



Business Coalition Development: Impact on Legislation & Public Policy

Pfizer, Inc.

Michigan Office of State Government Relations

*University of Tennessee
College Scholars Senior Project*



Hannah Kiser

May 1, 2002

Business Coalition Development:
Impact on Public Policy and Legislation

Executive Summary

My responsibilities as an intern with Pfizer, Inc.'s Michigan Office of State Government Relations focused on the development of public policy partnerships with numerous organizations including voluntary health associations and senior centers throughout the state of Michigan beginning January 1, 2002 and continuing until April 19, 2002.

Initially, I met with representatives of these groups and others, such as the NAACP and AARP, in order to raise the public's awareness of problematic changes to the pharmaceutical benefits provided by the state of Michigan to Medicaid 'fee-for-service' recipients and the beneficiaries of other state sponsored health care programs. For this purpose, I organized an informational meeting at which the attendees were informed of the adverse changes to Medicaid and the Elder Prescription Insurance Coverage programs, followed by a presentation on the innovative Pfizer Share Card, which extends prescription assistance to seniors who are enrolled in Medicare, lack a prescription drug benefit and meet specified income guidelines. I subsequently authored regular communication updates for the meeting attendees on Medicaid and Medicare related issues, as I continued to meet with additional patient advocacy groups. I was charged with the responsibility of extending invitations to serve on the Board of Directors for the newly incorporated Senior Citizens for Prescription Drug Fairness to representatives of the Visiting Physician's Association, NAACP, Epilepsy Foundation, Michigan Association of Senior Centers and Health Care Partners, and communication was facilitated through meetings, conference calls and email.

As changes to the prior authorization program that adversely affected many Medicaid recipients were implemented by the state of Michigan, a campaign strategy to defeat the initiative was developed, and I served as an information resource both internally and for the coalition members and various consulting firms. The campaign evolved into a support strategy for alternative legislation providing the state of Michigan with a new revenue source through the extension of Medicaid "best price" rebates to all state run health care programs by pharmaceutical manufacturers. The members of the coalition consequently became lead contacts in informational breakfasts and luncheons with key members of the House Appropriations committee.

Throughout my internship at Pfizer, I have learned that relationships between organizations with common interests are invaluable, and by leveraging such synergies, public policy can ultimately be influenced. The collaborative efforts of organizations involved with the campaign against prior authorization are currently being capitalized upon, and through this coalition, the changes implemented by the state of Michigan could be reversed and/or modified through legislation. My employment with Pfizer, Inc. has provided exposure to the reality of corporate initiatives with respect to influencing public policy through legislation. This experience has allowed me to complete numerous challenging tasks while enhancing various skills and abilities.

College Scholars Senior Project Preliminary Report

Hannah M. Kiser

January 9, 2002

The purpose of this communication is to inform you of my responsibilities and activities to date in my internship with Pfizer, Inc. All information transmitted is considered proprietary and confidential.

Background:

The State of Michigan is currently experiencing a fiscal crisis, as are many other states. In response to the current conditions of the state's finances, certain changes to programs have been proposed. The Michigan Department of Community Health has proposed a much more restricted formulary for those recipients of the Elder Prescription Insurance Coverage program as well as those Medicaid recipients who are in the "fee for service" category.

Under the current programs, doctors simply prescribe the drug that best suits the patient's need. In an effort to resolve a shortfall in the state Medicaid budget, physicians will now be required by law to obtain what is referred to as "prior authorization" before prescribing any drug not listed on the unrestricted Medicaid formulary. In order to obtain prior authorization, the physician must place a call to and receive approval from First Health, a pharmacy benefit manager in Virginia, a process estimated to take ten minutes per prescription on average. Due to the extremely limited unrestricted Medicaid formulary, many drugs now commonly prescribed to patients, such as Celebrex, Lipitor, Geodon, Zolof, and Aricept, are to be placed on prior authorization. This will most likely result in the patient being switched from a drug they are currently taking to another, possibly less effective treatment with an increased number of side effects. It is also expected that some physicians will discontinue the treatment of Medicaid and EPIC recipients due to the undue burden that this procedure places on them.

It is imperative for those individuals who will be affected by these changes in pharmaceutical availability to be aware of these developments, and the assistance of Voluntary Health Associations is being requested in order to ensure that this is carried out in the most efficient and effective manner. The best interests of patients and adequate patient care can best be protected through collaboration in order to communicate the impact of this policy on Michigan's most vulnerable citizens, the less fortunate and the elderly. The damage to patient care and physician participation promises to be monumental without the response of those who stand to lose the most.

The Pharmaceutical Research and Manufacturer's of America (PhRMA) sued the state of Michigan on the grounds that the process by which the prior authorization process was implemented was unconstitutional. Several Mental Health advocacy groups have also filed suit in this case due to the irreparable harm that this program would cause their constituents.

Developments:

On Monday, January 7, 2002, a hearing was held on the motion for preliminary injunction brought by PhRMA. The judge ruled in favor of the pharmaceutical and mental health plaintiffs and issued an injunction. The Attorney General's motion for stay pending appeal was denied, and the language of the order for injunctive relief is currently being worked out between the opposing sides. The Attorney General is expected to file an emergency appeal in the near future.

Responsibilities:

My role in the Michigan Medicaid formulary response is that of a liaison between the voluntary health organizations of the state and Pfizer. Over the past week, in addition to becoming familiar with the formulary issue, I have contacted approximately 28 VHA's to schedule briefings on this issue. Briefing materials for these meetings have been drafted and submitted for approval.

I began meeting with these groups on Tuesday, January 8, 2002 and have completed appointments in the Lansing and Metro-Detroit areas. The response from the associations has varied depending on the level that their particular patient bases are affected by the formulary changes.

Expectations:

If the committee deems it appropriate, I will report on a weekly basis throughout the duration of the internship and in person when possible. The internship is expected to last for sixteen weeks ending on April 19, 2002.

Committee Members and Contact Information:

Dr. Harold Black (Chair)	Phone: 974-1721	Email: hblack@utk.edu
	Fax: 974-1715	
Dr. David Tandy	Phone: 974-7705	Email: dtandy@utk.edu
	Fax: 974-7173	
Dr. Bob Cunningham	Phone: 974-7050	Email: rcunning@utk.edu

Contact Information:

Hannah Kiser
Pfizer, Office of State Government Relations
209 North Walnut, Suite C
Lansing, MI 48933
(517) 485-8301
Email: hannah.kiser@pfizer.com
hmkiser@utk.edu

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: January 21, 2002

RE: College Scholars Senior Project Report

Report

Over the past week, I have contacted forty-one voluntary health agencies, as well as the NAACP and AARP, in order to set up briefing appointments on the proposed changes to the Medicaid and Elder Prescription Insurance Coverage program [EPIC] formularies in Michigan. The response from the associations has varied; however, most have been very receptive. Some agencies have already taken a proactive approach to ensure quality patient care for their constituencies by informing government representatives and local media of the eminent adverse impact on Medicaid recipients and plan to continue to increase awareness among their populations. Still others are cognizant of the policy directive, but have not yet taken a position. A small minority of organizations has determined that they would be relatively unaffected by the possible change in policy and thus, are not planning to address the issue. This communication contains a synopsis of the ten group meetings that have taken place thus far in Detroit, Lansing and Kalamazoo.

In meeting with the American Cancer Society, the Director of State Government Relations made me aware of Michigan Partners for Patient Advocacy group. This loose coalition of voluntary health organizations aims to ensure and protect the quality of patient care in Michigan and has kept member groups, of which there are approximately 60, informed of the developments with respect to the proposed changes. This group requires consensus in order to take a collective stance on any given issue, but has authorized any member organization to react to the policy, as they deem appropriate.

The Mental Health Association has already responded by filing as an intervenor in the Pharmaceutical Research and Manufacturers of America v. Michigan Department of Community Health lawsuit. This group would be impacted, arguably more than any other would due to the specific nature of mental health drugs. The affidavits filed by two mental health patients indicate that any change to the treatment regimen they are now utilizing would be disastrous due to a decrease in the quality of life they now experience. The restrictive formulary advocated by the Michigan Department of Community Health would equate to catastrophe for these Medicaid recipients.

The Chronic Illness Awareness Coalition, although unable to lobby collectively, is aware of the issue at hand, and will communicate to member organizations that information on the formulary can be obtained from the Pfizer Office of State Government Relations. The Director of the Coalition is directly affected by this policy and provided a copy of their directory for further assistance. Although the Department of Community Health has indicated that any drugs not listed on the proposed changes list will be available without restriction, she is wary of these promises and wants to be kept up to date on all developments.

Paralyzed Veterans of America are not directly affected by the policy changes due to the fact that most of their population has military health benefits. They have, however, proved an invaluable resource by recommending other disability groups who have significant Medicaid recipient populations. I also participated in a briefing of the Michigan Association of Centers for Independent Living in order to make the disability agencies present aware of the situation and put them in contact with Pfizer.

The American Lung Association indicated that some physicians have voiced concern over the lack of choice in asthma treatments. They have not been proactive in advocating a position, but would be interested in meeting with other voluntary health agencies to discuss the problem and assist in suggesting solutions. The Director would also like to be kept abreast of any developments.

The Huntington's Disease Society was familiar with the Medicaid problem due to their participation in the Michigan Partners for Patient Advocacy. Personal experience with the disease led the President of the Society to be strongly opposed to the prior authorization process. Those suffering from Huntington's disease must have access to different medications as soon as possible due to the dynamic nature of this ailment, and the drug that may have worked in the past can become ineffective without warning. This group can be expected to be active in combating the prior authorization process.

The Leukemia Society of America was extremely involved in the initial reaction to the proposed changes and was very receptive to initiating a grassroots campaign effort. They provided a list of their most utilized medications and requested notification of the status of each, as well as, referrals to social workers and Gilda's Club, a non-profit home for individuals being treated for leukemia who are unable to afford overnight accommodations in the metro-Detroit area. The President is also going to brief the contact person on the West side of the state.

The Epilepsy Foundation of America activated their grassroots network in the initial fight against the formulary changes and is willing to do so again. Epilepsy drugs are similar to those in the mental health category in the sense that the treatment is very individual specific. Dilantin, one of the best in class anti-epileptic prescription drugs, is on prior authorization, which would without a doubt prove detrimental to the treatment of epileptics on Medicaid or the Elder Prescription Insurance Coverage program. While seizures can often be treated by other means, these alternative prescriptions may not prevent them as well as Dilantin does. This group was interested in the possibility of an open forum for agencies opposed to the restrictive formulary and offered to help with the organization of such an effort.

The American Liver Foundation was unaware of the proposed changes to the formulary, and while not affected quite as heavily as the other organizations, was not opposed publicizing the issue. The group was encouraged to promote letter writing by those who would be affected.

The Alzheimer's Association understood the magnitude of the issue and is willing to engage in a letter writing campaign. The most well-known prescription medication for Alzheimer's did not

require prior authorization; however, Aricept and another treatment are restricted. As was the case with mental health and epileptic medications, these treatments are very patient-specific, and restrictions as to necessary treatment would have an extremely negative effect on those suffering from this disease.

In addition, a meeting with the Michigan Association of Senior Centers has taken place and further contact and interaction with this pivotal group is anticipated. The Elder Prescription Insurance Coverage program is reported to have had minor glitches in coverage, but it is expected that prior authorization could completely incapacitate the program's ability to serve seniors effectively.

Summary

It is apparent that the voluntary health agencies are opposed to the implementation of a restricted formulary for Medicaid patients. Many of those whom I met with indicated that they understand the importance of fiscal responsibility, but were strongly opposed to the act of "balancing the budget on the backs of the most needy citizens." These individuals have more than enough difficulty accessing the health care system without the additional burden of this policy. There is also evidence that indicates that decreasing prescription coverage leads to increases in hospitalization and nursing home costs to the state. [See Print Media] To decrease pharmaceutical offerings would upset the delicate equilibrium of Medicaid fee for service recipients statewide, which constitutes irreparable harm as the Ingham County district court judge so clearly elucidated at the preliminary injunction hearing.

Developments

A three-judge panel of the Michigan Court of Appeals has ruled that the stay issued by the Ingham County district court is to be reconsidered after a hearing on the merits of the case. While this was not the ideal turn of events for the pharmaceutical companies or the patient advocacy groups, the outcome could go either way at the appeals level.

Meanwhile, Pfizer is preparing the sales force to deal with this issue by formulating the necessary forms to obtain prior authorization from the pharmacy benefit manager, should this process be implemented.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: January 28, 2002

RE: College Scholars Senior Project Report

Report

I have continued to contact voluntary health associations and other groups with a vested interest in the Michigan Medicaid issue. In addition, the Manager of Pfizer Civic Affairs, an office within the Corporate Affairs division located at corporate headquarters, was brought in for the purpose of giving me additional training in the method of mobilizing patient advocacy groups. Her insight was especially helpful, and I was able to learn several new techniques for engaging individuals who manage voluntary health associations. This process, which is more commonly referred to as alliance development, is an area of expertise that is currently under development; Pfizer has implemented this strategy on a national level over the past few years. Other groups such as the Pharmaceutical Research and Manufacturer's of America are also following this strategy as means of stimulating organizations to respond to issues which adversely affect them. The following is a brief synopsis of the meetings that I have had in the past week.

The American Heart Association is a part of Michigan Partners for Patient Advocacy. This group has experienced major cuts in state program funds and is looking for innovative ways to partner with other organizations in order to continue their assistance of those with heart disease and other heart-related conditions. They have been in contact with the sales force, but have yet to enact any programs. They have formed a coalition with the American College of Cardiologists on the state level, and this effort resulted in written statement expressing the College's displeasure with the proposed formulary changes. Although not affected greatly by the change to the Medicaid formulary, the group is concerned due to implementation of these same limitations on the EPIC program (Elder Prescription Insurance Coverage). The Heart Association seemed open to the possibility of being a more vocal advocate of patients' rights as a result of the EPIC changes.

The legislative director of the Arthritis Foundation informed me of their legislative priority to educate legislators as to the threat of arthritis at any age. The organization is currently developing a patient advocacy program which is intended to train individuals suffering from arthritis to speak with their legislator with the hopes of increasing funding for arthritis treatment and cure research. The director intends to attend the forum for voluntary health associations and senior centers, and she was in agreement about imminent adverse impact on patient care in the state. This group partnered with the Michigan Department of Community Health on a publication entitled the "Michigan Arthritis Action Plan," but the extent to which they are involved with the Department has yet to be determined.

