimated to be

- o November 1, 2001 through June 30, 2002, payments shall not exceed \$1,259,824,
- o For the period from July 1, 2002 through June 30, 2003, payments shall not exceed \$1,920,126,
- o For the period from July 1, 2003 through June 30, 2004, payments shall not exceed \$2,187,118,
- o For the period from July 1, 2004, through June 30, 2005, payments shall not exceed \$2,229,178.

Unexpended funds in any given State Fiscal Year shall be carried forward into the next year so long as the Maximum Total Amount for the length of the contract does not exceed \$7,596,246. In the event of increases in volume, caseload or costs the Department and the Contractor shall by mutual agreement and subject to approval by Governor and Council increase the Maximum Total Amount.

#### III) CONTRACTOR GUARANTEE

The Contractor guarantees upon the following terms that the Department, by implementation of the program initiatives listed below, will realize savings at least equal to the total Administrative Fee payable to the Contractor under Section I above:

- 1. Savings will be computed over a twelve-month period (except for the final contract year which may only consist of eight (8) months) (the "Savings Period"), commencing with the date the Contractor commences processing pharmacy claims for the Department.
- 2. Calculated savings will be compared against the Administrative Fee paid or payable by the Department to the Contractor over the same Savings Period.
- 3. The Contractor will be obligated to refund to the Department an amount equal to any excess (less any applicable withholds owed by the Department to the Contractor) of Administrative Fees paid or payable to the Contractor over demonstrated savings for the same period.
- 4. The parties agree that they anticipate savings from the program initiatives set forth in this Paragraph 4. In the event the Department elects not to implement each of the initiatives by the date set opposite each of them or terminates any program before the end of the contract, the savings guarantee by Contractor for that Savings Period in which any of the programs were not implemented or for which any program is terminated becomes null and void. Further, the guarantee is conditioned upon the Department implementing the following Contractor recommendations and criteria within the date specified, provided they are consistent with clinical best practice guidelines.
- Point of Service (POS) device with First Health Maximum Allowable Cost (MAC) pricing

,	November 1, 2001
Prospective Drug Utilization Review	November 1, 2001

• Early refill edits

• Therapeutic Duplication edits

•	Utilization Management	February 1, 2002
•	Disease Management	May 1, 2002
•	Auditing	May 1, 2002
•	Medicaid Drug Coverage Management	November 1, 2001
•	OBRA 90 Rebate Management	November 1, 2001
•	Prior Authorization Programs	November 1, 2001

Gastrointestinal Drugs

Arthritis Drugs

Narcotic Analgesic Utilization

7.

• Selective Seratonin Reuptake Inhibitors

•	Disease State Profiling	May 1, 2002
•	Provider Profiling	May 1, 2002
•	Clinical Detailing	May 1, 2002

- 5. The criteria, benchmarks, and formulae for measuring savings shall be mutually agreed to by the parties in writing no later than the date the contract for services is executed. The Department acknowledges that the criteria used by the Contractor is proprietary and that the methodologies for calculating savings, which includes the criteria, will not be subject to public disclosure.
- 6. The savings for each program will be calculated in the following manner. The year prior to the contract will always be used as the "base year" against which future savings will be measured in each contract year. Changes in the "base year" due, but not limited, to: new drugs, changes in drug status, population growth, changes in clinical practices, Consumer Price Index (CPI) adjustments, etc. will be agreed to by both the Department and the Contractor within 90 days of each Savings Period.

### POS with First Health MAC pricing/Medicaid Drug Coverage Management

The annual cost savings will be equal to the difference between Average Wholesale Price - 12% (lacking a Federal Upper Limit (FUL) or Health Care Financing Administration (HCFA) FUL and First Health MAC pricing for all paid claims for each drug with a First Health MAC price. For example, where the Average Wholesale Price of a drug minus 12% (\$64.15 - \$7.70) equals \$56.45, and the Contractor's Maximum Allowable Cost is \$50.00, the difference of \$6.45 is the annual savings.

## <u>Prospective Drug Utilization Review Professional Review Organization Drug Utilization Review (ProDUR)</u>

The annual savings for "soft" (informational) ProDUR edits will be calculated by subtracting the dollar amount of all "soft" edited claims reversed by the pharmacy and not resubmitted within thirty (30) days from the original claim submission

The annual savings for "hard" (denied) Therapeutic Duplication ProDUR edits will be calculated by adding the "allowable" (amount that would have been allowed for an eligible prescription per the reimbursement formula) cost of all claims denied annually and subtracting those claims that are prior authorized and paid. The value of a denied claim will be prorated to an annual cost savings for all claims not receive for at least 90 days after being initially denied.

The annual savings for "hard" Early Refill claims will be calculated by comparing the annualized refill frequency of denied claims and annualized frequency of paid claims

with the same GCN Sequence number. The savings will be the "allowable" cost of the claims not filled.

#### **Utilization Management**

The annual savings will be calculated by subtracting the allowed cost of all drugs in a Specific Therapeutic Class which were identified by Retroactive DUR and interventions for those patients profiled for six months after the intervention from the allowed cost of the drugs of the Specific Therapeutic Class before the intervention.

#### **Auditing**

The annual savings will be the amount that is identified by the Contractor auditors as being an overpayment for any reason, including but not limited to claims involving fraud, abuse, up-coding, etc. Savings will not be determined by the amount the Department ultimately collects from providers, but the amount identified.

#### **OBRA 90 Rebate Management**

The annual savings will be calculated by comparing rebate collection percentage in the "base year" to the rebate collection percentage in each subsequent year of the contract.

#### **Prior Authorization Programs**

The annual savings for all Prior Authorization programs will be calculated by adding the allowed cost of all claims which are denied annually and subtracting the allowed costs of those claims that are prior authorized. The value of a denied claim will be prorated to an annual cost savings for all claims for the recipient who has not had a claim received for at least 90 days after being denied.

#### **Disease State Profiling**

The annual savings will be calculated by subtracting the allowed cost of all drugs associated with the treatment of the profiled disease state that were intervened on for those patients profiled for six months after the intervention from the allowed cost of the drugs six months before the intervention. The calculations will be normalized to a PUPM (Per Unit Per Month).

#### **Provider Profiling**

The annual savings will be calculated by subtracting the allowed cost of all drugs in a Specific Therapeutic Class which was intervened on for those providers profiled for six months after the intervention from the allowed cost of the drugs of the Specific Therapeutic Class six months before the intervention. The calculations will be normalized to a PUPM.

#### **Clinical Detailing**

The annual savings will be calculated by subtracting the allowed cost of all drugs in a Specific Therapeutic Class which was intervened on for those providers detailed for six months after the intervention from the allowed cost of the drugs of the Specific Therapeutic Class six months before the interventions The calculations will be normalized to a PUPM (utilizing member month).

Negative savings will not be included in calculation of guaranteed cost savings however they will be reported to the Department.

8. Any overrides or reversals by the Department or otherwise of prescription denials made by the Contractor in accordance with agreed upon criteria in part 4 of this exhibit shall nevertheless be credited as a savings for purposes of calculating savings hereunder.

#### IV) SCHEDULE OF PAYMENT:

The Provider shall bill the Department on a monthly basis for the claims handled during the previous month. Invoices shall calculate the service payment in detail including the units, volume and price by service for each group under the contract as well as report the transactions volumes by month and year to date for the Coalition. The reports shall include numbers of users, number of prescriptions and cost per user and prescription as well as total cost both per month and year to date by State Fiscal Year. The invoice shall be sent to the Office of Community and Public Health at the address below in order to receive payment. All invoices shall be sent to the Department within 12 months of the date of service.

John Fransway, Budget Officer Medicaid Administration Bureau Office of Community and Public Health Department of Health and Human Services 6 Hazen Drive, Concord, NH 03301

## EXHIBIT C TO THE CONTRACT BETWEEN FIRST HEALTH SERVICES CORP. AND

#### THE STATE OF NEW HAMPSHIRE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **SPECIAL PROVISIONS**

#### **DEFINITIONS**

AGREEMENT: Shall mean the contract executed between First Health Services Corporation ("Contractor") and the Department of Health and Human Services ("Department") including the standard forms contract (Form p-37) and all exhibits A, A1, A2 through G.

COSTS: Shall mean those direct and indirect items of expense determined by the Department to be allowable and reimbursable in accordance with cost and accounting principles established in accordance with state and federal laws, regulations, rules and orders.

**PROPOSAL:** Shall mean the document submitted by the Contractor on January 9, 2001 as the Contractor's response to the request for pharmacy benefit management services issued by the Department on October 23, 2000. This document is also referred to as Exhibit A2.

TRANSACTION (or CLAIM): A transaction as defined by the NCPDP Transaction Code, that is received, processed, and responded to by the Contractor. A transaction can be received in multiple media as: (1) POS - a transaction received electronically via telephone lines from the Providers' Point of Service (2) Electronic Media - A batch of transactions received by the Contractor in electronic media (tape, diskette or electronic bulletin board) and submitted to Contractor System for processing, and (3) Paper - a transaction received on paper and data entered by the Contractor and submitted to the Contractor System for processing.

UNIT: As specified in Exhibit B of the Agreement.

FEDERAL/STATE LAW: Wherever federal or state laws, regulations, rules orders and policies, etc. are referred to in the Agreement, the said reference shall be deemed to mean all such laws, regulations, etc as they may be amended or revised from time to time.