American Autoimmune Related Diseases is an organization with a federally focused agenda. Recently, they were influential in advocating a \$420 million dollar legislative program within the Children's Health Act, which is designed to further Autoimmune disease research. Federal issues of this magnitude coupled with the rather small staff make it difficult for the group to be heavily involved in state issues. The organization has however, signed onto a statement opposing the proposed changes to the Medicaid and EPIC formularies, and they are also open to informing their population of the policy through direct mail. The director will be unable to attend the meeting, but would be interested in hearing the outcome.

In addition to these meetings, I have assisted with the preparation of a PowerPoint presentation summarizing the issues Pfizer is facing in Michigan for presentation to a national audience. [See attached.] This presentation explains the process of prior authorization, as well as, the effect that such a policy could have on the company's profit margin. The implications of this policy are not limited to the state of Michigan, as other states could follow this directive if implemented, which would result in a blow to the research and development industry. Without the input of those who stand to lose the most, any attempts made to defeat this policy by a pharmaceutical firm will be viewed as self-serving. Therefore, the input of all affected by this policy is imperative to a successful rebuttal of the proposed changes, and those in political office must be aware of the political magnitude of this decision.

Summary

The groups I have met with have all been in agreement that the proposed policy has a negative impact on patient care. Most of the groups are very concerned and have already been involved in a public response and are interested in a collaborative effort to prevent this from going into effect. It has been a learning experience to work with so many different individuals with such varied degrees of expertise and unique approaches. The job of developing relationships with such interesting people has been exciting, and I look forward to continuing to meet and interact with a variety of personalities marked by unique senses of purpose.

Developments

Pfizer also announced the Pfizer Share Card which allows Medicare recipients to purchase Pfizer prescriptions at the cost of \$15 per 30 day supply upon meeting minimal income qualifications. The program has no limits and is targeted at the 7 million Medicare recipients who currently have no prescription coverage. The voluntary health associations are pleased to hear that Pfizer is taking a stand and providing much needed assistance to this group of people.

As suggested by the senior campaign consultant, a meeting of all voluntary health associations who wish to participate has been scheduled for February 5, 2002. This meeting will allow those groups who have not yet been briefed regarding this issue to be brought up to speed, as well as refresh those organizations that are aware of the current situation. The goal of the meeting is to promote a collaborative effort between these organizations so that legislators and other public officials will become aware of the negative impact of this restrictive policy.

The changes to the Medicaid pharmaceutical policy are scheduled to take effect on February 1, 2002; however, there are indications that the pharmacy benefit manager may be unprepared to begin the provision of the services necessary to run the program. The Pharmaceutical Research and Manufacturer's lawsuit is still to be heard at the Court of Appeals, at which time the constitutionality of the policy will be determined.

Michigan Medicaid Issue

January 29, 2002



MBPPI

- "The MDCH will spend over \$1 billion this fiscal year in pharmaceutical costs, with costs rising 98% since 1999 for the fee-for-service population."
- "Without this initiative our current fiscal year budget would have to be reduced an additional \$42 million."



Michigan Pharmaceutical Best Practices Initiative

- James Haveman, *Michigan Department of Community Health:*

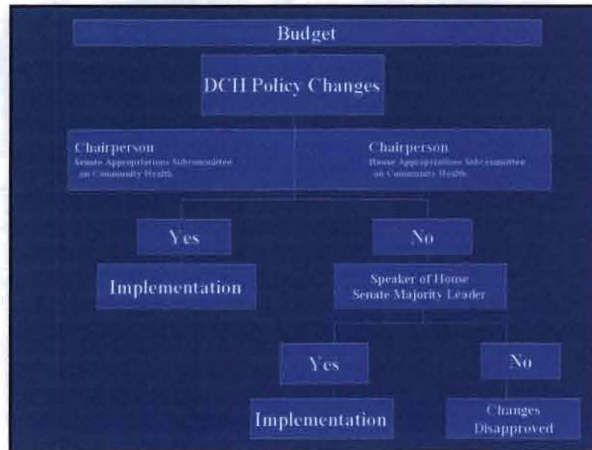
"Through the MPBPI, Medicaid beneficiaries will receive the best drugs available and Michigan taxpayers will not have to shoulder the entire burden of rising drug costs."



2001-2002 Budget

Section 2204:

- No later than September 30, 2001
- Changes to pharmacy policies for Medicaid "fee-for-service"
- Composite of pharmacy best practices by HMO's



Non Medicaid Population

• EPIC Elder Prescription Insurance Coverage	35,000 recipients
• State Medical Program	45,000 recipients
• CSICS Children's Special Health Care Services	25,000 recipients
• Mental Health Programs	200,000 recipients
• Refugees of Other Nations	10,000 recipients

Affected Medicaid Population

- 350,000-400,000 "fee-for-service" recipients



MI Medicaid Policy Changes



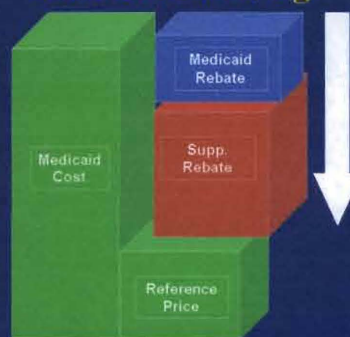
- Michigan Pharmacy & Therapeutic Committee
 - 11 members
 - First Health Services
 - 40 drug classes

Criteria For Expansion of Prior Authorization

- Drugs in a therapeutic class
 - Minimal clinical differences
 - Same or similar drug actions
 - Same or similar drug outcomes
 - Multiple effective generics available



Reference Pricing



Anti-depressant Drug Class

- Unrestricted SSRI's
 - Fluoxetine
 - Paxil



- Prior-authorized
 - Celexa
 - Luvox
 - Prozac
 - Zoloft

Pfizer "Book Of Business"

• Unrestricted

- Norvasc
- Zithromax
- Viracept
- Femlert
- Neurontin
- Celebrex (over 60)

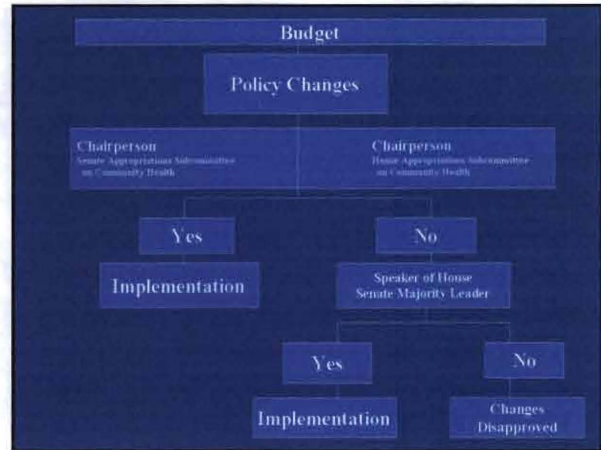
• Prior-authorized

- Aricept
- Diflucan
- Glucostrol/Glucostrol XL
- Geodon
- Lipitor
- Procardia/Procardia XL
- Viagra
- Zoloft
- Zyrtec
- Celebrex (under 60)

PhRMA Lawsuit

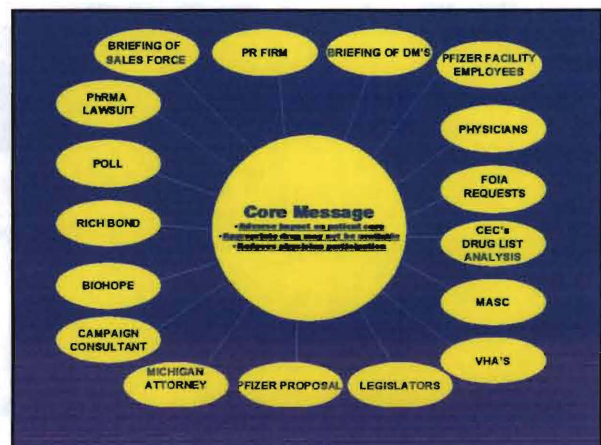


- Lack of statutory authority
 - Basic & supplemental rebates prior authorization in non-Medicaid programs
 - Supplemental rebates in Medicaid programs



Violation of Separation of Powers-MI Constitution

- Delegation to 4 members of the legislature (instead of the entire legislature) the right to approve/disapprove action by a state agency is prohibited



**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: February 4, 2002

RE: College Scholars Senior Project Report

Report

Over the past week, I have primarily focused on preparing for the meeting of voluntary health associations and senior centers, which will take place on Tuesday, February 5, 2002. The goal of this meeting is to brief the associations on the Pfizer Share Card and inform them of the changes to the Medicaid formulary. We hope to then gather feedback on ways that the groups can collaborate in order to change the proposed policy through grassroots advocacy. At the present time, we expect approximately 15 voluntary health associations to be represented, in addition to a number of senior center representatives.

In addition, I also met with the president of the Immune Deficiency Foundation of Michigan. Their population has a large number of Medicaid recipients, and they were very concerned with the changes, which were to be effective on February 1, 2002. The group has an interesting history of grassroots advocacy on a national level, as they recently battled Disney on the release of a movie entitled "Bubble Boy," which depicted a child with immune deficiency disorder in what was considered a romantic comedy. The group, although unsuccessful in preventing the release of the film, strove to educate the public about the gravity of the disease. While they have not yet been involved with the issue of the Medicaid formulary and are required to submit such proposals to their national affiliate prior to taking action, they were extremely open to weighing in on the issue due to the negative impact on their constituency.

One of the voluntary health association leaders with whom I had previously met contacted me early on the morning of February 1, 2002 to inform me that she had received a letter notifying her of the changes to Medicaid offerings on January 31. The

letter from the Director of Medicaid was dated “January 2002” and vaguely indicated that there would be changes to Medicaid pharmaceutical benefits in order to ensure the ongoing provision of coverage by the state. She indicated that had we not met to discuss the issue, she would not have realized the extent of the changes in pharmaceutical availability or the new procedural requirements. She voiced grave concern for Medicaid recipients, of which there are estimated to be 350,000 to 400,000 in the Medicaid “fee-for-service” population, due to the vague nature and poor timing of the letter. I was able to provide her with contact information for her state legislators, as well as the chairs of the Community Health subcommittee chairs in the Senate and House, so that she could voice her displeasure with the policy changes and the unacceptable manner in which the recipients were notified. She was very clear in articulating her concern that this policy change could have life and death implications for recipients in her organization’s population.

I am looking forward to the meeting of the voluntary health associations, because there has not yet been an organized open forum for the communication of specific concerns about this policy initiative. Due to the circumvention of the legislative process in the implementation of this policy, public response on the issue was never considered, and the changes were never submitted to the legislature as a whole. The individuals planning to attend include mental health advocates, AIDS representatives, as well as representatives organizations such as the Epilepsy Foundation, who represent segments of the population impacted significantly by changes in the availability of prescriptive treatments.

Summary

Up to this point, I have contacted approximately sixty voluntary health organizations in order to notify them of the changes to the formulary. Some have already weighed in on this issue, and those I have met with have voiced serious concerns regarding the effect this change will most likely have on the Medicaid and other affected populations. The inefficiency of the Medicaid agency has been alarming, and when questioned Friday on the schedule of implementation for the formulary changes, one Medicaid employee confessed, “It’s just one big mess.” It is unfortunate that the state has chosen to

haphazardly enact changes at the expense of Medicaid recipients, and it seems that the Medicaid agency is only beginning to comprehend the “mess” that has been created.

Developments

The formulary was scheduled to go into effect on Friday, February 1, but it seems that the Department of Community Health is not prepared to implement the proposed changes. In print media, one spokesperson for the Department of Community Health reported that the formulary changes would be effective as of February 1, but would not be enforced “for a few weeks”. In fact, changes to the list of drugs requiring prior authorization were evident on the morning of February 1, when Lipitor and possibly others were unexpectedly changed to unrestricted status. It is apparent that the policy changes were not thoughtfully considered, and now that the time has come to implement the proposal, neither the State nor the pharmacy benefit manager is prepared to enforce the changes.

There is also a meeting scheduled for Monday, February 4, which will allow consumer advocates and providers to voice input on the Governor’s expansion of Medicaid coverage to an additional 200,000 recipients through a broad waiver. The groups will be asked to comment on the eligibility, benefits and budgeting aspects of the expansion proposal. Several of the advocates with whom I have networked are planning to attend because they are concerned that the expansion will be employed at the expense of the existing beneficiaries, namely their constituents.

Also included with this report are materials prepared for the meeting of voluntary health organizations and senior centers to be held on Tuesday, February 5, 2002 such as Medicaid Health Alert and form letters directed toward legislative officials.

[Date]

The Honorable **[Full Name]**
State Representative
State Capitol
P.O. Box 30014
Lansing, MI 48909-7514

Dear Representative **[Last Name]**:

I am writing to inform you of my objections to the proposed changes in the Elder Prescription Insurance Coverage program. This program was established to “enhance access” to pharmaceutical medications for low-income senior citizens of the state of Michigan. The proposed changes to the program will not only restrict access to prescription medication, but could also prompt physicians to discontinue the treatment of EPIC recipients due to the undue bureaucratic burden placed on them through the prior authorization requirements and restricted formulary.

The physician should be the one to determine the best treatment for the patient if adequate patient care is to be achieved, and heightened prior authorization requirements will not only circumvent physician expertise but also simultaneously erode patient care. A healthcare operative in Virginia is not properly equipped to determine the appropriate prescription for the Michigan citizen.

The EPIC program is in place for the purpose of helping the senior citizens of Michigan with life sustaining prescription costs, and I assert that if seniors are forced to discontinue the use of medications which have currently stabilized their conditions and switch to other forms of treatment which may be less effective and cause additional side effects, the result will be disastrous. This group of citizens has contributed to the state of Michigan over the years, and it is an outrage to decrease the prescription benefits provided to these individuals.

*[I am currently taking _____, which is expected to be placed on prior authorization if the changes to EPIC are implemented.] I am very concerned for my own well being and the well being of the seniors of Michigan; I urge you to do whatever is necessary to ensure that these changes are reconsidered in a manner that would be advantageous for the seniors of Michigan.