1. Contractor Obligations: The Contractor agrees that all funds received by the Contractor under the Agreement shall be used only as payment to the Contractor for services provided to eligible individual and Contractor hereby further agrees as follows:

- 2. Fair Hearings: The Contractor understands that all applicants for services hereunder, as well as individuals declared ineligible have a right to a fair hearing regarding that determination. The Contractor hereby agrees that all applicants for services shall be informed of his/her right to a fair hearing in accordance with Department regulations. The Contractor further agrees to provide the Department with all information generated regarding adverse determinations and as necessary provides expert pharmaceutical fair hearing testimony.
- 3. Maintenance of Records: In addition to the eligibility records the Contractor agrees to maintain the following records during the term of the Agreement.
- 3.1 Fiscal records: Books, records documents and other data evidencing and reflecting all costs and other expenses incurred by the Contractor in the performance of the Agreement and all income received or collected by the Contractor during the term of the contract, said records to be maintained in accordance with accounting procedures and practices which sufficiently and properly reflect all such costs and expenses and which are acceptable to the Department and to include, without limitation, all ledgers, books, records and original evidence of costs such as purchase requisitions and orders, vouchers requisitions for materials, inventories, valuations of in-kind contributions labor time cards, payrolls and other records requested or required by the Department
- 3.2 Statistical records: Program statistical and enrollment attendance or visit records for each recipient of services during the contract term which records shall include all records of application and eligibility records regarding the provision of services and all invoices submitted to the Department to obtain payment for such services.

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- 3.3 Medical records: Where appropriate and as prescribed by the Department regulations the Contractor shall retain medical records on each patient/recipient of services.
- 4. Audit and Review: During the term of this Agreement and the period for retention, the Department, the United States Department of Health and Human Services and any of their designated representatives shall have access to all reports and records maintained pursuant to the Agreement for purposes of audit, examination excerpts and transcripts.
- 5. Audit Liabilities: In addition to and not in any way in limitation of obligations of the Agreement, it is understood and agreed by the Contractor that the Contractor shall be held liable for any state or federal audit exceptions and shall return to the Department all payments made under the Agreement to which exception has been taken or which have been disallowed because of such an exception.
- 6. Confidentiality of Records: All information, reports and records maintained in connection with this Agreement, or collected in connection with the performance of the services and the Agreement shall be confidential and shall not be disclosed by the Contractor provided, however that pursuant to state laws and the regulations of the Department regarding the use and disclosure of such information, disclosure may be made to public officials requiring such information in connection with their official duties

and for purposes directly connected to the administration of the services and Agreement; and provided further, that the use or disclosure by any party of any information concerning a New Hampshire Medicaid recipient or any other person served under the terms of this contract for any purpose not directly connected with the administration of the Department or the Contractor's responsibilities with respect to purchased services hereunder is prohibited except on appropriate written consent. Notwithstanding anything to the contrary contained herein the conditions contained this paragraph 6 shall survive the termination of the Agreement for any reason whatsoever.

- 7. Reports: Fiscal and Statistical: In addition to reports required pursuant to Exhibit A of this Agreement, the Contractor agrees to submit the following reports at the following times if requested by the Department:
- 7.1 Interim Financial Reports: Written interim financial reports containing a detailed description of all costs and non-allowable expenses incurred by the Contractor to the date of the report and containing such other information as shall be deemed satisfactory by the Department to justify the rate of payment. Such financial reports shall be submitted on the form designated by the Department or deemed satisfactory by the Department
- 7.2 Final Report: A final report shall be submitted within ninety (90) days after the end of the term of this Agreement. The final report shall be in a form satisfactory to the Department and shall contain a summary statement of progress toward goals and objectives stated in the Contractor proposal and other information required by the Department
- 8. Completion of services: Disallowance of Costs: Upon the purchase by the Department of the maximum number of units provided for in the Agreement and upon payment of the price limitation hereunder, the Agreement and all the obligations of the parties hereunder (except such obligations as by the terms of the Agreement are to be performed after the end of the term of this Agreement and or survive the termination of the Agreement) shall terminate; provided however, that if, upon review of the final expenditure report the Department shall allow any expenses claimed by the Contractor as costs hereunder the Department shall retain the right, at its discretion to deduct the amount of such expenses as are disallowed or to recover such sums from the Contractor.
- 9. Credits: All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services or the Agreement shall not be sent without prior approval by the Department and shall include the following statement:

The preparation of this (report, document etc.) was financed under an Agreement with the State of New Hampshire, Department of Health and Human Services with funds provided in part by the United States Department of Health and Human Services.

10. Operation of facilities: Compliance with Laws and Regulations: In the operation of any facilities for providing services, the Contractor shall comply with all laws orders

and regulations of federal, state, county and municipal authorities and with any direction of any public officer or officers pursuant to laws which shall impose an order or duty upon the Contractor with respect to the operation of the facility or the provision of the services at such facility, if any governmental license or permit shall be required for the operation of the said facility or the performance of the said services, the Contractor will procure said license or permit, and will at all times comply with the terms and conditions of each such license or permit. In connection with the foregoing requirements, the Contractor hereby covenants and agrees that, during the term of this agreement the facilities shall comply with all rules, orders, regulations and requirements of the State Office of the Fire Marshal and the local fire protection agency, and shall be in conformance with local building and zoning codes, by laws and regulations.

- 11. Dispute resolution: Order of Precedence: In the event that any provisions of this Agreement conflict and there is dispute among the parties regarding resolution of the dispute. The parties agree that the order of precedence for resolution of disputes shall be to look first to the language of the standard signed contract labeled Form Number P-37, second to the language of Exhibit B, third, to the language of Exhibit A, fourth, to the language of Exhibit A1 and then fifth to Exhibit A2. In the event that the parties are unable to informally settle any dispute arising under the Agreement, the Contractor further agrees and submits to the jurisdiction of the courts of the State of New Hampshire and agrees that venue for any legal proceeding against the State shall be filed in the Merrimack County Superior Court, Court Street, Concord, New Hampshire. The provisions of this paragraph shall not in any way be considered a waiver of sovereign immunity by the State of New Hampshire.
- 11.1 In the event that either party deems it necessary to take legal action to enforce any provision of the Agreement, each party shall bear its own costs associated with the litigation, including attorney fees. Any action against the State, including, but not limited to, actions for either breach of contract or for enforcement of its provisions, or both, shall commence within three (3) years from the date of completion specified in this Agreement. All defenses in law or equity shall be preserved to the State, including sovereign immunity.
- 12. Entire Agreement: This Agreement represents the entire agreement between the parties on the subject matter. All prior agreements, representations, statements, negotiations and understandings shall have no effect.
- 13. Applicable Law: This Agreement shall be governed by the laws of the State of New Hampshire.
- 14. Gratuities or Kickbacks: The Contractor agrees that it is a breach of this Agreement to accept or make a payment, gratuity or offer of employment on behalf of the Contractor, any Sub-Contractor or the State in order to influence the performance of the Scope of Services detailed in Exhibit A of this Agreement. The state may terminate this Agreement and any sub-contract or sub-agreement if the State determines that payments,

gratuities or offers of employment of any kind were offered or received by any officials, officers, employees or agents of the Contractor or Sub-Contractor.

- 15. Retroactive payments-Individual Services: Notwithstanding anything to the contrary contained in this Agreement or in any other document, agreement or understanding, it is expressly understood and agreed by the parties that no payments will be made to reimburse the Contractor for any services provided to any individual prior to the Effective date of this Agreement and no payments shall be made for expenses incurred by the Contractor for any services provided prior to the date on which the individual applies for services or (except as otherwise provided by the federal regulations) prior to a determination that the individual is eligible for such services.
- 16. Retroactive Payments Contractor Services: Notwithstanding anything to the contrary contained in this Agreement or in any other document, agreement or understanding, it is expressly understood and agreed by the parties that no payments will be made to reimburse the Contractor for any costs incurred for any purposes prior to the Effective date of the Agreement.
- 17. Debarment, Suspension and Other Responsibility Matters: If this Agreement is funded in any part by monies of the United States, the Contractor shall comply with the provisions of Section 319 of the Public Law 101-121, Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions; with the provisions of the Executive Order 12549 and 45 CFR Subpart A, B,C,D, and E Section 76 regarding Debarment, Suspension and Other Responsibility Matters, and shall complete and submit to the State the appropriate certificates of compliance upon approval of the Agreement by the Governor and Council.
- 18. No Third Party Benefits: Nothing in this Agreement, express or implied, is intended to confer upon any other entity or person (including without limitation any Member or health care provider) any rights or remedies under or by reason of this Agreement.
- 19. Compliance with Laws: The Contractor and the Department shall each be solely responsible for compliance with all laws, rules and regulations that are now or hereafter applicable to each of them and their own performance under this Agreement. The Contractor and the Department agree to inform each other of any and all special federal, state or local laws, rules or regulations and revisions there to that either party becomes aware of which impact the manner in which the Contractor processes claims required by the agreement.
- 20. HIPAA Compliance: Contractor represents that its operations and First SX POS shall comply with the requirements of HIPAA as such requirements currently exist. Notwithstanding the above, the Department acknowledges that the First SX POS will initially contain NCPDP 3.2 Version but be converted to NCPDP Version 5.1 prior to the HIPAA compliance date, currently proposed as October 16, 2002. The Department

further acknowledges that the Conversion/Implementation Fee assumes no significant changes in HIPAA requirements between the date of this Amendment and actual implementation. In the event of revisions to HIPAA requirements, either before or after implementation, modifications to First SX necessitated by such changes shall be billed in accordance with the Systems Maintenance Rates. Prior to undertaking such modifications the Department and Contractor shall agree upon the fixed price for the modifications or Contractor shall provide an estimate of the cost of the systems work.

- 21. Eligibility Lists: The Department acknowledges and agrees that the Contractor shall approve or deny benefits to Members in complete reliance upon the eligibility lists provided by the Department. In the event of any retroactive termination of Members, the Department shall be liable for all Claims approved for such Members prior to loading of the eligibility data deleting such Members.
- 22. Overpayments to Providers: In the event any overpayments are made to Providers, whether through the fault of the Contractor or otherwise, the Contractor may, in addition to any other rights or remedies it may have at law or in equity, recover such overpayments within Contractor System through offset against subsequent payments otherwise due to such Providers. Notwithstanding the recovery mechanism provided above, the Contractor shall not be liable for any overpayments unless such overpayments are solely the fault of the Contractor. If any network of pharmacies other than that of the Contractor is to be used under this Agreement, the Department shall assure that all agreements with pharmacies provide for such offset by the pharmacies.
- 23. Software Ownership: The parties mutually acknowledge that each respectively has no ownership in any of the software developed or owned by the other party and used in connection with services rendered pursuant to this Agreement. The Department specifically acknowledges and agrees that it acquires no right, title, interest, or license to FIRSTSX AND FIRSTIQ by virtue of this Agreement.

In the event the Department is granted possession of, or access to, any of the Contractor's proprietary software products, the Department shall execute in advance thereof a Software License Agreement.

Attachment# 8

Testimony: HB 1218; an act Relative to pharmacists and prescription drug orders.

April 9, 2002

Senate Committee: Executive Departments and Administration

My name is Michael J. Cohen and I am the Executive Director of the Alliance for the Mentally Ill, New Hampshire. On behalf of the over 500 families who comprise our organization I want to speak about this legislation and the importance of certain elements in order to assure that Medicaid insured citizens have open access to the best pharmaceutical interventions, NH has to offer. Previously I commented to the DHHS on the new pharmacy rules and regulations and I think it important enough that the committee hear the comments I made at the DHHS public hearing as you deliberate this bill and its amendment(s). The specific issue I would like to comment on is Prior Authorization (PA)

- NAMI NH endorses treatment based on the available scientific evidence and on the needs of the individual consumer. Research, and guidelines based on this research, calls for consumers with severe mental illness such as schizophrenia to receive the most efficacious medications, with the least number of side effects. Currently the National Institute of Mental Health (NIMH) is conducting a Comparative Effectiveness Study of Antipsychotic Medication is Patients with Schizophrenia; the CATIE Outcome Study, to evaluate the effectiveness of 5 atypical and conventional antipsychotic medication to determine the long term effectiveness and tolerability of these medications. At minimum, until this data is known and decisions can be made on the evidence there should not be any consideration given to placing any antipsychotic medications on any Prior Authorization (PA) list.
- No medication should be placed on a PA list solely on the basis of cost
- Final decisions for medication usage should be made on evidence and on an individual basis between the consumer and his/her physician and, not made by a pharmacist or the administrative unit- PBM managing the contract.
- Any appeal process procedure for a consumer to receive the medication prescribed, and then denied, must be clear and easy for both the consumer and physician to understand.
- Any prior authorization system should not discourage a physician from prescribing the most appropriate medication therapies because of cumbersome and time-consuming processes.
- Consumers should not, ever, have to fail at one medication before being placed on another known to be more effective and/or with lesser negative side effects.
- Individuals respond differentially to medications, even those medications that are in the same class, and therefore clinical judgment and informed consumer choice plays a vital role in medication selection-not cost.

- Consumers and advocacy organizations representing citizens who use Medicaid
  insurance should have input into the deliberations of the Pharmacy and
  Therapeutics committee, when it makes its decisions about medications to be
  placed on any PA list. Reasons for medications, or classes of medications to be
  placed on a PA list should be made public. The benefit manager should not be the
  sole decision maker in developing the PA list of medications.
- A mechanism should be in place to determine the cost/benefit ratio of the PBM.
   This benefit ratio should include input from physicians and consumers and not solely based on economic factors. It should include social and medical benefits/costs. A report on the findings should be issued at least annually and made available to public.

Thank you for your time and for the opportunity to speak on behalf of open access to the most efficacious medications. I will submit my comments for the written record.

I would have a strain with the latter, Can amount with the considerations noted above.

Muchael John

# Testimony Re: HB 1218 Amendment

Senate Executive Departments and Administration Russell E. Prescott, Chairman

Donald Shumway, Commissioner
New Hampshire Department of Health and Human Services
April 9, 2002

### Pharmacy Benefit Management

- Widely Used to Improve Quality and to Control Costs in Health Plans
  - Reduces Medication Errors
  - Prevents Fraud and Abuse
  - Assures Careful Control of Limited Resources
  - Moderates Effect of Manufacturer Marketing
- In New Hampshire Medicaid;
  - A. Initial Implementation EDS
    - February 2001
  - B. Expanded Implementation First Health,
    - November 2001

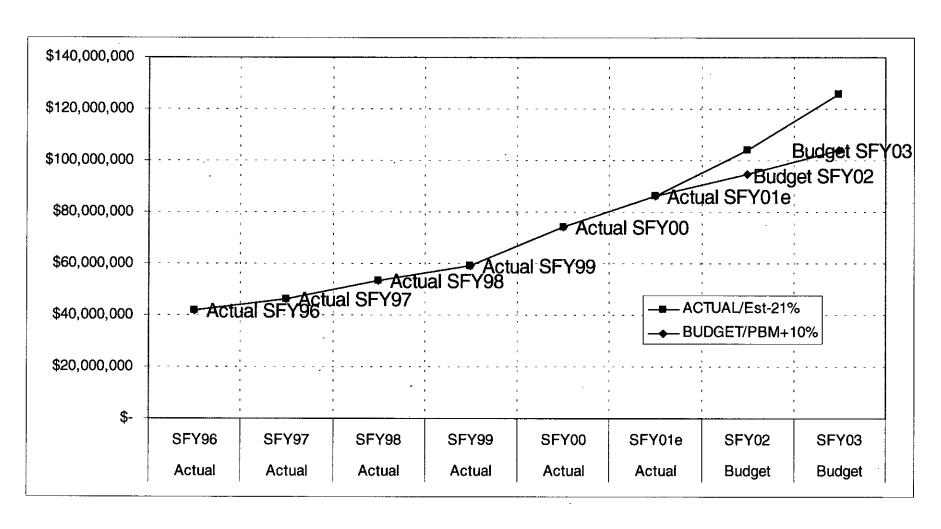
# Legislative Testimony '02-'03, Medicaid Pharmacy

- September 2000 SFY 2002-2003 agency budget submission included specific reference to pharmacy benefit management in the Form 6, Analysis of Change submitted to the Governor.
- November 15, 2000 Department testimony at the public Governor's Budget Hearing included specific testimony about the request for proposals for a pharmacy benefit manager. In anticipation of approval, the Department reduced its estimated inflation for prescription drugs from 20% to 10% in the budget requests.
- March 5, 2001 Initial Department budget presentation to full House Finance included a chart about prescription drug expenses and PBM. No questions from committee members. (13 members were present and 10 were absent.)
- March 17, 2001 OCPH testimony before House Finance Division III on pharmacy benefit management objective is to implement full-service pharmacy benefit management to achieve zero inflation in 03, per an overhead slide provided to the committee members. Reps Kurk, Emerton, Wendelboe, and Johnson asked questions about PBM.
- March 19, 2001 Initial Department budget presentation to Senate Finance included a chart and commentary about prescription drug expenses. Senators Barnes and Larsen asked questions about pharmacy benefit management.
- March 30, 2001 More prescription drug discussions with House Finance Division III with Rep Wendelboe asking questions.
- May 16, 2001 Senate Finance budget session included questions from Senator Boyce about moving pharmacy to a contractor other than EDS and the Department expecting to have PBM online by November 1, 2001.

# {Senate Finance Testimony 3/19/01} DHHS Financial Management During the Education Crisis

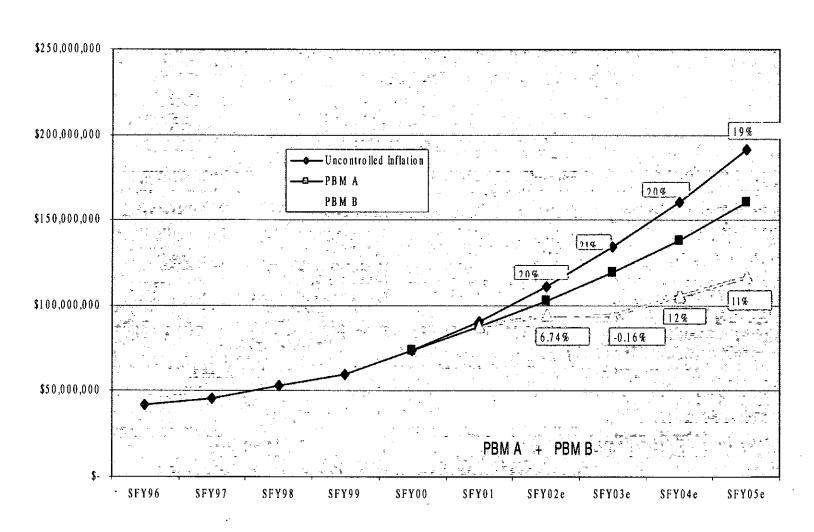
- Make Existing Programs Work
  - -No New Programs
- Contain Costs
- Generate Revenues
  - Produced More Than \$33 Million in FY '01

## Medicaid Cost Control Efforts: Pharmacy Benefit Manager



## Actual and Projected Experience

Medicaid Drug Cost Trend SFY 96 - SFY 05e



## Savings Basis

#### • Reductions in:

- Multiple Medication Filling
- Drug to Drug Interactions
- Excessive Duration of Addictive Substances
- Quantity Management (e.g. Day Supply)
- Therapeutic Duplication
- Early Refill

#### • Improvements in:

- Checks on Patient Age Medication (e.g. young children)
- Restoring Medicaid as "Payor of Last Resort"
- One Time Cash Flow (Weekly to Bi-Weekly Payment)
- Prior Authorization Based Alternatives
- Use of Generics
- State Medicaid Allowable Charge Limits (Rapid Updating of Generic Costs)

	SFY96	SFY97	SFY98	SFY99	SFY00	SFY01	SFY02e	SFY03e	SFY04e	CEVec	05)(00.55
BM B	01100	0.107	01150	01 133	3F 100					SFY05e	SFY02-05
BM A					674.007.707	\$ 67,999,034	\$ 93,928,380	\$ 93,773,450	\$ 105,026,264	\$ 116,579,153	\$ 409,307,247
	\$ 41 754 350	\$46,004,469	R E2 251 100	£ 50 246 726	\$74,007,727	\$ 67,999,034	\$ 102,322,991	\$ 119,004,745	\$ 138,218,776	\$ 160,102,589	\$ 519,649,101
Incontrolled Inflation	\$41,734,330	\$40,004,400	\$ 23,331,190	\$ 58,510,735	\$74,067,727	\$ 90,806,283	\$ 110,783,665	\$ 134,048,235	\$ 160,857,882	\$ 191,420,879	\$ 597,110,660
							\$ 16,855,285	\$ 40,274,785	\$ 55,831,618	\$ 74,841,726	\$ 187,803,413
		SFY97	SFY98	SFY99	SFY00	SFY01	SFY02e	SFY03e	SFY04e	SFY05e	
ncontrolled Inflation		10.18%	15.97%	11.18%	24.87%	22.60%	22,00%		20.00%	19.00%	
BM A						18,81%	16.28%		16.15%	15.83%	
BM B						#DIV/0!	6.74%		12.00%	11,00%	
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lotes: SFY 01 EDS P	BM initiatives sa	ved \$2 807 249	Feb-June		<del></del>		• • • • • • • • • • • • • • • • • • • •				
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#### The Union Leader

September 27, 2001

#### OXYCONTIN ROBBERIES PROVE MAJOR CONCERN

By JODY RECORD
Union Leader Correspondent

**DOVER** — Abuse and misuse of the painkiller OxyContin is becoming a major concern for law enforcement official with reports of a third Seacoast pharmacy robbed of the powerful drug in the past month.