Sincerely,

[Your Name & Address]

[Date]

The Honorable [Full Name]
State Representative
State Capitol
P.O. Box 30014
Lansing, MI 48909-7514

Dear Representative [Last Name]:

I am writing to express my strong opposition to the implementation of increased prior authorization procedures in Michigan's Medicaid and Elder Prescription Insurance Coverage (EPIC) programs. It is wrong to remedy budget shortfalls by making appropriate treatments less accessible to Michigan's most vulnerable citizens, the less fortunate and the elderly. Furthermore, this process strips the physician of the ability to prescribe the most appropriate medication by limiting access through a restricted formulary or alternately, requiring approval from an out of state pharmacy benefit manager with no knowledge of the patient's needs.

The Michigan Department of Community Health's mission statement reads as follows:

1. to promote access to the broadest possible range of quality services and supports
2. to take steps to prevent disease, promote wellness and improve the quality of life
3. to strive for the delivery of those services and supports in a fiscally prudent manner

Clearly, the limitation of pharmaceutical availability through prior authorization requirements and a restricted formulary directly oppose the goal of promoting access to the broadest range of quality services and supports, while forcing patients currently stabilized on medications to alter their treatment contradicts the promotion of wellness and the improvement of the quality of life. It is therefore impossible to deliver the aforementioned services and supports, defeating the goal of doing so in a fiscally prudent manner. Increases in prior authorization requirements and restricted formularies are clearly contradictory to the mission of the Michigan Department of Community Health.

It is the duty of elected representatives to uphold the principles of equality and democracy by ensuring that the well being of their constituency is protected. The proposed changes to the Medicaid/EPIC formulary violate the very purpose of the Michigan Department of Community Health and in doing so, endanger the well being of the Medicaid/EPIC recipients. It is my hope that you will hold the Michigan Department of Community Health to its mission by ensuring that the proposed changes are reconsidered, and thereby protect the well being of the citizens of the state of Michigan.

Sincerely,

[Your Name & Address]

[Date]

The Honorable **[Full Name]**
State Senator
State Capitol
P.O. Box 30036
Lansing, MI 48909-7536

Dear Senator **[Last Name]**:

I am writing to inform you of my objections to the proposed changes in the Elder Prescription Insurance Coverage program. This program was established to “enhance access” to pharmaceutical medications for low-income senior citizens of the state of Michigan. The proposed changes to the program will not only restrict access to prescription medication, but could also prompt physicians to discontinue the treatment of EPIC recipients due to the undue bureaucratic burden placed on them through the prior authorization requirements and restricted formulary.

The physician should be the one to determine the best treatment for the patient if adequate patient care is to be achieved, and heightened prior authorization requirements will not only circumvent physician expertise but also simultaneously erode patient care. A healthcare operative in Virginia is not properly equipped to determine the appropriate prescription for the Michigan citizen.

The EPIC program is in place for the purpose of helping the senior citizens of Michigan with life sustaining prescription costs, and I assert that if seniors are forced to discontinue the use of medications which have currently stabilized their conditions and switch to other forms of treatment which may be less effective and cause additional side effects, the result will be disastrous. This group of citizens has contributed to the state of Michigan over the years, and it is an outrage to decrease the prescription benefits provided to these individuals.

*[I am currently taking _____, which is expected to be placed on prior authorization if the changes to EPIC are implemented.] I am very concerned for my own well being and the well being of the seniors of Michigan; I urge you to do whatever is necessary to ensure that these changes are reconsidered in a manner that would be advantageous for the seniors of Michigan.

Sincerely,

[Your Name & Address]

[Date]

The Honorable **[Full Name]**
State Senator
State Capitol
P.O. Box 30036
Lansing, MI 48909-7536

Dear Senator **[Last Name]**:

I am writing to express my strong opposition to the implementation of increased prior authorization procedures in Michigan's Medicaid and Elder Prescription Insurance Coverage (EPIC) programs. It is wrong to remedy budget shortfalls by making appropriate treatments less accessible to Michigan's most vulnerable citizens, the less fortunate and the elderly. Furthermore, this process strips the physician of the ability to prescribe the most appropriate medication by limiting access through a restricted formulary or alternately, requiring approval from an out of state pharmacy benefit manager with no knowledge of the patient's needs.

The Michigan Department of Community Health's mission statement reads as follows:

1. to promote access to the broadest possible range of quality services and supports
2. to take steps to prevent disease, promote wellness and improve the quality of life
3. to strive for the delivery of those services and supports in a fiscally prudent manner

Clearly, the limitation of pharmaceutical availability through prior authorization requirements and a restricted formulary directly oppose the goal of promoting access to the broadest range of quality services and supports, while forcing patients currently stabilized on medications to alter their treatment contradicts the promotion of wellness and the improvement of the quality of life. It is therefore impossible to deliver the aforementioned services and supports, defeating the goal of doing so in a fiscally prudent manner. Increases in prior authorization requirements and restricted formularies are clearly contradictory to the mission of the Michigan Department of Community Health.

It is the duty of elected representatives to uphold the principles of equality and democracy by ensuring that the well being of their constituency is protected. The proposed changes to the Medicaid/EPIC formulary violate the very purpose of the Michigan Department of Community Health and in doing so, endanger the well being of the Medicaid/EPIC recipients. It is my hope that you will hold the Michigan Department of Community Health to its mission by ensuring that the proposed changes are reconsidered, and thereby protect the well being of the citizens of the state of Michigan.

Sincerely,

[Your Name & Address]

OPTIONAL PARAGRAPHS

According to the Michigan Constitution, public health and the general welfare of the people of the state of Michigan are matters of primary public concern. As a concerned citizen of this state, it is my firm belief that the practice of denying appropriate care to Medicaid recipients through pharmaceutical formulary limitations and prior authorization requirements is unacceptable. It is clear that the creators of the proposal for Medicaid reform have chosen to balance a budget at the expense of the individuals in the most critical need of proper medical attention, while the importance of public good has been lost and the focus has been shifted instead to the bottom line. While fiscal responsibility is of the utmost importance, this priority should not preempt the provision for those individuals least able to access proper medical attention as is so adequately stated by the Constitution of this state. The shortfall in the Medicaid budget should certainly be addressed and remedied, but not at the expense of Michigan's most vulnerable citizens.

While a committee may be able to determine the least costly drugs in each class, the "best in class" title chosen for such Medicaid prescription medication is certainly far from accurate. The formulary drugs were not chosen with regard to effectiveness or efficiency, two of the criteria the Michigan Department of Community Health purports to adhere to in their health care delivery policy. Regardless of the extensivity of the research behind such classifications, it cannot replace a physician's expertise. When given a choice between an unbiased physician analysis and a restricted prescription determined by a committee that the patient has never met, the physician's analysis would undoubtedly be preferred. In fact, if the committee members responsible for the "best in class" drug list were subject to this limited formulary, they might be more likely to expand the offerings provided to Medicaid beneficiaries. The poor and elderly should not suffer merely because it is the most convenient way to solve budget shortfalls.

The quality of patient care for Medicaid recipients is in jeopardy if the proposed changes to the Medicaid pharmaceutical offerings are not more closely examined and revised. The list of drugs requiring prior authorization is copious, and one can only imagine the effect of switching a patient from an effective, slightly more expensive medication to a less expensive, less effective prescription with additional side effects. For those taking a number of prescription medications, this process could be catastrophic and the damage irreparable. The trauma for Medicaid recipients could be completely avoided, however, if the Michigan Department of Community Health remained cognizant of the agency's goal, which aims to "design and implement a service delivery system...that is accessible, efficient, effective and innovative." A restricted formulary and severely diminished access to pharmaceuticals through prior authorization meets neither of these criteria and in fact, is contradictory to the aforementioned goal of the agency. Patient care should be the utmost priority for the Department of Community Health as the agency so aptly states, however, the current proposal is lacking and should therefore be revised.

Mental health may be one of the most sensitive aspects of managed health care. Due to the fact that numerous attempts to find a successful treatment are often necessary and compliance with the successful regimen is essential, the current modifications to the Medicaid formulary will likely result in grave damage to the mental health care of Medicaid and EPIC recipients. Not only will the doctors be limited to a restricted number of approved prescription options, but they will also be subject to prior authorization requirements should they deem a restricted pharmaceutical the most appropriate choice for their patient. These patients' needs are no less important than those who can afford to pay top dollar for mental health care, and these individuals should not be forced to carry the burden of balancing a Medicaid budget shortfall. Rather, the Michigan Department of Community Health should reconstruct a plan more sensitive to the needs of some of Michigan's most vulnerable and at-risk citizens.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: February 11, 2002

RE: College Scholars Senior Project Report

Report

On Tuesday, February 5, 2002, representatives from fifteen voluntary health associations and thirty senior centers came together at the first coalition meeting to discuss the changes to the Michigan Medicaid and EPIC formularies and the effect these changes will have on their respective populations. The meeting opened with frank input from the meeting participants regarding the positive aspects, as well as the shortcomings, of the current Medicaid and EPIC programs. Many of the individuals employed at the senior centers deal with EPIC patients on a daily basis as they assist enrollees with the application procedure. The voluntary health association representatives, which included an HIV/AIDS advocate, Epilepsy Foundation staff, Lupus Foundation Director and home care registered nurses, among others, are in contact with recipients of the Medicaid "fee-for-service" recipients and are consequently able to assess the likely impact of changes to benefits on this constituency. The changes to the EPIC program evoked frustration and even anger from a number of senior center representatives who have enrolled individuals believing that it would provide access to the necessary pharmaceuticals for seniors who had no other prescription coverage. These senior center representatives voiced concern that those seniors who are currently stabilized on treatments, which will require prior authorization under the changes to be enforced on February 11, 2002, will be adversely affected by the policy.

After questions were fielded on the Medicaid issue, I gave a presentation on the Pfizer Share Card program. [See attached.] The group was extremely interested in this new approach to senior assistance and seemed excited to be able to offer such a reachable option to those seniors who qualify. In total, over 3200 requests for Share Card brochures were turned in, indicating the overwhelmingly positive response to this innovative initiative. Over lunch, meeting attendees commented that other pharmaceutical companies should consider implementing comparable programs. Several senior centers requested that a representative of our staff present the program to

that a representative of our staff present the program to their respective senior centers. The meeting concluded by answering any remaining questions from the audience.

I met with the governmental relations representative of the AARP to discuss the Medicaid issue, and this meeting turned out to be surprisingly advantageous. The organization generally advocates preferred prescription medication lists and formularies, believing that such practices place “downward pressure” on pharmaceutical prices. While the representative did acknowledge that prescription medicine can lower hospital and nursing home care costs, they asserted that policies encouraging the use of generics are of benefit due to their belief that it causes a decrease in the price of brand name drugs. When it was pointed out that Pfizer does not dispute the use of generic medications, but brand name drugs are sometimes more appropriate treatments, they did not disagree but were not swayed in their mindset.

Their representative also reported that they were planning to file an amicus curiae brief on behalf of the state of Michigan on this particular issue. Anticipating that seniors would perceive AARP as being in favor of pharmaceutical restrictions, he also indicated that the group was planning to produce a brochure directing seniors to their pharmaceutical company to inquire as to why the company had not provided the requested rebates to the state. He also suggested that our corporate headquarters contact their national office, so that the state offices would have the authority to refer inquiries to the Share Card 800 number, despite the supportive press release of the national office on the Share Card. This information was of note to Pfizer, NY, and subsequently another vocal senior group has been contacted for their input on the changes to the Medicaid and EPIC program.

After these developments, I have followed up with the groups present at the meeting, while also trying to schedule appointments with those who were not able to attend. The groups present have been very complimentary and are excited about the Share Card. It will be more of a challenge to see that they follow through with contacting their legislative officials on the subject of the changes to Medicaid and EPIC. A follow-up email was sent to the attendees, while contact is also being made by phone as well.

Summary

The meeting of the health associations and senior centers was a success in that it provided a forum for groups to come together and discuss the current policy, as well as, comment on the negative aspects of the changes. Representatives have indicated to me that it was beneficial for them to interact with their contemporaries and discuss possible solutions to current situations. Meeting with AARP provided me with valuable information that allowed Pfizer to take a proactive approach to their alliance with the state on this issue.

Developments

The sales force has started to relay horror stories from physician's offices frustrated by the increase in red tape. One office reported being put on hold for over twenty minutes in an attempt to get prior authorization for a single prescription, only to be denied and then directed to the emergency number, where the staff member was put on hold for another fifteen minutes. After explaining the medical necessity of the prescription due to the patient's aggressive behavior, the request was finally approved. This is just one instance that has been reported, and it is anticipated that this will be the rule rather than the exception. When our office asked for a copy of the Medicaid and EPIC prior authorization forms on Wednesday, February 6, 2002, the pharmacy benefit manager representatives were less than equipped to answer questions, but finally provided our office with the necessary documents. Meanwhile, members of the sales force are trying to come up with ways to assist physicians and their staffs in the onerous process of receiving prior authorization.

Pfizer Share Card



Pfizer Share Card Program

- \$15 Pfizer prescriptions
- Information for healthy living
- Someone to talk to with any questions at any time



Qualifications

- Enrolled in Medicare
- No other prescription drug coverage
- Gross income of less than \$18,000 for individual and less than \$24,000 for couples



What you will need to apply



- Call 1-800-717-6005 for enrollment kit
- Fill out and sign an application
- Send copies of your 2000 tax return or your Social Security Benefit Summary Statement

- If you qualify, your card will be received in the mail 3 to 4 weeks after your application has been received.



Your Savings



- The average price of a 30-day supply of a Pfizer prescription is \$65.
- With the Share Card, you pay only \$15 for any drug, which amounts to a savings of 75% off the retail cost of most Pfizer medicines.

How does the program work?

- Take the Share Card to any participating local pharmacy.
- You will pay \$15 for up to a 30-day supply of medicine per prescription.



Frequently Asked Questions



- To qualify for the Share Card, do I have to be age 65 or older?
- NO. Any person enrolled in Medicare can apply for the Share Card.

Frequently Asked Questions

- Are persons who qualify for both Medicare and Medicaid eligible for the Share Card?
- NO. Only those who qualify for Medicare will be eligible for the Share Card.

Frequently Asked Questions

- Are assets included in gross income?
- No.
- Are there any limits to the program?
- No. There are no caps or limits on the number of prescriptions per patient, per month, or per year.

What Pfizer Medicines are Covered?

- | | |
|--------------------------|--------------------------|
| • Aricept | • Procardia Procardia XL |
| • Diflucan | • Viagra |
| • Glucotrol Glucotrol XL | • Zithromax |
| • Lipitor | • Zoloft |
| • Neurontin | • Zyrtec |
| • Norvasc | • And many others |



Call **1-800-717-6005**
today for your enrollment kit

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

RE: College Scholar Senior Project Report

DATE: February 18, 2002

Report

Following up with the individuals who attended the February 5 meeting has been an involved process. In addition to informing them that we will be able to send the Pfizer Share Card enrollment kit, I have also been inquiring as to whether or not they have been in contact with any legislative officials with respect to the changes to the Michigan Medicaid formulary. Most are waiting to contact their officials until they have personal interaction with an individual who has difficulty accessing their prescription medication due to the prior authorization policy, however, the Department of Community Health recently issued a letter stating that February 1-8 was a designated "testing period" and that the prior authorization system would not be implemented until "at least February 25." The Department then plans to phase in drug classes on a specified schedule, the first to be affected being the antianxiety, antihistamines, glucocorticoids and macrolides.

I have updated those who attended the coalition meeting of the Department's announcements, as well as the position of AARP on this issue. The response to the AARP amicus brief has been surprising. One senior center representative who is also in charge of the local AARP chapter was shocked at the organization's position and contacted the AARP State Government Affairs Representative, with whom I had previously met to discuss the issue of the changes to Medicaid prescription benefit. She intends to advise neighboring AARP chapters of the position taken by the state office and was incensed that there was no chance for local chapters to offer input.

The Visiting Physician's Association has begun compiling data on the amount time devoted by the staff to prior authorization requests and the outcome of such requests.

Their representative reported that the care coordinators, whose job it is to submit prior authorization requests, are extremely frustrated and would have the data together by the end of the week to be sent electronically.

The Leukemia and Lymphoma Society Patient Services Representative who attended the Michigan Health Alert coalition meeting indicated that the Medicaid issue was of importance to their population, however, the state branches are not permitted to act without the approval of the national office on any given issue. She referred me to the organization's Government Relations spokespersons in Washington, D.C., and through Pfizer's Civic Affairs office in New York contact was made. The Government Relations spokesperson was extremely pleased to hear that members on the state level were interested in patient advocacy initiatives and approved mobilization of the patient advocacy base in Michigan.

In addition, I have drafted language for the contracts to be submitted to the consulting firms whose services are to be employed in the campaign against prior authorization. These contracts will include deliverables and payment schedules, as well as a complete listing of expectations specific to each firm.

On behalf of Pfizer, Inc., I attended the Michigan League of Conservation Voters Legislative Awards Breakfast, where four state legislators were honored for their exemplary commitment to environmental issues, such as proposing a process to develop a set of land use planning goals to guide state investments and effecting strategies to contain invasive species and mitigate their impact on the Great Lakes. One of the representatives recognized represents the district in which the Pfizer Global Research and Development facility is located and has explored previous partnerships between Pfizer and the HIV/AIDS Alliance located there.

Modifications to the Michigan Medicaid Changes presentation were also necessary to prepare for presentation to the sales force. The documents necessary to the understanding

of this complex issues are to be explained in full detail, so the field force representatives can assist physicians in the prior authorization process.

Developments

The Michigan Department of Community Health released a letter on February 11, 2002, which detailed the Department's plans to postpone the implementation of the prior authorization system. While the communication included a schedule of proposed implementation dates, the letter stated the system would not be enacted until "at least February 25, 2002." [See attached.]

The Seniors Coalition, a vocal national organization of senior citizens, is planning to file an amicus brief siding with the Pharmaceutical Research and Manufacturers of America in the lawsuit against the Michigan Department of Community Health.

Summary

While AARP's decision to side with the state of Michigan on the prior authorization issue was certainly surprising and not of assistance to our efforts, the anticipated response by the Seniors Coalition will be an asset to the campaign against prior authorization. In fact some of the local AARP chapters have been contacting the state office with inquiries as to why this particular position was taken. In addition, they are not pleased that the local chapter constituencies were neither consulted nor informed of this decision.

The phase-in announced by the Department is indicative of the pharmacy benefit manager's inability to accommodate the prior authorization demand of the physicians and their staffs and the Department's haphazard approach to implementing the program. By phasing in classes of drugs, the Department hopes to be able to employ the program more successfully than was done in the disastrous "testing period." Meanwhile, the various aspects of the campaign against prior authorization are moving forward.

STATE OF MICHIGAN



JOHN ENGLER, Governor

DEPARTMENT OF COMMUNITY HEALTH

LEWIS CASS BUILDING

LANSING, MICHIGAN 48913

JAMES K. HAVEMAN, JR., Director

February 11, 2002

Dear Provider/Prescriber:

On February 1, 2002, the Michigan Department of Community Health began the implementation of the expanded prior authorization program for pharmaceuticals without denial of drugs that will require prior authorization. The week of February 1 - 8 was designated as a testing period and a time for prescribers to fax in or call in prior authorization requests. This pre-implementation prior authorization period will be extended to February 24, 2002. Thus, prior authorization will not be required to fill prescriptions until at least February 25, 2002. On February 25, 2002, the department will begin phasing in specific drug classes requiring prior authorization to dispense. The phase in will continue through March 18, 2002. The classes of drugs and dates of implementation of the prior authorization requirement are enclosed.

Prior authorization may be requested for any of the drugs that will require prior authorization at any time during this phase in by calling the First Health Services Corporation's [FHSC] Clinical Call Center at 1-877-864-9014 or by faxing your request to FHSC at 1-888-603-7696 or 1-800-250-6950. A fax form is enclosed and may be duplicated for your use. The form identifies the information that will be required to grant prior authorization.

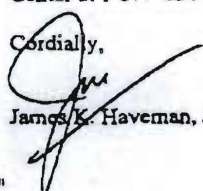
FHSC will prioritize prior authorization requests according to the phase in date for the therapeutic class of drug requested. Requests for drugs in the February 25, 2002 phase in will be addressed prior to requests for drugs from later phase in dates.

Also enclosed is a list of drugs that do not require prior authorization in most cases. We urge providers to prescribe from this list and only call for prior authorization when clinically necessary.

Please note, drugs that required prior authorization before February 1, 2002 will continue to require prior authorization, and all related edits will remain in force. The department does not cover refills until 75 percent of the previous prescription has been used.

For general questions regarding this program, providers should contact the FHSC Technical Call Center at 1-877-624-5204.

Cordially,


James K. Haveman, Jr.

DCM-0207 (2/98)



L 02-09

Michigan Department of Community Health

Timeline For Therapeutic Class Phase In of the Implementation of the Expanded Prior Authorization
February-March 2002

February 25, 2002	March 4, 2002	March 11, 2002	March 18, 2002
- Antianxiety — Antihistamines - Glucocorticoids - Macrolides	- CNS Stimulants - Oral Hypoglycemics 1st Gen. Cephalosporins 2nd Gen. Cephalosporins - Angiotensin Receptors - Beta Blockers - NSAIDs - Atypical Antipsychotics - Typical Antipsychotics	- Alzheimers - ACE Inhibitors - Anti-Fungals - Coronary Vasodilators - Insulins - Anti-Hyperlipidemic Agents - Narcotics - Platelet Inhibitors - Quinolones - Respiratory Beta Adrenergic Inhalers - Sedative Hypnotics Non-Barbituates — Steroids, Nasal - Steroids, Topical - Topical Nitroglycerin	- PPIs - Anti-Depressants - Calcium Channel Blockers - Osteoporosis Agents - Bipolar Agents - Antivirals - H2 Antagonists

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: February 25, 2002

RE: College Scholars Senior Project Report

Report

Additional partnerships with voluntary health associations have been fostered over the past week. My initial contact with the Juvenile Diabetes Research Foundation International (JDRFI) led me to believe that this organization would not be of much assistance to the campaign against prior authorization; however, when I met with them, they were extremely interested in the issue and its ramifications. The advocacy of this organization tends to be on the national level, as their chief goal is to increase research funds to find the cure of juvenile (Type I) diabetes. Their representative works closely with other non profit groups because of personal health experience and referred me to a small, but active mental health advocacy group, which she thought would be interested in this issue and might possibly weigh in. JDRFI asked to be kept up to date on the issue and was open to the possibility of making a position statement and involvement in a letter writing campaign.

Through a joint meeting with the National Family Caregivers Association, the Well Spouse Foundation, House Call Physicians and the Maria Madeline Project, I was made aware of the priorities of these groups as they relate to home bound individuals. The Well Spouse Foundation primarily focuses on providing emotional support to the spouses of the disabled, while National Family Caregivers is similar in these interests and is supported by Pfizer on the national level. House Call Physicians works hand in hand with the Academy of Home Care Physicians, and provides service to Medicare recipients. The Maria Madeline Project is an organization that has developed intergenerational software for use at senior centers, nursing homes and retirement facilities. These groups, with the exception of the Maria Madeline Project, are active members of the Chronic

Illness Coalition, and are very interested in the possibility of pharmaceutical companies taking a more proactive role with this group. All the groups expressed concern over the prior authorization issue and were open to relaying information on the failure of the system upon its implementation. In fact, one of the Health Care Partners nurses at the meeting indicated they had already experienced adverse patient care effects with their clients during what was considered the “testing period”. The groups were pleased to hear about the Share Card and are planning to promote it to their populations.

Each group also had suggestions for possible partnerships with Pfizer. The Maria Madeline Project is interested in Pfizer moderating a chat room on their interactive website for seniors (www.mariamadeline.com). I indicated that I would make the appropriate corporate contacts aware of this idea, and that upon the submission of a proposal including budgetary figures, the grant review committee would consider this possibility. The site is currently providing medical advice through the Health Care Partners group, as well as spiritual reflection and cooking expertise for seniors. Partnerships with Ford Motor Company and the UAW have made the software program available in two of their retirement centers in Michigan and Texas with plans to expand to thirty-one national centers.

House Call Physicians expressed interest in a Pfizer representative presenting on the Share Card at the annual conference of the American Academy of Home Care Physicians and the American Geriatrics Committee in May, while the President of National Family Caregivers and the Chronic Illness Coalition would like Pfizer to present on the Share Card and prior authorization issue at one of the bimonthly meetings and their semiannual forum. In addition, they are interested in sponsoring a special event at which celebrity physician and founder of Gesundheit Institute, Patch Adams would be the keynote speaker.

The National Organization for Rare Disorders has been, up to this point, a solely national organization. The Michigan state branch, which is presently in the development stage, will serve individuals diagnosed with any of 6,000 rare disorders in tandem with the

national organization on state level issues. The Michigan state branch is to serve as a model for all other state branches and is now beginning to identify and consider state issues. Their representative was opposed to the prior authorization policy from both a personal and organizational standpoint. She is planning to submit the issue to the national office to receive authorization to weigh in, but regardless will personally write to indicate her opposition to the policy. The organization is in favor of research and development due to the necessity of innovative treatments to be used in search of cures for rare diseases, and thus hopes to cultivate a relationship with Pfizer for the benefit of the organization's population.

Summary

The organizations I have met with over the past week have proven to be valuable assets with beneficial insight and networking capabilities. Each is unique in its focus, but the common goal of quality patient care results in partnership possibilities of benefit to their organizations and Pfizer. The groups have all been very interested in hearing the status of the prior authorization process, since it has the capacity to impact their constituents with such gravity. The Share Card is of interest to them as well due to their interaction with disabled individuals who are Medicare recipients as a result of their disability. It is exciting to see the tie-ins and be able to develop a network of individuals with such amazing potential to effect change within their given niches.

Developments

The implementation of the prior authorization process is scheduled to go into effect today, February 25, 2002. It will be interesting to see if the phase-in approach is successful in alleviating the problems experienced during the initial implementation procedure. Since the initial implementation, contact with the voluntary health associations and senior centers has been solidified through the initial coalition meeting and follow up communication, and through this network we hope to be able to communicate the experiences of individuals who are adversely impacted to state government officials as quickly and efficiently as possible.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: March 4, 2002

RE: College Scholars Senior Project Report

Report

The coalition in opposition to the prior authorization policy implemented by the state on February 25, 2002 is now at the point of incorporation. Last week the government policy firm under contract with Pfizer in Michigan drafted the articles of incorporation for a group titled 'Senior Citizens for Prescription Drug Fairness'. At the direction of the Manager, State Government Relations, I extended offers to participate on the leadership committee of this organization to four individuals, two senior center representatives and two voluntary health association representatives. One representative, who works with the Visiting Physicians Association, the largest home care physician network in the nation, accepted promptly and is excited about the position. In addition, one of the senior center representatives who had asked that a presentation on the Share Card be made at the Senior Leaders conference and also attended the initial coalition meeting has agreed to serve. The other two individuals have yet to respond and are waiting for a formal written offer detailing the leadership position.

The Share Card shipment that had been temporarily delayed due to the overwhelmingly positive response the program arrived this week. Thus, over 3000 brochures were repackaged and mailed out in the requested quantities to those represented at the coalition meeting and others who were unable to attend that day. A few of the sixty plus organizations that received brochures have already utilized this initial supply and are submitting requests for additional brochures.

The contracts for the consultant firms engaged in the campaign against prior authorization were found to need revision, and after this project was completed, they were forwarded to the campaign coordinator for his final review.

The President of the Maria Madeline Project, the intergenerational technology program, submitted a proposal detailing the possible partnership with Pfizer. I sent this proposal to the New York office of Civic Affairs to be reviewed by the grant review committee. This committee regularly considers all philanthropic partnerships presented to Pfizer and will determine whether or not moderating the ExperienceSeniorPower chat room opportunity will be pursued.

A regional meeting with the Western counterparts called for presentation materials on the status of supplemental rebates in different states. I assisted with the graphics in the presentation, which provided an overview of the current situation in California, Michigan, Florida and Illinois.