On Monday, an employee at Brooks Pharmacy in Dover handed over an undetermined about of OxyContin, an opioid compared in strength to morphine, when a man gave the clerk a note saying he had a gun.

Last week, a CVS store in Stratham was robbed of the painkiller at gunpoint. And on Aug. 28, a man walked into the CVS pharmacy in Portsmouth, indicated he had a gun and demanded OxyContin.

While these are the first robberies in the area, theft of the painkiller is nothing new, said Dover police chief William Finneman. Reports of holdups in Maine, Virginia and Kentucky have been widely reported in the five years since Purdue Pharma L.P. of Connecticut began offering the drug.

"This is the first theft in Dover but we figured it was just a matter of time," Finneman said yesterday. "I don't think this is necessarily a geographic phenomena. There have been quite a few cases of robberies in other states. The incidents here could be the result of Massachusetts' influence."

The question of whether changes in how Massachusetts pharmacies are handling sales of the drug — limiting the amount they carry or, in some cases, not selling it at all — have likely pushed abusers to seek OxyContin elsewhere, Finneman said.

Chief Michael Daley of Stratham agreed.

"It's our belief that the robbery here was done by people from out of state who have returned to out of state," Daley said.

The Stratham police chief also speculated that the robbers are likely dealers looking to resell the costly drug rather than users wanting to get high.

According to Purdue Pharma's Web page, OxyContin carries the warning that breaking or crushing the pills can lead to rapid release and absorption, resulting in a potentially toxic dose.

Abusers have turned OxyContin into a street drug by doing just that, or, in some cases, inhaling the drug or crushing it to inject like heroin.

"There may be some of them who use the drug to get high but we believe, for the most part, it's stolen to be sold," Daley said. "And at a \$1 a milligram, it can add up to a lot of money."

The drug manufacturer's Web page shows at least two state attornies general have contacted the company regarding misuse of the drug, urging Purdue Pharma to change its marketing approach for OxyContin.

In July, according to data on the Web page, Purdue Pharma altered its prescribing information and sent letters to more than 800,000 health-care providers warning of the potential for abusing OxyContin.

The labeling change includes a "black box warning," considered the most stringent type of caution for FDA approved drugs.

The proactive move is aimed at limiting the drug from being inappropriately prescribed, the company Web page said.

Finneman said his department has been trying to be proactive in its approach to the Seacoast robberies.

Dover police have contacted all pharmacies in the city to discuss increased security measures, suggesting the use of panic alarms and/or video cameras.

Daley has tried to do the same thing in Stratham but has found that some loss prevention representatives of pharmacies are not receptive to discussions.

"In a few cases, we have not been well-received," Daley said. "But this is a problem we want to avoid. They're using guns; the potential exists for someone to get hurt."

While he admits cameras are a good idea, it's more likely cameras would help after a robbery has taken place, rather than in preventing one.

"In some cases they may serve as a deterrent but not many," Daley said. "Maybe if pharmacists were in locked vaults like gas station attendants, it might help."

Whatever will help is what Rochester police chief Daniel Auger is willing to try. He feels fortunate that — for now, at least — there hasn't been a theft of the drug in his city.

"We have talked to all drug stores in (the) city regarding recent robberies and have increased patrols around these stores. We are still working with them to minimize the problem and hope it doesn't happen in our community," Auger said.

Like most of the communities polled, Auger said Rochester has not seen an increase in drug-related arrests or emergency room service related to the morphine-like OxyContin.

The Lilac City chief went on to say legal use of the drug has to be evaluated before there can be a move to remove it from pharmacies.

"You have to weigh the necessity of the drug because it does have a pharmaceutical benefit for people in a great deal of pain, like cancer patients," Auger said. "But there has to be a balance. That's what the manufacturer and the pharmacies need to consider."

None of the pharmacies contacted for this article would talk about their practice of carrying OxyContin.

#### HHS X-Drug Program

#### Issues with the HHS PBM Program

My main concern is that the enacted program did not receive a proper review from a policy committee prior There should have been an to implementation. opportunity to review, discuss and debate the RFP process, the criteria for selection of the PBM including but not limited to prior authorization, prospective drug utilization review, retrospective drug utilization review and data analysis and decision support. Incumbent on the last point is that there should be an independent audit procedure in place to quantify and verify the projected savings and ensure the maintenance of quality.

Over a year ago, DHHS presented this program to the House Finance committee Division III, of which I am a member. We were told that an RFP was in progress. We were told that the PBM selection would reduce the prescription drug spending increase from 13-15% to 7-9%. Our reaction was immediate and quite pointed. We wanted to have verification as to the projected reduction and the approach the program would use to achieve this reduction. It has been my experience that if improperly installed, a PBM can have deleterious effects, achieving savings at the expense of the people served. As we are talking about our indigent elderly and/or disabled population, it is imperative that we get this right the first time. This group has a fragile health status to begin with and any improper steps here could have disastrous consequences. My main concern stated at that hearing was a desire to see a chronic disease management system in place to augment the PRODUR system to ensure quality and to reduce healthcare

expense on the medical as well as the pharmaceutical side. When we were told that no savings were anticipated from the Medicaid medical portion, I knew we would have problems, and I stated so at that hearing.

In review of similar programs installed recently, I have found several items common to successful programs. Massachusetts has prior authorization for biotech drugs and other drugs characterized as "high-risk" or used for specific, very narrow indications. Massachusetts also has put in the caveat that a drug cannot be substituted if the prescription is noted "dispense as written". The Massachusetts plan, which went into effect on November 28,2001, would only apply to generic drugs that have the same chemical makeup of the brand name versions. Stephen B. Soumerai of the Harvard Medical School and Helene L. Lipton of the University of California School of Pharmacy brought this issue

forth initially in June of 1995 when the New England Journal of Medicine published their article entitled "Computer-Based Drug-Utilization Review—Risk, Benefit or Boondoggle? They stated that some forms of computer-based drug-utilization review, however well intentioned, have been implemented without satisfactory evidence of their efficacy and safety. Current programs focus on errors of commission, without examining problems of underuse; they also emphasize savings in the short-term (e.g., reductions in doses or refills of costly medications) rather than longer-term efforts to achieve system wide savings (e.g., reduced rates of hospitalization due to increased compliance with antihypertension regimens). Here, the so-called hassle factor creates the atmosphere of injudicious use of a prior-authorization can become a barrier to essential care.

Alan Lyles, Ilene Zuckerman, Susan DeSipio and Thomas Fulda took this one step further in their October 1998 article in Health Affairs. They stated that there was little rigorous research evaluating the impact of these programs, and much of the claims of savings come from the vendors themselves and lack independent verification. To be effective, prospective DUR programs must have;

- 1. Consistent definitions and unique identifiers for a core health data set across plans and providers
- 2. An integrated, comprehensive database for each beneficiary
- 3. Rules or criteria that define alerts foe medication-related concerns
- 4. Software algorithms to implement these rules

A survey of private sector DUR plans found that they emphasize cost and adherence to contracts; there was low interest in active review and assessment of pharmacotherapy.

The committee should focus on the following issues; was there a proper vetting of the PBM policy relative to its effect upon the population served (was the possible this policy discussed implications of policymakers)? This requires a complete evaluation of prior authorization, proDUR and retroDUR, and the evaluation of chronic disease management and its efficacy in this process. Is the theoretical savings from the current program worth the potential harm to the patient population, and has anyone considered what our liability as the plan sponsors may be if someone is harmed by a program we put in place prior to the established rules and public hearings for such an endeavor. While I do not recommend we suspend the program, I do suggest we eliminate prior authorization for the time being until we are sure this is the policy we

want in place, and it can be adjudicated with relative assurance that no one will be harmed by its use. I also suggest that we create an independent audit function on an ongoing basis to maintain our confidence in the reported financial savings and that the administrative protocols are followed.

NO. 4946 7. 2

Attachment # 12

#### **Full Text Articles**

Many on Medicaid Lack Drugs, Study Says By ROBERT PEAR

04/09/2002 The New York Times Page 20, Column 4 c. 2002 New York Times Company

WASHINGTON, April 8 -- States have become so aggressive in trying to control Medicaid spending on prescription drugs that many Medicaid recipients do not get all the drugs prescribed for them, researchers said today.

Although Medicaid covers prescription medicines in every state, one-fourth of patients enrolled in the program reported that they could not afford to fill some of their prescriptions in the last year, the researchers said. In an environment of rapidly rising drug prices, they said, states' cost-control efforts were the leading factor.

Most states are experiencing fiscal problems, and drug spending for Medicaid recipients has been rising 15 percent to 20 percent a year. So state officials have adopted numerous measures to rein in costs -- some of them requiring co-payments, for instance, others limiting the number of each patient's prescriptions.

"It appears that a consequence of aggressive cost-control policies is a reduction in beneficiary access to prescription drugs," said the researchers, from the nonpartisan Center for Studying Health System Change, who were led by Peter J. Cunningham.

The study was based on a survey of 39,000 adults, including nearly 1,800 on Medicaid. By most measures, it said, Medicaid recipients and people with private insurance have similar access to medical care. But, it said, prescription drugs appear to be an exception; some Medicaid recipients have almost as much difficulty as the uninsured in obtaining medications.

Twenty-six percent of Medicaid beneficiaries ages 18 to 64 reported that they could not afford to get all their prescriptions filled in the last year, the report said. That was just slightly less than the 29 percent of uninsured people who reported similar difficulty.

By contrast, 8 percent of people with employer-sponsored health coverage and 8 percent of elderly people with Medicare said costs prevented them from obtaining medicines. (Medicare generally does not cover prescription drugs outside the hospital, but about two-thirds of Medicare beneficiaries have drug coverage from other sources.)

Len M. Nichols, vice president of the Center for Studying Health System Change, said, "The findings are surprising because Medicaid is expected to ensure access to affordable care for the poorest and sickest Americans."

Medicaid is financed jointly by the federal government and the states. The states have broad discretion to decide on the details of their individual programs, within federal guidelines, and all have chosen to cover prescription drugs. Having made that choice, states must cover most drugs that have been approved by the Food and Drug Administration. They cannot arbitrarily refuse to cover drugs for a particular illness.

Pharmacenness Research and Munifocuries of America

Cost-control methods vary by state. Some states charge a co-payment of \$1 to \$3 for each prescription. Some limit the number of prescriptions, allowing no more than three to six in a month. Some require doctors to get authorization before prescribing certain drugs. Some require the substitution of generic drugs for brand-name medicines, or require doctors to try lower-cost drugs before prescribing more costly ones.

But Ray Hanley, the Medicaid director in Arkansas, which requires co-payments, said he found it hard to believe that people were going without prescription drugs because of cost controls. "If anything," Mr. Hanley said, "the co-payments need to be higher. The limits on co-payments have not changed in 20 years, and many people, including children and pregnant women, are exempt from co-payments."

Joan Henneberry, a health policy expert at the National Governors' Association, said: "There's no question that cost-containment measures affect access to prescription drugs, but that may be a positive outcome. We know that Medicaid beneficiaries are often getting too many medications, duplicative medications from various doctors and, in some cases, medications that are contraindicated and dangerous."

Some of the cost-control techniques used by Medicaid are also used by private insurers. But Mr. Cunningham, the lead author of the new study, said these measures were more likely to curtail access to prescription drugs among Medicaid recipients because they had lower incomes and were more likely to have chronic illnesses. About 40 percent of Medicaid recipients with two or more chronic ailments reported that they could not afford prescription drugs that they needed, the study said.

No cost-control technique by itself severely impaired access to prescription drugs, the study said. But a combination of such techniques made it more likely that Medicaid recipients would be unable to afford medicines, it said.

In states with four or five cost-control techniques, an average of 33 percent of Medicaid recipients reported that costs kept them from filling some prescriptions, the study said. By contrast, 15 percent of beneficiaries said they had trouble filling prescriptions in states using one cost-control technique, or none.

The states with four or five cost-control measures, the report said, are Arkansas, North Carolina, South Carolina and West Virginia.

Chart: "AT ISSUE: Access to Drugs Under Medicaid" A study has found that 1 in 4 Medicaid recipients was unable to afford a full complement of prescription drugs last year, largely a result of efforts by states to control Medicaid drug spending. MEDICAID VS. OTHER TYPES OF COVERAGE — Percentage unable to afford prescription drugs at least once in the last year, by type of coverage: Blderly with Medicare: 8% ADULTS AGE 18 TO 64 With employer coverage: 8 With Medicaid or other state coverage: 26 Uninsured: 29 IMPACT OF COST-CONTROL EFFORTS — Percentage of people on Medicaid unable to afford prescription drugs at least once in the last year: Number of cost-control methods used by the state None or one: 15% Two or three: 25 Four or five: 33 (Source: Center for Studying Health System Change)

Attachment # 13

Sen. Prescott, Dist. 19 April 10, 2002 2002-3356h 10/01

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33

pharmacy lock-in program; and

#### Amendment to HB 1218

1	Amend the title of	the bill by replacing it with the following:
2		
3 4 5 6	AN ACT	relative to the regulation of pharmacists and prescription drug orders and granting rulemaking authority for managing certain plan benefits under Medicaid.
7	Amend the bill by	replacing all after section 6 with the following:
8		•
9	7 New Parag	raphs; Commissioner of Health and Human Services; Rulemaking Added; Report.
10	Amend RSA 126-A	A:5 by inserting after paragraph XII the following new paragraphs:
11	XIII. The	commissioner, in order to manage plan benefits under Medicaid, shall adopt rules
12	under RSA 541-A	relative to:
13	(a) A	medical pharmacy lock-in program to prevent recipients from obtaining excessive
14	quantities of, or fr	om inappropriately using, prescription drugs through multiple pharmacies; and
15	<b>(b)</b> A	A prior authorization process in which a prescriber seeks approval by the
16	department, throu	igh its designated agent, to make payment for drugs which are considered to have
17	a high potential fo	or misuse or abuse, are high cost, or should be monitored for correct adherence to
18	clinical protocols.	
19	XIV.(a) T	he commissioner shall report to the legislative oversight committee established in
20		by November 1 of each year with respect to the Medicaid prescription drug benefits
21	management progr	
22	(1)	The cost savings to the state that have been realized during the current budget
23		institution of a prior authorization program;
24	(2)	The unintended costs in other Medicaid healthcare services programs, including
25		missions, hospital admissions, emergency room visits and physician visits during

the current budget biennium from the institution of a prior authorization program;

pharmacy services or to expand pharmacy benefits to additional populations.

required to comply with under the terms of the pharmacy benefits management contract;

(3) A report on the volume of prior authorizations as a percentage of total claims,

(4) A report of the effectiveness of the department and health and human services'

Recommendations for other opportunities to improve the management of

average call waiting time and other issues that the state's pharmacy benefits administrator is

#### Amendment to HB 1218 - Page 2 -



4,-

(b) For the purpose of legislative oversight of the Medicaid prescription drug benefits management program administered by the department under rules adopted pursuant to paragraph XIII, there is established a legislative oversight committee consisting of 3 members of the house of representatives appointed by the speaker and 3 senators appointed by the senate president. The committee shall meet as needed and shall elect a chair from among the members. The committee shall review the reports of the commissioner under subparagraph (a) and may request additional information as needed. The committee may request the assistance of the legislative budget assistant in auditing the program and in reviewing its performance and effectiveness. The committee may make recommendations for proposed legislation, and shall report any findings or recommendations, including the commissioner's report under subparagraph (a), to the speaker of the house, the president of the senate, the governor, and the chairman of the joint legislative committee on administrative rules by January 1 of each year.

8 Effective Date.

- I. Section 7 of this act shall take effect upon its passage.
- 15 II. The remainder of this act shall take effect 60 days after its passage.

#### Amendment to HB 1218 - Page 3 -



2002-3356h

#### 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, and the filling of prescriptions by automated pharmacy systems.

This bill also grants the commissioner of health and human services the rulemaking authority, concerning managing plan benefits under Medicaid, for a medical pharmacy lock-in program and a prior authorization process. The bill establishes a legislative oversight committee and requires the commissioner to report annually to the committee on the savings, cost, effectiveness, and recommendations for such Medicaid programs.

# Speakers

#### SENATE EXECUTIVE DEPTS. & ADMIN. COMMITTEE

Date APRIL 9,2002 Time 8:30 A.M Public Hearing On HB 1218

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Address	Representing
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	Carroll 9
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	Purdue Pharma
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#### SENATE EXECUTIVE DEPTS. & ADMIN. COMMITTEE

Date APRIL 9,2002 Time 8:30 A.M Public Hearing On HB 1218

Appearing in F2 Speaking?	Name	Address	eck box at left to spea Representing
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DON SHI			PHHS
Steven L	avwers + Debbie Ste	phens (amendment)	First Hody
MANJON	it Paver		
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	PPOSITION: (Please Prin Name	nt) Please check box Address	°at left to speak. Representing
Appearing in of			

# Testimony

#### New Hampshire General Court Statutory / Chaptered Study Committees



#### MEDICAID PRESCRIPTION DRUG BENEFITS MGMT PRGM LEGISLATIVE OVERSIGHT COMMITTEE

Year:

2002

(b)

Bill No.:

HB1218

RSA Chapt.:

Chapter Law:

0281:9,IV

Effective Date:

5/23/2002

Rpt. Filed:

Yes

Report Date:

9/5/2003

Additional Dates:

Yes

Report Due:

1/1/2004

Title:

(New Title) 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.