The representative from the Juvenile Diabetes Research Foundation International had inquired as to which insulin treatments required prior authorization. I located this information on the changes to the Michigan Medicaid formulary and sent the requested information.

Developments

On Friday, March 1, 2002, one of the district managers informed our office that a member of the Pharmaceutical and Therapeutics Committee had relayed that Zoloft and the other drugs in the SSRI class had been carved out from the prior authorization policy. The behavioral drugs are now to be grand fathered in, and only those individuals who are receiving prescriptions for the first time will be required to go through the prior authorization process. This was a notable development, but has not yet been confirmed with the state Medicaid office. I placed calls on Friday to the appropriate state employees to verify the assertion, but have not yet been able to confirm this change to the policy.

Summary

The campaign against prior authorization is continuing to develop, however, simultaneously negotiations with state officials regarding alternative solutions are underway. While no consensus on this front has yet been reached, both sides are attempting to find a solution. It would be advantageous to reach a compromise without the full blown campaign due to the possibility that such a campaign has the inherent risk of alienating the state and prompting those implementing the policy to become further entrenched in their position. Due to the uncertainty of the negotiations, the consultants and the coalition are still fully engaged and prepared for a campaign.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

DATE: March 11, 2002

RE: College Scholars Senior Project Report

Report

The week began with a presentation over lunch to employees, including physicians, pharmacists and other staff of one of the Community Mental Health facilities in the Lansing area. These individuals are most directly involved with Medicaid patients in need of mental health care and in this capacity have had experience with the prior authorization process firsthand for an extended period. Their reports confirmed that the process has serious ramifications for mental health patients, and they were interested in drafting a document so that they could track the prior authorization process in a uniform manner. They raised the issue of the patient's right to appeal and exchanged suggestions on how to submit a prior authorization request so that it would have a better chance of being approved.

In meeting with the Michigan Psychiatric Society, I learned that the state had postponed the implementation of the process the first time due to the fact that they had not given the Medicaid recipients the federally mandated ten days notice. In addition, the vague nature of the letter that was subsequently sent to Medicaid recipients left many in a state of panic and confusion. It is reported that the pharmacy benefit manager received over 900 calls the first weekend from individuals concerned that they would not be able to access their current medications. Some individuals even called cabs and showed up at the Community Mental Health facilities in hysterics because they were so concerned. The seventy-two hour emergency prescription provided for in the pharmacy benefit manager's contract is not being honored by some pharmacies due to the inability to be reimbursed for the expense, and now at least one of the health management organizations has implemented a prior authorization system prior to the state-mandated schedule. It is

rumored that the HMO's, which were supposed to have the prior authorization system implemented on April 1, will now not be participating in this program until next year due to the disastrous effects experienced on the "fee-for-service" side. As anticipated, some primary care providers are now refusing to see Medicaid patients due to the increased burden on the physician and their staff. They have been sending these patients to the Community Mental Health facilities, where the caseload is already high. The Michigan Psychiatric Society representative provided me with information on a public hearing being held by the Michigan House's Health Policy Subcommittee on Increasing Access to Quality Health Care at which many of the health advocacy groups are planning to testify. She also provided a draft of a prior authorization tracking form.

A presentation on the Pfizer Share Card was made to the Senior Leaders Conference on March 7, 2002, and the group was enthusiastic about this new initiative. Many reported that seniors were already inquiring as to how to enroll in the program and were glad to have been able to ask questions and receive program information. The senior leaders provided valuable insight on how to improve the program for seniors, such as allowing the senior center representative to fill out the application for those seniors who have difficulties with such tasks.

A meeting with the contract lobbyist firm on the incorporation of the coalition was held later in the week, and the details of the incorporation were discussed. I received acceptances of the invitation to serve on the board of directors from all of the seven individuals to whom I extended an invitation. The leadership committee of this organization will consist of representatives from the Visiting Physicians Association, Michigan Association of Senior Centers, NAACP, Epilepsy Foundation, Health Care Partners, National Kidney Foundation of Michigan and the Chronic Illness Coalition. This group is excited about their leadership role in the Senior Citizens for Prescription Drug Fairness and is scheduled to participate in a conference call in which officers will be appointed and the goals of the organization formalized on Monday, March 11, 2002.

In addition, I participated in a conference call of the campaign participants. The campaign calendar has been determined and the first informational luncheon for senior citizens in the Detroit area will take place on March 19, 2002. Some 300 seniors are being invited to attend and media will be present to cover the event. The coalition leadership will have the opportunity to participate in this event.

The Seniors Coalition is planning to file their amicus brief on the side of the pharmaceutical companies in the lawsuit against the state within the week. The group is also presenting policy socials at senior centers throughout the state on the prior authorization issue and will conclude with a press conference in one of the state senator's offices tomorrow. This group is opposed to prior authorization and has been extremely active in informing the senior population about the possible negative effects of this policy.

Developments

Confirmation of the grandfathering of the antidepressant class was received, meaning that individuals who are currently stabilized on such drugs will not be subject to the prior authorization process. The state employee overseeing this aspect of the implementation has had experience with mental health disorders within his immediate family, and he was reported to have said that he would not want his family member to be forced to switch medications due to the length of time required to find the proper combination of medications.

Summary

The alternative solution continues to be explored, however, due to the uncertainty of the outcome, the campaign is being implemented. The past week had many promising developments and in meeting with the various groups, crucial information to the campaign against prior authorization was gathered. The health advocates and senior center representatives on the board of directors of the coalition are excited about the opportunity to serve and will be more formally introduced to each other within the week.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

RE: College Scholars Senior Project Report

DATE: March 19, 2002

Report

The individuals who have agreed to serve on the Board of Directors participated in their first meeting by conference call along with the Director of Government Relations, the contract lobbyist and myself. At this time officers were appointed, and the goals and objectives of the organization, scheduling a Detroit Seniors Day and extending invitations to other organizations were discussed. The group also talked about legal aspects of non-profit corporate involvement and scheduled the first meeting of the board. They were interested in targeting legislators who would be influential in the budget process and understood the timeliness of the issue at hand. I began preparing a presentation that would subsequently be presented to the group on the prescription policy in Michigan. [See attached]

I also met with a mental health advocacy group on the West Side of the state later in the week. This group consisted of a city commissioner, several health professionals who regularly deal with the Medicaid population, an environmental engineer and mental health advocate, a minister and a Medicaid patient. This group has experienced the adverse impact of the prior authorization system and is interested in being a part of a coalition movement. Although the group has not yet weighed in on the issue, they are planning to organize a public forum to which legislators and other public officials will be invited. They extended the invitation for me to attend their meetings on a regular basis and also asked to be updated on hearings and other opportunities to testify on the process.

The Subcommittee on Increasing Access to Quality Health Care held a public hearing entitled "Access to Pharmaceuticals." In this hearing, one of the members of our Board

testified on the prior authorization system on behalf of another coalition of which she is part. The Michigan Psychiatric Association, Mental Health Association and Michigan Association for Children with Emotional Disorders also provided input on the recent changes. The legislators were interested in obtaining definitive data that would indicate the current system is not working.

The Seniors Coalition, a national grassroots advocacy network, completed their statewide tour of Michigan with a press conference in the Capitol. The group's spokesperson is seventy-nine year old Grandma (Flora) Green. She travels with her staff from state to state informing seniors of policies that will impact them and their access to health care. In Michigan, they have held policy socials on the prior authorization system and partnered with a state senator and practicing physician for the press conference. I was able to attend and had the pleasure of meeting Grandma Green. This group is also filing an amicus brief in response to the AARP amicus brief filed on the side of the state. [See attached article]

A public policy coordinator from the Civic Affairs division came to meet with me and discuss the progress of the coalition. She provided several good contacts and some valuable insight on the process of coalition building. The proposal submitted to Civic Affairs on behalf of the Maria Madeline project was discussed. This proposal was also forwarded to a district manager in the Ann Arbor area for his review. He indicated that due to the FDA regulations prohibiting the giving of pharmaceutical advice to anyone other than health care professionals, this project could not be pursued. I relayed his comments to the Civic Affairs contact so that she would have this feedback prior to the submission of the proposal to the grant review committee.

I also participated in conference calls between the Director of Government Relations and the various consultants throughout the course of the week to update them on the progress of the coalition, and spoke with members of the field force on the prior authorization issue and our efforts.

Developments

The alternative that was drafted by the Senate Appropriations Subcommittee on Community Health staff and with input from our office has passed out of the Senate Appropriations Committee and is now to be reviewed by the full Senate. This compromise would allow the state to receive Medicaid best price for all taxpayer funded programs and has the possibility of remedying the current pharmaceutical budget shortfall. This is seen as a positive solution for everyone involved.

In addition, my immediate supervisor has decided to take short-term disability leave due to a health condition. This has resulted in an increase in my workload due to the gravity of the prior authorization issue. Consequently, I have been asked to participate in conference calls more frequently so that his direct supervisor is aware of all current developments and have also been trying to keep the consultants up to speed on the coalition progress.

Summary

The formalizing of the coalition has been a very detailed process with numerous legal, financial and personal issues. The group is very vocal and educated on health care and senior related issues and I am optimistic that they will be of great value to the cause of increasing access to pharmaceuticals in the short and long term. It has been challenging to make sure that the concerns and requests of the all of the individuals involved in the process are taken care of, since there are occasionally opposing views on how information should be conveyed and issues should be handled.

Michigan Prior Authorization Policy

PRESCRIPTION DENIED

March 19, 2002

Michigan Pharmaceutical Best Practices Initiative

- James Haveman, *Michigan Department of Community Health*:

"Through the MPBPI, Medicaid beneficiaries will receive the best drugs available and Michigan taxpayers will not have to shoulder the entire burden of rising drug costs."



Affected Medicaid Population

- 350,000-400,000 "fee-for-service" recipients



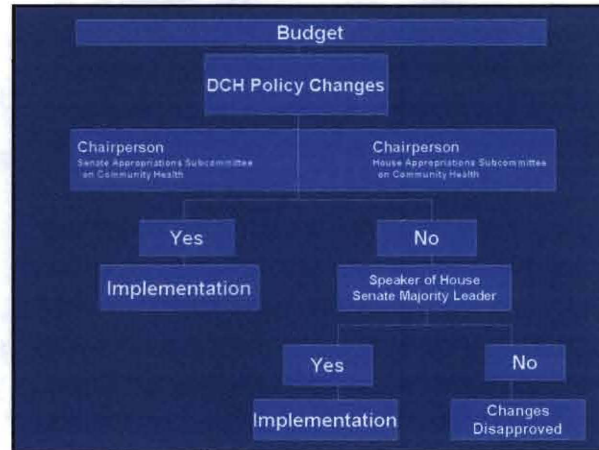
Non Medicaid Population

- EPIC 35,000 recipients
Elder Prescription Insurance Coverage
- State Medical Program 45,000 recipients
- CSHCS 25,000 recipients
Children's Special Health Care Services
- Mental Health Programs 200,000 recipients
- Refugees of Other Nations 10,000 recipients

MI Medicaid Policy Changes



- Michigan Pharmacy & Therapeutic Committee
 - 11 members
 - First Health Services
 - 40 drug classes



Violation of Separation of Powers-MI Constitution

Delegation to 4 members of the legislature (instead of the entire legislature) the right to approve/disapprove action by a state agency is prohibited



PhRMA Lawsuit



- Lack of statutory authority
 - Basic & supplemental rebates /prior authorization in non-Medicaid programs
 - Supplemental rebates in Medicaid programs

Scheduled Implementation Dates

January 1, 2002

January 14, 2002

February 1, 2002

February 11, 2002

➔ February 25, 2002--PHASE-IN



How Does PA Work?

Physician or Member of the Physician's Staff must submit requests by:

•Telephone

•Fax

•Mail

TO: FIRST HEALTH SERVICES
4300 COX ROAD
GLEN ALLEN, VA 23060

Most Commonly Prescribed Meds Require PA



Celebrex

Vioxx

Procardia

Vasotec

Lipid

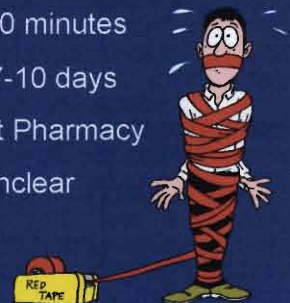
Zocor

Glucotrol

Micronase

Problems Experienced

- On Hold for over 30 minutes
- No Response for 7-10 days
- Patients Waiting at Pharmacy
- Appeal Process Unclear
- Try and Fail



Lack of Communication

- Changes to Medicaid Program Benefits
- Scheduled Implementation
- Grandfathering of Antidepressants



Prior Authorization interferes with the physician-patient relationship.

Adverse Effect on Patient Care

People are not generic and need to be treated based on their individual needs.



Appropriate Drug May Not Be Available



- *"It victimizes those persons suffering from mental illness and prevents access to proven, effective drug therapies."*
- Mark Reinstein, Vice President of the Mental Health Association in Michigan

Lack of Physician Participation

- One More Form
- Staff Time
- Erosion of Primary Care
- Community Mental Health



Prior Authorization

- Will cost all of us in the long run
- Increased number of hospitalizations
- Increased number of chronic conditions
- -- Ray Gauthier, Board Member of the National Alliance for the Mentally Ill in Michigan

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

RE: College Scholars Senior Project

DATE: March 25, 2002

Report

Before the first formal meeting of the Board of Directors for Prescription Drug Fairness, an informational briefing on prior authorization was sent out via email. The agenda for the first meeting was drafted and submitted to both the Director of Government Relations and the Chairperson/President of the coalition. The Chairperson/President of the coalition has had experience in health care administration and requested further information on how similar undertakings in other states have been facilitated. In response to this inquiry, a representative from the Pfizer Civic Affairs division in New York was asked to be present at the meeting to field any questions along these lines. The presentation on the Michigan prescription policy was approved by the Director of Government Relations with a couple of minor changes, and consequently an informational packet for the Board of Directors members was assembled, including a contact list, examples of the required prior authorization forms and a hard copy of the presentation.

I met with the branch manager of the statewide bank chosen by the Board of Directors to obtain the paperwork necessary for opening a corporate checking account. He indicated that it would be helpful if the Board of Directors members who would serve as signors on the account were present at the time the account was opened due to the need for personal information. I relayed the information provided by the bank to the Director of Government Relations and the Campaign Coordinator by conference call, and they were in favor of the Chairperson/President and the Treasurer having access to the funds available.

The first meeting of the Board of Directors began in the morning at the offices of the media relations firm in Detroit. Six of the seven directors were present, and the meeting opened with the presentation on the Michigan prescription policy. The consultant coordinating the campaign against prior authorization was to follow this presentation with an overview of the campaign plan, but due to transportation difficulties had to make the presentation by conference call. Following his presentation and questions from the Board, the government relations firm fielded questions on lobbying requirements. The media relations firm then explained the senior luncheon aspect of the campaign. The Board concluded the meeting with two motions: the first being the approval of the conceptual design of the campaign as presented and the second the scheduling of the first senior luncheon in Detroit on April 4, 2002.

Due to the inability of the Director of Government Relations to be present at this first meeting, a conference call was held involving all parties who presented to the coalition at the first meeting. The general consensus was that the group, in addition to being well educated on the issue, was politically astute, and it was agreed that following one more meeting they would be prepared to kick off the media campaign at Detroit Seniors Day. The second meeting was scheduled for March 26, 2002 at the offices of the government relations firm in Detroit. This meeting would involve the Board of Directors as well as the Campaign Coordinator, two members of the New York Civic Affairs team, the State Government Relations managers from Indiana and Ohio, and the consultants responsible for lobbying, direct mail and media relations. The goals of this meeting are to introduce all the key players in the campaign, submit the campaign plan to the board for review and input, as well as formally establish the coalition.

Another conference call with the State Government Relations managers from Indiana and Ohio was held late in the week to bring them up to speed on the Michigan issue in the absence of the Michigan State Government Relations manager. The oversight of the Michigan field force was delegated to the Indiana manager, due to his previous employment in that capacity prior to holding the government relations position.

Information regarding the prior authorization status of Pfizer products and all previous communications from our office to the sales force were forwarded for this purpose.

Developments

Unfortunately, one of the directors of the coalition resigned the position late in the week due to her organization's conflict of interest on the prior authorization issue. The voluntary health association of which she is employed has a large line item in the Michigan Department of Community Health budget, which constitutes a substantial portion of the organization's operating budget. This organization has historically partnered with Pfizer on the state level and was forced to make a difficult decision. She indicated that she was personally opposed to the prior authorization policy, but could not participate as a representative of her organization.

Summary

As the Board of Directors reviews and tailors the campaign against prior authorization, they are being directly connected with the consultants involved with the campaign. As this progression takes place, my role shifts from founding and organizing interested parties to serving as more of a resource for the group as they define their organizational parameters. While I provide information and serve as an intermediary for between the Board and the consultants, this role is continually diminishing as the consultants assume the direct responsibility of their various aspects of the campaign and advise the Board of Directors on these matters.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

RE: College Scholars Senior Project Report

DATE: April 1, 2002

Report

In preparation for Tuesday's coalition meeting, I spent most of Monday gathering documents which answered questions raised by the Board of Directors at the previous coalition meeting. This included a summary document of the RFP process by which First Health was selected, as well as a list of the Pharmaceutical and Therapeutics Committee members who were appointed by the Governor to determine the "best in class" drugs. In addition, articles of incorporation were made available for their convenience.

The second board meeting was extremely productive, despite the inability of three of the board members to attend due to illness, prior engagements and religious holidays. That morning I met with the senior account manager of the Civic Affairs division to discuss the coalition and the steps that had led up to the current situation. His previous involvement with a like coalition in Washington State provided helpful input, and he was able to attend the board meeting to give input on how grassroots advocacy had been successful in other states.

Prior to the Board meeting, I met with the Secretary who was unable to attend, so that she could sign the necessary bank documents.

The meeting began with a presentation on the recent grassroots defeat of a Medicaid prior authorization policy in Washington State—a program more restrictive than the current Michigan plan. The board members had questions as to how the patient advocacy coalition had begun and gained credibility and subsequently discussed opening the membership of the coalition to gather a broader base of organizations, in addition to looking into other sources of funding.

A legislative update on the alternative, which passed out of the Senate prior to the Spring Break was then given. The alternative would extend the Medicaid "best price" rebate to all taxpayer-funded programs. In return for the participation of the pharmaceutical companies, each company that chose to extend rebates to the state run programs would receive unrestricted status on the formulary. Several pharmaceutical companies have indicated that they would be interested in participating in this alternative. The board was very supportive of the alternative and felt that it relieved many of the current program's issues while providing the state with the revenue necessary to alleviate the budget shortfall. The members had input on the prior authorization program's current shortfalls--such as inefficient response time; in fact, the Chairperson/President of the coalition had spend over thirty minutes on hold when attempting to receive approval for an elderly woman who had been stabilized on Glucotrol for diabetes. She felt very strongly that the coalition should support the alternative legislation, as did the representatives from the two senior centers present.

The campaign plan as developed with a Senate focus was then discussed, and it was decided that such a strategy was no longer relevant. A House strategy was thus drafted with the coalition member's input, and the senior lunches as scheduled were cancelled with the exception of one. The coalition was conflicted on the issue of media involvement, as some felt that they were not yet ready to undertake such a campaign, while others asserted that media could play a key role in mobilization efforts. Direct mail pieces were also scrapped due to the relatively short time frame within which the alternative would have to be advocated.

The necessary parties signed the bank documents, and I had a bank employee and legal counsel review them prior to forwarding them to the treasurer who would open the account. Later in the week, I then drafted the unrestricted grant request that would ultimately be submitted to the Director of State Government Relations by the officers of the coalition and sent it to the President/Chairperson for her review.

In addition several conference calls were held between members of the coalition and the parties involved in the forming of the coalition. It was decided that regular communication between all involved would be the best way to remain up to date on the coalition and other aspects of the campaign. The campaign coordinator then formulated a list of tasks to be completed by each of the consultants and Pfizer employees in order to ensure that the schedule set forth was maintained.

Summary

The coalition members are extremely vocal and can be counted on to provide valuable input. They are also politically savvy and fully comprehend and consider the scope of the implications of their actions. Many of them have been active in advocacy prior to this campaign and have significant health care expertise. It is a constant challenge to make sure that their questions are answered, in addition to the internal responsibilities.

Developments

The coalition members have decided to hold legislative breakfasts within their districts that will target the members on key committees with respect to the legislative alternative. These breakfasts will include a cross section of health care professionals who can attest to the shortcomings of the current prior authorization and the adverse impact on patients, as well as the increased staff time required to ensure that quality health care is being practiced. These breakfasts will provide a forum for the professionals to indicate their displeasure with the prior authorization system and their support of the program that would be put in place by the legislative alternative.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

RE: College Scholars Senior Project Report

DATE: April 8, 2002

Public Policy Report: Washington State

Due to the impact of the policies enacted or eliminated by other states on the political climate and thus, decisions regarding critical public policy issues in the state of Michigan and others, a study of the state of Washington provides valuable insight. Subsequently, the defeat of the prior authorization system in Washington can be utilized as a model for a successful campaign against prior authorization and as a tool for learning how to advocate appropriately against an issue. While an identical outcome is not guaranteed by any means, the process by which the ultimate goal was achieved in Washington can be patterned in Michigan following careful consideration of each aspect of the campaign, while maintaining a sense of the broader issue.

The Washington legislation included mandatory therapeutic substitution, a preferred drug list and prior authorization which is similar to the current Michigan prescription policy mandating prior authorization for all drugs not included on the preferred drug list or explicitly grandfathered. The initial response in Washington to these impediments to access was an attempt to amend the bills so that they would be more palatable; however, when this tactic proved unsuccessful, the goal became to eliminate the legislation. The negativity of the public policy was emphasized, as well as the potential to adversely impact other states that might follow Washington's lead. The following is a more detailed analysis of the actions taken in Washington.

Efforts were coordinated on a number of fronts including the print media, the biotech industry, Voluntary Health Associations, the NASDAQ, Pharmaceutical Research and Manufacturers of America and the Pfizer sales force. Through the collaboration of these

groups, a groundswell of opposition to the policy was evidenced, leading to the ultimate demise of the policy. Those opposing the legislation would support measures such as targeted disease management in hopes of reducing long-term costs and enhancing the quality of life, as opposed to restrictive measures focusing more on the short term.

The policy was not opposed by all; in fact, some key groups supported the changes, including the local chapters of the American Heart Association, American Lung Association and the American Cancer Society, along with the state medical association, pharmacists and labor. These supporters based their position on the need to do something to address the rising cost of pharmaceuticals, a consideration undisputed by many of the opponents.

A voluntary health association coordinator was employed to bring together those organizations opposing the policy, among them: the American Diabetes Association, Epilepsy Foundation, National Alliance for the Mentally Ill, Paralyzed Veterans of America, National Association of Black Veterans and others. In addition, position papers were written by the National Venture Capital Association and the biotech industry asserting the belief that the policy would have a negative impact on the economy. Seattle is one of the two largest national biotech markets; thus, an interest in the effect on this aspect of the economy was no doubt of great importance to legislators and other state officials.

The National Alliance for the Mentally Ill underwrote the cost of transporting members of the minority community to Olympia in order to testify to the legislature. The press characterized this action as “playing the race card,” which was promptly answered by an opinion editorial asserting that legislators were attempting to minimize the legitimacy of the issue. Consequently, the minority press opposed the legislation, and members of the minority community effectively lobbied their state legislative officials.

The sales force was informed through several action alerts providing them with form letters to distribute to physicians and their staff, so that these individuals could express their dissatisfaction with the changes in the health care delivery requirements. Talking points were developed regarding the economic, political and social implications of the policy and were

distributed to various audiences, including the GOP caucus. These documents detailed the difficulty presented to individuals seeking an exception to the policy, as well as, the minimal dollar figure anticipated in savings by the state of Washington.

An alternative was also proposed, which invalidated the assertion that the pharmaceutical industry will not advocate options resulting in savings to the state. In fact, the contracting firm identified over \$50 million dollars that could be saved by the state of Washington through the enacting of programs that would not inhibit pharmaceutical access.

Clearly, similarities exist between the Washington and Michigan policies, such as:

- Restrictions to pharmaceutical access
- Minimal savings being realized by the state through changes enacted
- Adverse impact on Medicaid population, especially the minority community
- Mixed review among voluntary health associations, with strong groups represented on both sides of the issue
- Alternative legislation which offers a solution to the current issue

It is important to note as well the conflicted media messages that fueled the issue and increased the public's awareness. While some print media in Michigan has covered the issue, polling indicated that much of the public is currently unaware of the two-tiered health care system created by this type of policy.

The response to the Michigan prior authorization has mirrored that of the Washington reaction, in that an alternative has been proposed and is now being considered by the legislature through the budget process. It is advantageous to assure legislators of the necessity of supporting this alternative. At the current time, members of the House Appropriations Committee are being invited to legislative breakfasts initiated and coordinated by directors of the Senior Citizens for Prescription Drug Fairness to ensure that the issue is appropriately understood and addressed by the legislators in the budgetary process to come.

**TO: Dr. Harold Black
Dr. Bob Cunningham
Dr. David Tandy**

FROM: Hannah Kiser

RE: College Scholars Senior Project Report

DATE: April 15, 2002

Report

The Michigan Department of Community Health presented their budget for the fiscal year 2002-2003 on Wednesday, April 10 to the House Appropriations Subcommittee on Community Health. The Michigan Pharmaceutical Best Practices Initiative consumed the majority of the discussion, and the Department released a twelve-page document that provided their analysis of the prior authorization program's results to date. In addition, the Department asserted in their testimony that there had been no appeals or complaints of negative consequences resulting from patients being switched from a restricted drug to an unrestricted drug. They anticipate that the volume of calls to First Health will decrease as compliance with the preferred drug list is achieved and indicated that calls with technicians now average between three and a half to five minutes per call.

When asked about the cost savings being realized by the state, the Director commented that the program had only been in place a few weeks, and consequently, he would prefer to disclose this information at a later date. Questions were also raised as to how the drugs were selected for preferred status, whether or not cost considerations were formally utilized in this process, and the reasoning behind the lack of public input. At this point in time, control groups have not been employed to ascertain the effect of the program on Medicaid patients. Interestingly, a recent study by the Center for Studying Health System Change, which is funded by the Robert Wood Johnson Foundation, indicates that barriers to access such as prior authorization, prescription limits and step therapy have a higher impact on the Medicaid population due to low income and chronic illness considerations. [See Print Media.]

Public input hearings will be held on April 17, 2002 and April 24, 2002. This will provide health care professionals and consumers the opportunity to present their experiences with the prior authorization system.

I met with the Mental Health Advocates group in Grand Rapids later in the week, at which time I was able to inform them of the current alternative legislation. Several individuals were extremely supportive and plan to attend the public input hearings to rebut the testimony given by the Department. I also extended invitations to the legislative breakfasts in their districts, and they are interested in attending these as well. Another topic of discussion at the meeting was the Medicaid waiver which would draw down federal funding--allowing many of the currently uninsured in Michigan to be eligible for Medicaid. The waiver has drawbacks, however, and several mental health groups are in opposition.

A representative of the Michigan State Medical Society contacted our office with a request for sponsorship of the annual Capitol Checkup. He indicated that this year's theme would be pharmaceutical access, specifically prior authorization. When asked what the group's position on prior authorization was, he reported that many of the physicians are frustrated with the current policy due to the increased burden on their staffs. He went on to say that the best solution would be the legislation involving pharmaceutical companies paying Medicaid best price rebates to all state funded programs as it would replace the prior authorization system with unrestricted access for the participating companies.

In addition, I participated in several conference calls involving both the coalition and other groups. Several mental health groups are in the process of setting up a toll free number, so health care professionals, consumers and caregivers can relay their stories about the prescription policy. The volume of the calls would then be used to convince legislators that the policy has not functioned in the way the Department presented both prior to and after its implementation. The coalition members have located leaders for the

small breakfasts with legislators, and it seems that a variety of constituents will be present to educate legislators on their experiences.

Developments

Up to this point, the Pharmaceutical Research and Manufacturers of America have been neutral on the legislative alternative. There have been reports that some of the larger companies which provide deep discounts are now in opposition to the legislation and that PhRMA may, in fact, oppose the legislation openly. Despite this development, Pfizer's position would remain unchanged, and the campaign against prior authorization would continue without alteration. PhRMA is not advocating any other solutions or alternatives, and would simply be in opposition to both the current policy and the alternative.