Comm. Status:

New

Comments:

Reports due annually on Jan 1;

Docket:

Date

Description

5/23/2002

[Committee to elect own Chair; Committee to meet as needed; Reports, including Health and Hum Srycs Commn's Report, to Speaker, President, Governor and Chair of Jt Comm on Admin Rules by

brycs Commin's Report, to Speaker, President, Governor and Chair of Jt Comm

Jan 1 of each year]

5/23/2002

3 Representatives, appt by Speaker:

5/23/2002 3 Senators, appt by President:

Committee Members

<u>Member/Appointed by</u>

Member/Appointed by

Dalrymple, Janeen (Chair) - by SPKR

Johnson, Rogers (Chair) - by SPKR

Dexter, Judson - by SPKR

Prescott, Russell - by PRES

Gatsas, Theodore - by PRES

Larsen, Sylvia - by PRES

Meetings:

<u>Date/Time</u> <u>Location</u>

8/13/2002 10:00:00 AM RM205, LOB - Organizational meeting

9/19/2002 10:00:00 AM RM205,LOB - Regular meeting RM205,LOB - Regular meeting 11/13/2002 10:00:00 AM 4/16/2003 3:30:00 PM RM205,LOB - Regular meeting 5/14/2003 3:30:00 PM RM205,LOB - Regular meeting 9/3/2003 3:30:00 PM RM205,LOB - Regular meeting 9/25/2003 10:00:00 AM RM203,LOB - Regular Meeting 10/16/2003 11:00:00 AM RM206,LOB - Regular Meeting 12/4/2003 10:00:00 AM RM205,LOB - Regular Meeting

Priev Next Results List New Query (



Nicholas J. Vailas Commissioner

> Lori H. Real Director

# 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 1-800-852-3345 Ext. 5254 Fax: 603-271-8431 TDD Access: 1-800-735-2964

July 31, 2003

The Honorable Janeen A. Dalrymple 7 Penobscot Avenue Salem, NH 03079-1531

#### Dear Representative Dalrymple:

As requested, the following comments are provided on the Draft 2, 2002 PBM Oversight Committee, Annual Report.

- p. 2 November 13, 2003 Change Swanson to Swenson. Change second sentence to: "These savings were based upon the EDS contract from July through October 2001 and First Health contract from November 2001 through June 2002.
- p. 3 Change second sentence to: "They found that there were no adverse effects due to prior authorization and that prior authorization was conducted on only .3% of all pharmacy program drug claims." Strike the word rulemaking from "H/HS at this time was still engaged in the development process regarding:"

#### p. 3 Findings:

#### Conduct a financial audit to track the funding and find where the money goes.

Response: The PBM savings lower pharmacy payments in the DHHS provider payment budgets. Drug rebates go to DHHS in full. First Health's April 7 letter reports that they have no rebate agreements, or other contractual relationships, with pharmaceutical manufacturers. See copy of letter previously provided to the Committee.

#### Rebates should go to Revenue Admin and then to DHHS.

Response: The legislature has set up a revenue account for drug rebates in SFY 04-05.

#### A quarterly PTAC report should be instituted.

Response: As required by law, the Department submitted an annual report to the oversight committee. It also provided the meeting materials, minutes and brief verbal update after each of the PTAC meetings. In addition, an interim savings report was also requested and prepared in May 2003. What additional information is being requested?

The Honorable Janeen A. Dalrymple July 31, 2003 Page 2

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

Response: The Department has supplied PTAC updates and minutes with supporting documentation. It has presented PBM program components and PBM annual reports. The Department is not aware that that there is requested information outstanding. Would it be possible to have minutes of each PBM Oversight Committee meeting prepared and remaining action items identified to prevent any confusion concerning expectations for meeting follow-up?

#### Identify the net positive gains

Response: The Department prepared for the Committee the SFY 02 Annual Report with savings. Also, in addition to the Committee's request a SFY 03 Interim Savings Report was prepared.

#### Committee Meeting Timeline:

- PTAC met on August 27, October 31, January 16 and March 27.
- The PBM Legislative Oversight Committee met on September 17, November 13, February 5, April 16 and May 14.

Thank you for the opportunity to comment on the Committee's annual report.

Sincerely,

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



## The Senate of the State of New Hampshire

107 N. Main Street, Room 302, Concord, N.H. 03301-4951

SYLVIA B. LARSEN District 15 November 13, 2003

Office 271-3076

TTY/TDD 1-800-735-2964

His Excellency, Governor Craig R. Benson 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

Re: <u>MINORITY REPORT</u> - 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

Dear Governor Benson, Senator Eaton and Representative Chandler:

In early September, you received the Annual Report of the HB 1218 legislative oversight committee, under a cover letter dated January 1, 2003. This committee oversees the Medicaid prescription benefit management (PBM) program administered by the Department of Health and Human Services. As vice-chair of the oversight committee, I expected the opportunity to review and comment on the Annual Report before it was filed. Because this did not occur, I am submitting the following *Minority Report*. I have both procedural and substantive objections to the report.

#### I - PROCEDURAL OBJECTIONS:

Report Sign Off: Because I had another meeting on September 3<sup>rd</sup> my staff person, Marlene Taylor, went to the meeting scheduled and spoke directly with Representative Dalrymple. Representative Dalrymple told her that they planned to hand out a "draft report" and that depending on what happened the next day (when the House and Senate were to be in session to vote on the budget), the report might require additional changes. Marlene offered to pick up a copy of the draft report but was assured by the secretary that she would deliver it to our office the next day. As the next meeting day was approaching, Marlene called the secretary and asked for a copy of the report. She was then told that they were mailed out yet neither I nor Senator Gatsas ever received one. On September 24<sup>th</sup> when preparing for the next meeting, we again sought a copy of the report and questioned how it turned into a "final report" that was filed. We were told that the committee voted on it on September 3<sup>rd</sup>. It is my understanding that the other two Senators on the committee did not see a draft of the report before it was filed. The result is that a majority of committee members did not review the report prior to its being "final."

**Recommendation:** In the future, I recommend that committee members be required to either sign off on an Annual Report before it is filed or signoff on their abstention.

Meeting Minutes: The "Review" section of the Annual Report consists of a summary of the meeting minutes from each of the three-committee meetings that were held in 2002. Although the meeting minutes are attached to the Annual Report, they were not always distributed to me, nor do I believe they were received by each of the other committee members. I found these minutes to be one-sided and not fully representative of what happened at the hearings. Because we did not review or approve minutes there was no opportunity for revision. This lack of balance was carried into the Annual Report.

**Recommendation:** I recommend that a legislative staff person be assigned to maintain minutes at each meeting and ensure their distribution to all committee members prior to the next meeting of the committee. This would allow any member to offer comments on the minutes at the next meeting.

Quorum: Only one meeting (September 19) had four of the six members in attendance, which is the minimum required for a quorum to transact business under House Rule 105. The August 13 and November 13 meetings had only three members present. The committee's problems with attendance have continued in 2003.

Recommendation: I believe all committee members need to give their full attention to the PBM program, given its importance in generating budget savings around Medicaid prescription drugs. If members' schedules consistently do not permit them to attend, I believe replacements need to be found.

#### *II - SUBSTANTIVE OBJECTIONS:*

Report Findings: The "Findings" section of the report lists five concerns that it says were raised by the oversight committee. These findings were not received or approved by a majority of the committee and they fail to mention the response to those concerns from the Department of Health and Human Services. A draft of the annual report was appropriately distributed to DHHS, which responded by letter dated July 31, 2003. The Department's letter responded to each of the concerns raised, but the Annual Report did not take those comments into account nor did the committee review the Department's response. Some of those comments from DHHS ranged from requests to correct simple typographic errors to a rebuttal of more egregious insinuations of deliberate Departmental falsehoods.

**Recommendation:** Departmental responses to the committee's draft findings should have been received and discussed by a quorum of members prior to drafting and submitting a final report. At the very least, the Annual Report ought to have included a copy of the agency response as an attachment to the report (copy attached).

I appreciate your consideration of these concerns and my recommendations, which I believe will clarify and strengthen the deliberations of this committee.

Sincerely,

Senator Sylvia B. Larsen

Vice-Chairman

Enclosures

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

Committee Members:

Representative Janeen A. Dalrymple, Chair Representative Rogers J. Johnson Representative Judson K. Dexter Senator Russell E. Prescott Senator Theodore L. Gatsas



# 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 27<sup>th</sup>. 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 <u>Profiting from Pain: Where Prescription Drug Dollars Go.</u> 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**

May

PTAC

August 27

September 17

October

November

December

January

February

March

June

April

<sup>\*</sup> Pharmaceutical and Therapeutics Advisory Committee (PTAC)

## ATTACHMENT A

Minutes of the Meeting HB 1218 Legislative Oversight of the Medicaid

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

TDD Access: Relay NH 1-800-735-2964



# 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

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 19<sup>th</sup> 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 19<sup>th</sup> 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 800-862-3345, 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

NH Pharmacy & Therapeutics Advisory Committee Page 2 of 2 August 16, 2002

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 Southern NH Internal Medicine Associates 44 Birch Street, Suite 300 Derry, New Hampshire 03038

Internal Medicine

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

Pediatrics

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

Family Practice

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

Psychiatry

### 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. Lakes Region General Hospital 80 Highland Street Laconia, New Hampshire 03246

Pharm. D.

#### **SUMMARY OF PUBLIC COMMENTS**

#### PTAC PUBLIC HEARING, AUGUST 26, 2002

<u>Purpose of Hearing</u>: 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.

<u>PTAC Members Present</u>: 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.

Specialis -

#### 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	<ul> <li>All brand name products that have an approved generic equivalent such as Zantac®, Tagamet® and Pepcid®</li> </ul>
	<ul> <li>All Proton Pump Inhibitors such as Prilosec®, Nexium®,</li> <li>Aciphex®, Protonix® and Prevacid® will be allowed for twelve</li> <li>(12) weeks within a lifetime before a prior authorization is required</li> </ul>
Controlled Substances	<ul> <li>All brand name products that have an approved generic equivalent such as Percocet®, Darvocet®, Tylenol® #3, Fiorinal®, MS Contin®, Vicodin®, Demerol®</li> </ul>
	All Oxycontin® products
Arthritis Medication/Non- Steroidal Anti-Inflammatory	<ul> <li>All brand name products that have an approved generic equivalent such as Motrin®, Naprosyn®, Ansaid®, Anaprox®, Relafen®, Daypro®</li> </ul>
(NSAIDs):	<ul> <li>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</li> </ul>
Erectile Dysfunction	All drugs for erectile dysfunction treatment require a prior
Treatment Medications:	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



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 Honorable Rogers Johnson September 16, 2002 Page 2

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.

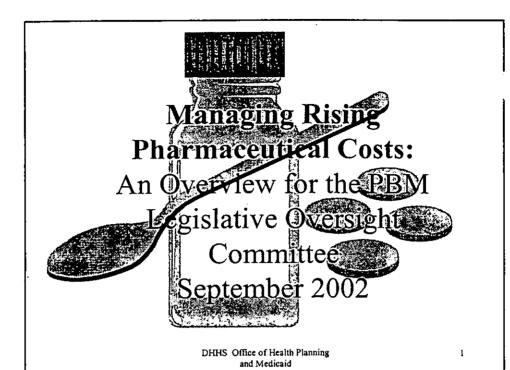
Again, thank you for your offer of assistance to provide a personal audit of the pharmacy claims. If you have any questions concerning this information, please contact me at (603) 271-8946.

Sincerely,

Janice Paterson, Esq.

in C. Fader

cc: Lori H. Real



## 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.

DHHS Office of Health Planning and Medicaid

### 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.

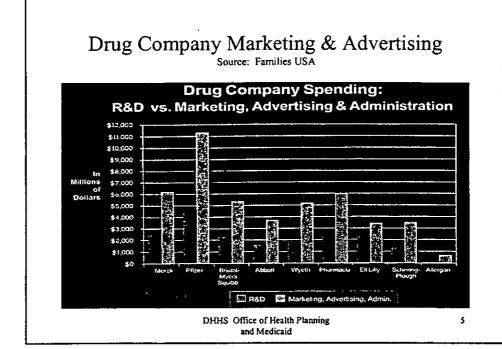
DHHS Office of Health Planning and Medicaid

3

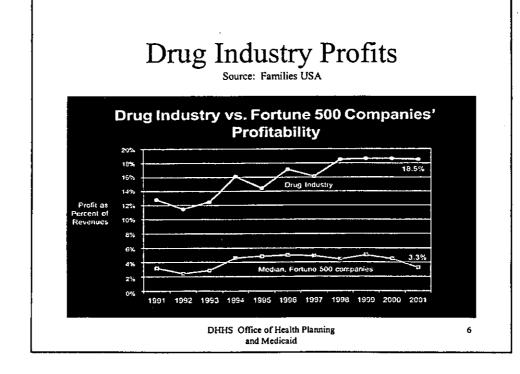
Why are pharmaceutical costs rising?

DHHS Office of Health Planning and Medicaid

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Projets 18.5 % projets
puter 527
3.37)

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

measurer dely to

DHHS Office of Health Planning and Medicaid

7

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

DHHS Office of Health Planning and Medicaid

### 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

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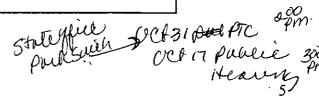
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### Pharmacy and Therapeutics Advisory Committee (PTAC) Responsibilities

- 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.

Lockin

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## 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.

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# 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

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### Improving the Quality of Care

- Prospective Drug Utilization Reviewprevents 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

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# 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

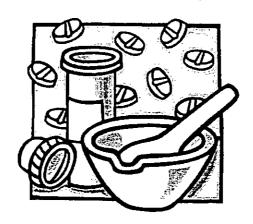
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# Questions?

- 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

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# PROPOSED CRITERIA RECOMMENDATIONS



P&T Committee August 27<sup>th</sup> 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 <sup>®</sup>	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		

<sup>\*</sup> 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.

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#### 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<sup>+</sup>/K<sup>+</sup> 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 <sup>®</sup>	Pantoprazole	20 mg, 40 mg, 40 mg/vial (IV)	

#### ALL DOSES REQUIRE AUTHORIZATION AFTER 8 WEEKS 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 <sup>®</sup>	Esomeprazole Nexium <sup>®</sup>	Lansoprazole Prevacid <sup>®</sup>	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. Stort 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 22<sup>nd</sup> 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.

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# OXYCONTIN® CRITERIA

### Pharmacology:

Oxycontin<sup>®</sup> 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	
eria for Authorization:		10 mg, 20 mg, 40 mg, 80 mg  hum your J Z mo  fullum D 2  EPT for requests for hospice patier	search of the
equests for Oxycontin® will rej	ject at the pharmacy EXCI	EPT for requests for hospice patier	its. Albert

Criteria for Authorization:

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<sup>®</sup> 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 Long Term Care:

Initial: 3 months

Follow-up: 6 months

Follow-up: 6 months

**Dispensing Limits:** 

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

### References:

- 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.

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### **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
I 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

Zemine

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.

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### **BRAND NAME NSAIDS**

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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:
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# (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

mittee Approved:
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### (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:
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## 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 <sup>®</sup>	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<sup>®</sup>)

### Fibric Acid Derivatives:

- clofibrate (Atromid-S<sup>®</sup>)
- fenofibrate (Tricor<sup>®</sup>)
- gemfibrozil (Lopid®)

### Bile Acid Sequestrants:

- > cholestyramine (Questran®)
- colestipol (Colestid®)

### Nicotinic Acid:

> nicotinic acid

Committee Review:	Reason for Review:	Date Committee Approved:
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### 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<sup>2</sup> with no risk factors OR
  - Greater than or equal to 27 kg/m<sup>2</sup> 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 comorbidity) 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	<ul> <li>Type 2 diabetes</li> <li>Established coronary heart disease</li> <li>Other atherosclerotic disease</li> <li>Sleep apnea</li> </ul>
Other risk factors	<ul> <li>Hypertension</li> <li>Dyslipidemia</li> <li>Impaired fasting glucose concentration</li> <li>Cigarette smoking</li> <li>Family history of premature heart disease</li> <li>Age (men &gt; 45 years, women &gt; 55 years or postmenopausal)</li> <li>Gynecologic abnormalities</li> <li>Osteoarthritis</li> <li>Gallstones</li> <li>Stress incontinence</li> </ul>

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.

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# ATTACHMENT B

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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.



Kathleen G. Sgambati Acting Commissioner

> Lori H. Real Director

# 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

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 19<sup>th</sup> 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 19<sup>th</sup> to review this information.

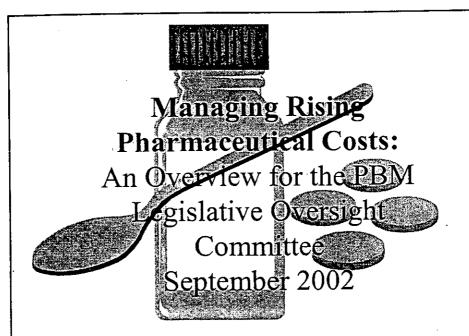
Sincerely.

Lori H. Real, M.H.A.

Director

**Enclosures** 

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



DHHS Office of Health Planning and Medicaid

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# 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.

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# Pharmacy Benefit Management Legislative Oversight Committee

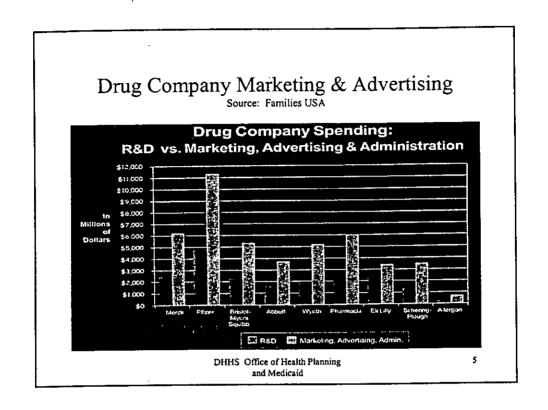
- Review Department of Health and Human Services Annual Report (due November 1st);
- 2. Review report of actions taken by the Pharmacy and Therapeutics Advisory Committee;
- 3. May request assistance of legislative budget assistant in auditing the program; and
- 4. May make recommendations for proposed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

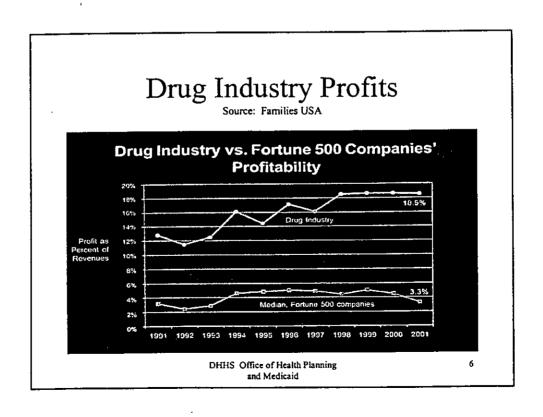
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Why are pharmaceutical costs rising?

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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

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

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## 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

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# 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.

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## 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.

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# 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

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# 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

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# 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

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# 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

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### SUMMARY OF PUBLIC COMMENTS

### PTAC PUBLIC HEARING, AUGUST 26, 2002

<u>Purpose of Hearing</u>: 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.

<u>PTAC Members Present</u>: 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

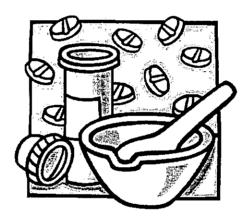
- 1. Introductions and welcome to Committee members.
- 2. Review of the prior authorization criteria for the following drugs and classes of drugs:

Therapeutic Class	Products Requiring Prior Authorization
Gastrointestinal Medications	• All brand name products that have an approved generic equivalent such as Zantac®, Tagamet® and Pepcid®
	<ul> <li>All Proton Pump Inhibitors such as Prilosec®, Nexium®,</li> <li>Aciphex®, Protonix® and Prevacid® will be allowed for twelve</li> <li>(12) weeks within a lifetime before a prior authorization is required</li> </ul>
Controlled Substances	<ul> <li>All brand name products that have an approved generic equivalent such as Percocet®, Darvocet®, Tylenol® #3, Fiorinal®, MS Contin®, Vicodin®, Demerol®</li> </ul>
	All Oxycontin® products
Arthritis Medication/Non- Steroidal Anti-Inflammatory	<ul> <li>All brand name products that have an approved generic equivalent such as Motrin®, Naprosyn®, Ansaid®, Anaprox®, Relafen®, Daypro®</li> </ul>
(NSAIDs):	<ul> <li>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</li> </ul>
Erectile Dysfunction	All drugs for erectile dysfunction treatment require a prior
Treatment Medications:	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 27<sup>th</sup> 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 <sup>®</sup>	Alprostadil (Prostaglandin E1; PGE1)	12.45mcg, 24.9mcg, 49.8mcg	6
Caverject <sup>®</sup>	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	

<sup>\*</sup> 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<sup>+</sup>/K<sup>+</sup> 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 <sup>®</sup>	Pantoprazole	20 mg, 40 mg, 40 mg/vial (IV)

### ALL DOSES REQUIRE AUTHORIZATION AFTER 8 WEEKS 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 <sup>®</sup>	Rabeprazole Aciphex <sup>®</sup>	Pantoprazole Protonix <sup>®</sup>
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)	<del>-</del>
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 22<sup>nd</sup> 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:
Phonon & Thomas C.		
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 <sup>®</sup>	Oxycodone	10 mg, 20 mg, 40 mg, 80 mg

### Criteria for Authorization:

All requests for Oxycontin<sup>®</sup> 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<sup>®</sup> 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

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.