Summary

The campaign against prior authorization has evolved into advocacy for the alternative legislation. The representatives with whom breakfasts have been scheduled were the most inquisitive of the Department at the hearing, and it has been reported that many legislators feel as if the Department had misled them regarding prior authorization. The legislative breakfasts, opportunities for public input and toll free number should provide means for the public to communicate their displeasure with the enacted policy. The process of informing legislators is now in action, and the outcome of this process will primarily determine the ultimate conclusion with regard to pharmaceutical access in the state of Michigan.

SPECIAL ARTICLE

EFFECTS OF MEDICAID DRUG-PAYMENT LIMITS ON ADMISSION TO HOSPITALS AND NURSING HOMES

STEPHEN B. SOUMERAI, Sc.D., DENNIS ROSS-DEGNAN, Sc.D., JERRY AVORN, M.D.,
THOMAS J. McLAUGHLIN, Sc.D., AND IGOR CHOUDNOVSKIY, B.S.

Abstract Background. Many state Medicaid programs limit the number of reimbursable medications that a patient can receive. We hypothesized that such limitations may lead to exacerbations of illness or to admissions to institutions where there are no caps on drug reimbursements.

Methods. We analyzed 36 months of Medicaid claims data from New Hampshire, which had a three-drug limit per patient for 11 of those months, and from New Jersey, which did not. The study patients in New Hampshire ($n = 411$) and a matched comparison cohort in New Jersey ($n = 1375$) were Medicaid recipients 60 years of age or older who in a base-line year had been taking three or more medications per month, including at least one maintenance drug for certain chronic diseases. Survival (defined as remaining in the community) and time-series analyses were conducted to determine the effect of the reimbursement cap on admissions to hospitals and nursing homes.

Results. The base-line demographic characteristics of the cohorts were nearly identical. In New Hampshire,

the 35 percent decline in the use of study drugs after the cap was applied was associated with an increase in rates of admission to nursing homes; no changes were observed in the comparison cohort ($RR = 1.8$; 95 percent confidence interval, 1.2 to 2.6). There was no significantly increased risk of hospitalization. Among the patients in New Hampshire who regularly took three or more study medications at base line, the relative risk of admission to a nursing home during the period of the cap was 2.2 (95 percent confidence interval, 1.2 to 4.1), and the risk of hospitalization was 1.2 (95 percent confidence interval, 0.8 to 1.6). When the cap was discontinued after 11 months, the use of medications returned nearly to base-line levels, and the excess risk of admission to a nursing home ceased. In general, the patients who were admitted to nursing homes did not return to the community.

Conclusions. Limiting reimbursement for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may increase Medicaid costs. (N Engl J Med 1991;325:1072-7.)

CONCERN has mounted that cost-containment policies implemented during the 1980s may be compromising the quality of care and the health of vulnerable populations, such as poor and chronically ill elderly people, although few studies have examined this question.^{1,2} Charges to the patient or monthly limits on medications and other "optional" services are characteristic of most Medicaid programs.³ Although such restrictions on specific services could increase admissions to hospitals and nursing homes among chronically ill elderly people, this has not been demonstrated in a controlled study. Decades of clinical research and experience document the effectiveness of many medications in treating both acute life-threatening illnesses and chronic debilitating conditions.⁴⁻⁶ Lack of compliance with drug therapy has been associated with increased admissions to hospitals and nursing homes.⁷⁻¹⁰ Logically, then, policies that reduce access to effective medications may increase the rate of adverse clinical outcomes and the accompanying costs.

In an earlier study¹¹ we examined the effects of a three-drug payment limit, or cap, on the use of med-

ications among 10,734 Medicaid patients in New Hampshire. Among 860 recipients of three or more drugs, the cap was associated with significant reductions in the receipt of several important medications (e.g., 28 to 30 percent reductions for insulin, thiazides, and furosemide) that were not offset by increased out-of-pocket purchases. When a copayment of \$1 per prescription replaced the cap one year later, the use of most agents quickly approached precap rates.

In that study, data were not available to measure possible changes in use of institutional services. One hypothesized effect of the cap was an increase in nursing home admissions, due either to deteriorating health or to a desire to shift to an environment exempt from the cap. If the loss of essential medications led to an acute deterioration in health, one might also expect increased hospital admissions. In the current study, we analyzed 36 months of additional nondrug claims and enrollment data from Medicaid to answer the following question: Among low-income, elderly Medicaid patients, is limiting access to medications associated with increased rates of admission to nursing homes and hospitals?

METHODS

Study Design

This study used survival (defined as remaining in the community) and interrupted time-series analyses to evaluate the effects of the drug-payment restriction. Outcome data included 36 months (July 1980 to June 1983) of patients' nursing home and hospital inpatient claims in two state Medicaid programs. We compared the rate of admission to nursing homes and hospitals before, during, and after the cap in a defined cohort of chronically ill elderly patients in the

From the Department of Social Medicine, Harvard Medical School (S.B.S., D.R.-D., T.J.M.), and the Program for the Analysis of Clinical Strategies and the Department of Medicine, Harvard Medical School and Beth Israel Hospital (J.A., I.C.), Boston. Address reprint requests to Dr. Soumerai at the Department of Social Medicine, Harvard Medical School, 643 Huntington Ave., Boston, MA 02115.

Supported by grants from the Agency for Health Care Policy and Research, Department of Health and Human Services (HS05947), the John A. Hartford Foundation, and the National Institute on Aging.

Presented in abstract form at the annual meeting of the Association for Health Services Research, Washington, D.C., June 19, 1990.

study state (New Hampshire) with the rate in an identically defined comparison cohort in a state without a cap (New Jersey).

The three-drug payment limit implemented by New Hampshire Medicaid during months 15 to 25 of the 36-month study period is described in detail in our previous report.¹¹ With less than two months' notice to providers and patients, the legislatively mandated cost-containment measure restricted most Medicaid patients to three prescriptions per month. After 11 months the cap was eliminated and replaced with a copayment of \$1 per prescription. The comparison state, New Jersey, was the only northeastern state whose Medicaid program had no cost-sharing requirements or payment limitations for drugs during the study period.

Availability and Quality of Data

Data on enrollment, the use of study drugs, and hospital and nursing home admissions came from the computerized Medicaid management information systems of the two states. Enrollment files were used to determine the age, sex, race, and category of enrollment of the patients, according to study month. Previous reports indicate that data from the Medicaid management information systems are highly reliable and valid for studying the prescribing of drugs or admission to nursing homes.¹²⁻¹⁶ Drug claims identified the product, number of units dispensed, patient, and date.

For every Medicaid resident of skilled-nursing and intermediate-care facilities, a monthly claim is submitted by the nursing home provider for basic services. Because the study population was already eligible for Medicaid at the beginning of the study, any nursing home stay would automatically be reimbursed from the first month of residence; we thus avoided the problem of missing data during periods when patients must expend their resources in order to reach eligibility levels.

Since all the members of the study cohorts were eligible for both Medicare and Medicaid, Medicare was the primary payer for hospital services. The Medicaid management information systems contain data on all such services for which Medicaid paid a deductible or coinsurance amount. For the first inpatient admission in each spell of illness, Medicaid pays a fixed deductible amount. We used the Medicaid data to determine inpatient hospital episodes by identifying each overnight service delivered at an acute care hospital for which the reimbursed amount was greater than or equal to the deductible amount for the current or previous year.

Definition of the Study Groups

The study groups represented a vulnerable, noninstitutionalized population of Medicaid patients over the age of 60 who were being treated for specific chronic illnesses at base line. Patients without Medicare coverage were excluded because in New Hampshire, patients enrolled only in Medicaid had limits on physicians' services and hospital days in addition to the cap on medications, whereas those enrolled in both Medicaid and Medicare ("crossover" patients) had stable coverage for these services. Patients were included in the study if they had 10 or more months of enrollment in Medicaid during the base-line year (July 1, 1980, to June 30, 1981); were 60 years of age or older and enrolled in Medicare by the start of the payment cap; were white (to control for the absence of nonwhite patients in the New Hampshire cohort); were living in the community at base line, with no nursing home claims during the 6 months before follow-up began; had an average of three or more prescriptions per month and at least one prescription per quarter during the base-line year; and used medication for one or more of five major chronic illnesses (diabetes, heart disease, chronic obstructive pulmonary disease and asthma, seizures, or conditions requiring the use of anticoagulants). Because outpatient diagnoses are often unreliable,¹⁶ the regular receipt, before the cap, of medications commonly used to treat these illnesses served as markers for them. To eliminate occasional users of these drugs, we defined regular users as patients receiving eight or more prescriptions in any category of marker medications during the base-line year, and at least one per quarter.

A panel of geriatricians, internists, and clinical pharmacists identified specific classes of marker medications, including antianginal drugs, loop diuretic agents, antiarrhythmic agents, bronchodilators, inhaled steroids, insulin, anticoagulants, and anticonvulsant agents,

hereafter referred to as the core drugs. Medications were chosen for study if their sudden withdrawal was liable to precipitate institutionalization. Agents were excluded if they were frequently used for nontargeted as well as targeted illnesses (e.g., beta-blockers are indicated for both hypertension and angina), had questionable efficacy, or were associated with less serious levels of illness. Thus, although they led to the exclusion of some patients with targeted illnesses, the strict criteria for regular drug use served to increase the base-line comparability of the study and comparison cohorts.

Regular Use of Other Medications

In addition to the core drugs, we also identified 21 other classes of drugs commonly used to treat chronic health problems. These included other agents to treat cardiovascular diseases (diuretic agents, beta-blockers, other antihypertensive drugs, and potassium supplements); oral hypoglycemic agents and diabetes-testing supplies; psychoactive medications (anxiolytic, hypnotic, antipsychotic, and antidepressant drugs); nonsteroidal antiinflammatory agents, analgesics with addictive potential, and those used to treat migraine; oral steroids; and medications to treat ulcers, thyroid disorders, glaucoma, parkinsonism, gout, and chronic diarrhea. As a measure of base-line comorbidity, we counted the number of these 26 classes of drugs for which each member of the study groups received eight or more prescriptions in the base-line year (Table 1).

Standardization of Use of Study Medications

To track drug use for the different study medications, we used base-line data on the entire Medicaid populations of both states to create an index of standardized monthly doses for each of the core medications. One standard dose equalled the median number of milligrams of active ingredient per month received by all the patients who filed a claim for each study drug.

Statistical Analysis

Using survival analysis, we measured the rate of admission to hospitals and nursing homes in New Hampshire and New Jersey during three periods: base line (April 1981 to August 1981), the cap (September 1981 to July 1982), and after the cap (August 1982 to June 1983).^{17,18} We also calculated the relative risks of institutional

Table 1. Base-Line Characteristics of the Study and Comparison Cohorts.

CHARACTERISTIC	NEW HAMPSHIRE STUDY COHORT (N = 411)	NEW JERSEY COMPARISON COHORT (N = 1375)
	percent	
Age (yr)		
60-69	27	21
70-79	43	46
≥80	30	33
Female sex	80	80
Regular use of core medications		
Cardiac	77	86
COPD and asthma*	19	15
Insulin	16	9
Anticonvulsants	6	7
Anticoagulants	1	2
Number of study medications used regularly†		
1	16	12
2	36	32
3	30	28
≥4	18	27
≥1 inpatient episodes during 6 mo before cap	25	23

*COPD denotes chronic obstructive pulmonary disease.

†The core medications plus the 21 other classes of drugs commonly used to treat chronic health problems.

ization and 95 percent two-sided confidence intervals in the study groups.¹⁹ We used segmented time-series regression models to estimate changes in drug use, including a constant term, a linear time trend, and terms to estimate changes in the mean level of use of core drugs during an "anticipatory" precap month (August 1981) and during the cap and copayment periods.¹¹

RESULTS

Background Characteristics of the Study Groups

The base-line demographic characteristics and rates of drug use were similar in the New Hampshire and New Jersey groups (Table 1). The high proportion of women in both cohorts (80 percent) reflects the predominance of women in frail, elderly populations. In the year before the cap policy was instituted, approximately four out of five patients in both cohorts were regular recipients of core medications indicated for heart disease; rates of regular use of medications for chronic obstructive pulmonary disease and asthma, diabetes, and seizures were all similar, as were rates of use of anticoagulant agents. The total number of classes of drugs taken regularly was slightly higher in the comparison cohort; we controlled for the potential effects of this difference through the stratified analyses reported below. Although patient-specific data on income were unavailable, both cohorts were very poor, with incomes substantially below federal poverty levels; at the time of the study, the monthly income of elderly recipients of supplemental security income who lived alone was about \$350 in both states.²⁰ During the follow-up period, similar proportions of patients (35 percent in New Hampshire and 28 percent in New Jersey) died or left the Medicaid program for other reasons.

Changes in the Use of Study Medications

During the base-line year the median number of standardized monthly doses of core drugs per month was stable at 2.8 in New Hampshire and 2.3 in New Jersey. There was no change in the use of these agents in New Jersey during the study period. In New Hampshire, however, the time series of drug use dropped by 35 percent, to 1.9 standardized monthly doses per patient per month after the cap was instituted (two-sided $P < 0.001$).

After the cap was replaced by the \$1 copayment, these rates rose almost to base-line levels.