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### **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 <sup>®</sup>	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		
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### (MULTI-SOURCE BRAND NAME) NARCOTICS

Criteria	For.	Aut	hor:	izati	on:

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		
Tharmacy & 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 (Pravachoi®)
- simvastatin (Zocor®)

#### Fibric Acid Derivatives:

- clofibrate (Atromid-S<sup>®</sup>)
- > fenofibrate (Tricor®)
- gemfibrozil (Lopid<sup>®</sup>)

#### 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<sup>2</sup> with no risk factors OR
  - Greater than or equal to 27 kg/m<sup>2</sup> with at least 1 very high risk factor OR at least 2 other risk factors (See Table 1)

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:

- On-going prescriber documentation of adherence to a low calorie diet AND a
  regimen of increased physical activity (unless medically contraindicated by comorbidity) 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	<ul><li>Type 2 diabetes</li><li>Established coronary heart disease</li></ul>	
	Other atherosclerotic disease	
	Sleep apnea	
	Hypertension	
	Dyslipidemia	
	Impaired fasting glucose concentration	
0.1	Cigarette smoking	
Other risk factors	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		



#### Kathleen G. Sgambati Acting Commissioner

# 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

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<sup>3</sup>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

NH Pharmacy & Therapeutics Advisory Committee Page 2 of 2 August 16, 2002

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 Southern NH Internal Medicine Associates 44 Birch Street, Suite 300 Derry, New Hampshire 03038 Internal Medicine

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

Pediatrics

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

Family Practice

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

Psychiatry

### 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. Lakes Region General Hospital 80 Highland Street Laconia, New Hampshire 03246

Pharm. D.

### ATTACHMENT C

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

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.

The Honorable Janeen Dalrymple November 1, 2002 Page 2

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 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.

Department of Health and Human Services Medicaid Pharmacy Benefit Management SFY 02 Annual Report

### **Prior Authorization Volume**

3Prior Authorization	Total Claims	MotalPAIRequests	PA as % of Claims
11/01-6/02	2,509,037	7,485	. 0.30%

### First Health Key Performance Indicators

e alndicator de la	Measure Measure	Actual Results	Notes 1
Call Center Wait	95% of calls	100% of calls	*Start Up Phase:
Time	answered within	answered within	43 seconds
	30 seconds	31 seconds	·
			Operational:
			24 seconds
Call Center	3% or less	3.61%	*Start Up Phase:
Abandoned			4.73%
Call Rate			
			Operational: 2.24%
Claims Processing	98%	99.8%	
Financial Accuracy		•	
Claims Processing	< 2 times per	8 times	
System Downtime	contract year		
		Average duration	
	< 24 hour duration	per episode: 1.9	
		hours	
Rebate Reporting &	Within 30 days of	100% within 30	
Payment	Receipt	days	
Prior Authorization	100% within	100% within	_
Processing	24 hours	24 hours	

<sup>\*</sup> Start Up Phase includes the initial implementation period of November 2001 through January 2002.

Department of Health and Human Services Medicaid Pharmacy Benefit Management SFY 02 Annual Report

### 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.

Pharmacy and Therapeutics Advisory Committee, August 27, 2002 Page 3 of 3

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.

### (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

Pharmacy and Therapeutics Advisory Committee, August 27, 2002 Page 4 of 4

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

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

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.

Pharmacy and Therapeutics Advisory Committee, August 27, 2002 Page 5 of 5

Motion: A motion was made to accept the proposed criteria with the recommendation to change the point value for concomitant or all corticosteroids from one to two and with "chronic" being added, and to include the PTAC suggestions of adding history of pepticulcer at two points, chronic renal disease at two points, and history of dyspepsia at one point.

### (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: 19.49. Oppose: 10.49. Abstain: 1.49.

### (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 Coppose 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 Additional 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

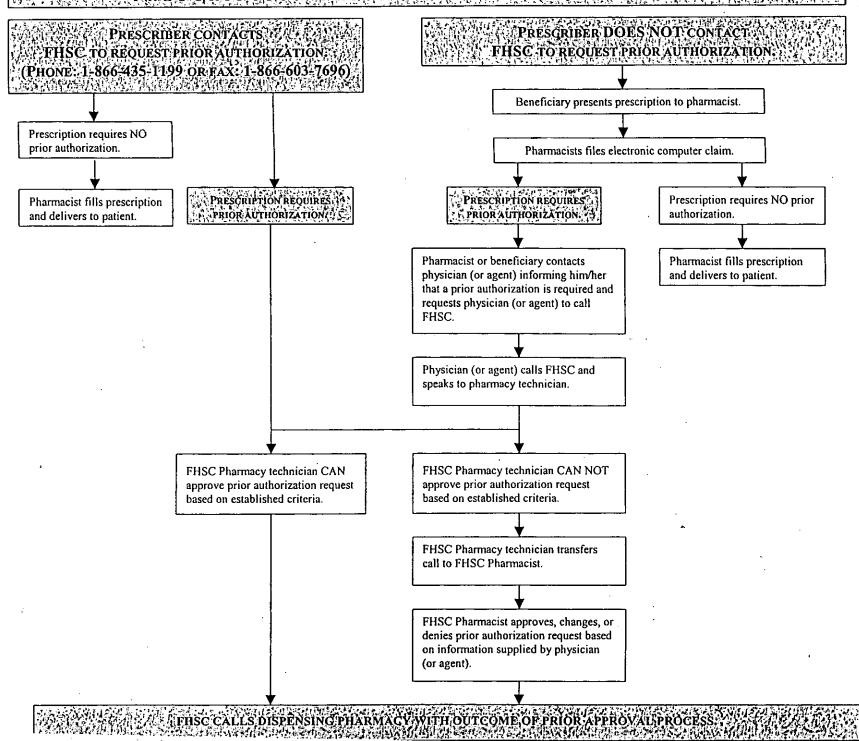
(603) 271-4419 or 4210

Formal Appeal:

Administrative Appeals Unit

1-800-852-3345, ext 4292 (in state only)

or (603) 271-4292



# Committee Report

### STATE OF NEW HAMPSHIRE

### **SENATE**

### REPORT OF THE COMMITTEE

· Date:

THE COMMITTEE ON Executive Departments and Administration to which was referred House Bill 1218

AN ACT

relative to the regulation of pharmacists and prescription drug orders.

VOTE: 5-0

AMENDMENT # 2002-3389s

Having considered the same, report the same with the following amendment and recommend that the bill: AS AMENDED OUGHT TO PASS.

Senator Russell E. Prescott For the Committee <u>Home</u>

Bill Status◆

Members ◆

Calendars/Journals ◆

Miscellaneous •

### |HB1218 Docket

Next|Prev|Results List|Main|Bill Status

Bill Title: (New Title) 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.

<b>Date</b>	Body	<b>Description</b>
6/26/2001	H	Introduced and ref to Exec Depts & Admin; HJ78, p1994
12/14/2001	H	Copy to Chairman on 12/18/2001 Report due on 2/21/2002
12/14/2001	H	Hearing Feb 5 10:00 RM100, State House
2/12/2002	H	Subcom Work Session Feb 20 9:00 RM105-A,St House
2/20/2002	H	Maj Report OTP for Mar 6 (vote 14-0;CC)
3/6/2002	H	Passed; HJ25, p956 + 1036
3/14/2002	S	Introduced and Ref. to Executive Departments & Administration; SJ 7, Pg.198
3/22/2002	S	Hearing; === CANCELLED === April 3, 2002, Room 104, LOB, 1:45 p.m.; SC18
3/29/2002	S	Hearing; === CANCELLED === April 17, 2002, Room 104, LOB, 1:15 p.m.; SC20A
4/2/2002	S	Hearing; === RESCHEDULED === April 9, 2002, Room 103, LOB, 8:30 a.m.; SC21
4/9/2002	S	Hearing; === RECESSED === RECONVENE === April 17, 2002, Room 104, LOB, 1:30 p.m.
4/10/2002	S	Committee Report; Ought to Pass with Amendment {3389}, (New Title) [04/11/02]
4/11/2002	$\mathbf{S}$	Ought to Pass with Amendment (3389), (New Title); [Not Voted On]
4/11/2002	S	Sen. Prescott Moved Laid On Table, MA, VV
4/16/2002	S	Sen. Hollingworth Served Notice Of Reconsideration; SJ 11, Pg.351
4/18/2002	S	Sen. Hollingworth Remove From Table, MA, VV; SJ 12, Pg.417
4/18/2002	S	Ought to Pass with Amendment {3389}, AF; SJ 12, Pg.417
4/18/2002	S	Ought to Pass, MA, VV; SJ 12, Pg.417
4/18/2002	S	Sen. Francoeur Floor Amendment {3615},(New Title), AA, VV; SJ 12, Pg.417-419
4/18/2002	$\mathbf{S}$	OT3rdg; RC 23y - 0n, MA; SJ 12, Pg.419
4/25/2002	H	House Conc with Sen Am, Rep Peterson MA VV;

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**Docket Abbreviations**