Effects on Nursing Home Admissions

The most clearly observable effect of the payment cap in New Hampshire was an increase in nursing home admissions (Fig. 1). The proportions of patients entering nursing homes were similar in the study groups before the cap: 2.3 percent in New Hampshire and 2.1 percent in New Jersey. After the institution of the cap, there was a marked separation of the two survival curves showing the probability of remaining in the community; by the end of the 11-month cap

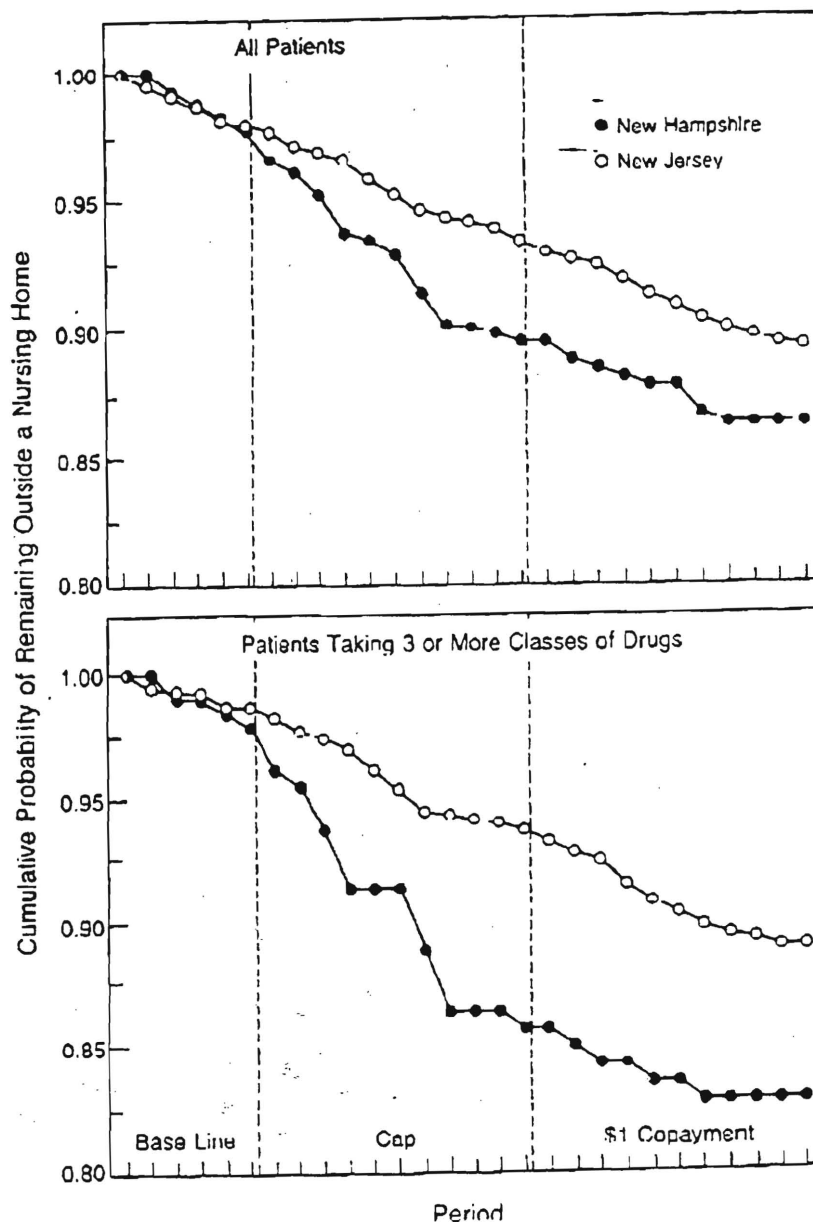


Figure 1. Cumulative Probability of Remaining outside a Nursing Home. The top panel shows the curves for all patients in the New Hampshire ($n = 411$) and New Jersey ($n = 1375$) groups. The bottom panel shows the curves for patients who regularly used drugs from three or more classes at base line ($n = 198$ for New Hampshire and 762 for New Jersey).

period, 10.6 percent of the New Hampshire patients and 6.6 percent of the New Jersey patients had been admitted to nursing homes. The difference between the two survival curves during this period was significant (two-sided $P = 0.006$), and the relative risk of admission associated with the cap was 1.8 (95 percent confidence interval, 1.2 to 2.6). After the cap policy was discontinued, the use of core drugs returned almost to precap levels and the excess risk of new admissions to nursing homes ceased, as evidenced by the approximately parallel curves.

Further analyses were stratified according to the proxy variable for comorbidity (the regular use of 3 or more of the 26 classes of drugs). Again, the rates of nursing home admission in the two states were similar before the cap began and after it was replaced with the \$1 copayment (Fig. 1). During the period of the cap, however, the excess risk of admission to a nursing home was even greater for these sicker patients in the study cohort, more than double the rate in the comparison cohort (relative risk = 2.2; 95 percent confidence interval, 1.2 to 4.1; two-sided $P = 0.0004$). By the end of the cap period, an estimated 14.4 percent of New Hampshire patients regularly taking drugs from three or more classes had entered nursing homes, as compared with only 6.2 percent of such patients in New Jersey. For the patients taking drugs from fewer than 3 of the 26 drug classes there was no significant difference between the study and comparison cohorts, indicating that the cap's adverse effect was most pronounced for the patients who were most disabled.

We next investigated whether this loss of independence tended to be permanent or temporary. Figure 2 shows trends in the proportions of patients residing in nursing homes in the two study groups. All the patients were included in this analysis until they died or became permanently ineligible. The data indicate that nursing home stays were not short-term. After the cap was instituted, there was a steady rise in the proportion of New Hampshire patients in nursing homes that persisted until the end of the cap period. By then, 7.7

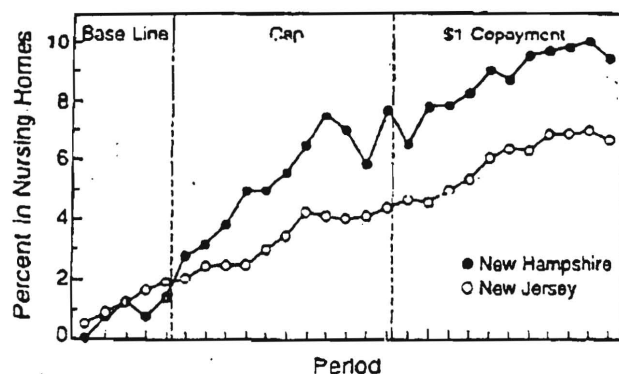


Figure 2. Monthly Proportions of Study Patients Residing in Nursing Homes.

The curves include all New Hampshire ($n = 411$) and New Jersey ($n = 1375$) patients.

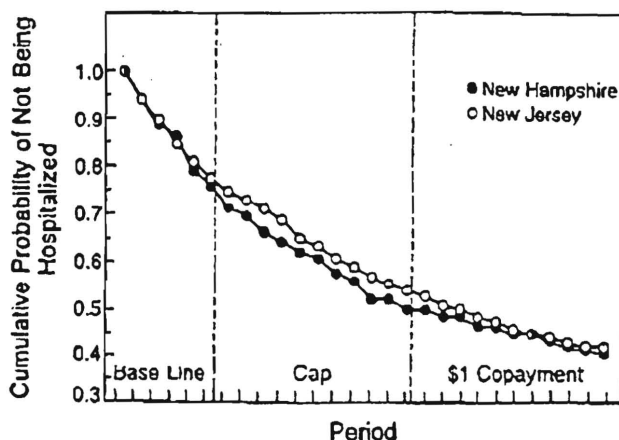


Figure 3. Cumulative Probability of Not Being Hospitalized.

The curves include the New Hampshire ($n = 198$) and New Jersey ($n = 762$) patients who regularly used drugs from three or more classes at base line.

percent of the 325 remaining New Hampshire patients were institutionalized, as compared with 4.4 percent of the 1147 New Jersey patients, even though the time series was approximately parallel before initiation of the cap and after its abandonment.

We also calculated the distribution of lengths of stay among the New Hampshire patients who entered nursing homes ($n = 46$). Among the 37 patients who entered nursing homes just before or during the period of the cap (for whom 12 or more months of follow-up were available until the end of observation), 32 percent stayed for 6 months or less and 57 percent had stayed for 1 year or more; 90 percent of the long-term residents were still in nursing homes during the final month of observation.

Effects on Hospital Admissions

Analyses of time to first inpatient hospital episode were similarly stratified according to the number of classes of drugs the patients took regularly. Patients who regularly used drugs from three or more classes had comparable rates of hospitalization before the cap was instituted (Fig. 3). After the introduction of the cap, there was a moderate trend toward increased hospitalization among the New Hampshire patients that did not reach statistical significance (relative risk = 1.2; 95 percent confidence interval, 0.8 to 1.6); this trend disappeared when the cap was replaced with the \$1 copayment policy (Fig. 3). No increased risk of hospitalization was found in the patients who used drugs from fewer than three classes before the cap.

DISCUSSION

Although quasi-experimental evaluations of policy changes can never provide ironclad evidence of cause-and-effect relations, our results provide strong indications of a direct relation between the introduction of a three-drug reimbursement limit, a resulting reduction in the use of medications, and an approximate doubling of the rate of nursing home admissions among

chronically ill elderly patients. Rates of admission to nursing homes among the study and comparison cohorts were similar before the cap was instituted, diverged soon after its introduction, when the use of medications declined, and once again became similar after the cap was abandoned. These effects were concentrated among patients who regularly used three or more study medications, indicating heightened vulnerability among patients with more than one chronic illness. A separate, ongoing analysis in New Hampshire also indicates an association between the rate of reduction in drug use due to the cap and the risk of institutionalization (data not shown).

Were nursing home admissions caused by declining health or by the desire to maintain the use of essential medications, because the three-drug limit did not apply in long-term care facilities? Since admission records were not available for this study, we could not distinguish between these two mechanisms of effect. The increase in nursing home admissions among the patients at highest risk suggests that the loss of medications could have exacerbated preexisting medical problems. However, because patients are often admitted to nursing homes without earlier hospitalization,²¹ and given case reports by New Hampshire Legal Assistance of several patients who were transferred to nursing homes to avoid the policy's effect, the cap probably precipitated nursing home admissions for financial reasons as well. Regardless of which mechanism explained the excess admissions, the economic impact of preventable institutionalization and its effects on quality of life are severe.

Although we observed a slight trend toward increased hospitalization during the period of the cap, the absence of a significant effect on rates of hospitalization deserves comment. Increases in the rate of hospitalization may have been too low to be measured against the high background rate in a chronically ill population. In addition, the measure used (time to first hospital episode) is insensitive to changes in the rates of repeated events; we unfortunately did not have access to data from the primary payer for hospital services, Medicare, which would have allowed time-series analyses of all admissions.

The study and comparison cohorts were well matched at base line for patterns of drug use, sex, and race, as well as nursing home and hospital use. The New Jersey cohort was slightly older and received more regular medications than the New Hampshire group, but this would be expected to reduce observed differences in outcomes. All the patients received more than 36 prescriptions in the base-line year, a rate of medication use strongly associated with fair-to-poor health in an earlier national study of Medicare beneficiaries.²² The increase in the rate of entry into nursing homes immediately after the initiation of the cap makes it less likely that differences in the patients' characteristics were responsible for these effects.

It is unlikely that other changes in policy influenced the observed changes in the rates of institutionalization. A potential confounder would have had to begin

at the initiation of the cap and end at its termination, which is improbable. Since all the study patients were eligible for Medicare, they were exempt from the limits on hospital and physicians' services imposed on non-Medicare patients in New Hampshire during the cap period. Changes in the supply of beds might influence the rate of admission to nursing homes.²³ However, the supply of nursing home beds per 1000 elderly people in New Hampshire actually declined by 3.5 percent from 1981 to 1982, the period during which we observed increases in the rates of admission as compared with those in New Jersey.²³

Previous studies have indicated that the New Jersey diagnosis-related-group program initiated in 1980 probably caused a slight decline in length of stay and a small increase of 0.8 percent per year in hospital admission rates.²⁴ The program, if it had any effect at all, would thus have shortened the time to first hospital admission slightly in the comparison cohort, resulting in a smaller relative difference between the two cohorts.

At present, about one fourth of state Medicaid programs have limits on drug reimbursement in effect. Our findings raise questions about the clinical and economic wisdom of such policies. Our best estimate of the excess person-months of nursing home use in the study cohort equals the difference between the proportions of the two study groups residing in nursing homes each month. During the 22-month observation period after the cap was instituted, this excess was estimated to be 171 person-months. Given New Hampshire Medicaid's daily reimbursement rate of \$59 in fiscal year 1982-1983 (the average of the rates for skilled-nursing facilities and intermediate-care facilities),²⁵ these excess months in nursing homes cost \$310,745. This underestimates the true cost, since it does not include other incremental expenses (e.g., physicians' services) and it assumes no months in nursing homes beyond the observation period. Additional increases in hospital and nursing home admissions in other vulnerable populations that we did not study (e.g., the chronically mentally ill) could raise such unintended costs well over the estimated statewide savings of \$300,000 to \$400,000 achieved by the cap.¹¹

Changes in health care reimbursement policies have probably had sizable effects on elderly and low-income patients over the past decade, but objective data on their effects on quality of care are extremely limited. The challenge for researchers and policy makers is to discover which cost-containment methods are most efficient in reducing ineffective care while preserving access to forms of medical technology that benefit both individual patients and society as a whole.

We are indebted to Dan Gilden, director of JFN Associates, for statistical and data processing support; to Elin Griesbach for coding and graphic presentation of data; to Jerry Gurwitz, M.D., and John Foley, Pharm.D., for excellent clinical advice; to Dr. Stephen Lagakos for important insights into the structuring of the statistical analysis; to the officers and staff of the New Hampshire and New Jersey Medicaid programs who supplied the data; and Laura Goldberg for assistance in the preparation of the manuscript.

REFERENCES

1. Fitzgerald JF, Fagan JF, Tierney WM, Dittus RS. Changing patterns of hip fracture care before and after implementation of prospective payment system. *JAMA* 1987;258:213-21.
2. Lurie N, Ward NB, Shapiro MF, Brook RH. Termination from Medi-Cal — does it affect health? *N Engl J Med* 1984;311:480-4.
3. Holahan JP, Cohen JW. Medicaid: the trade-off between cost containment and access to care. Washington, D.C.: Urban Institute Press, 1986.
4. Veterans Administration Cooperative Study Group on Antihypertensive Agents. Effects of treatment on morbidity in hypertension. *JAMA* 1967;202:1028-34.
5. *Idem*. Effects of treatment on morbidity in hypertension. *JAMA* 1970;213:1143-52.
6. The Norwegian Multicenter Study Group. Timolol-induced reduction in mortality and reinfarction in patients surviving acute myocardial infarction. *N Engl J Med* 1981;304:801-7.
7. Levy M, Mermelstein L, Hemo D. Medical admissions due to noncompliance with drug therapy. *Int J Clin Pharmacol Ther Toxicol* 1982;20:600-4.
8. Stason WB, Weinstein MC. Allocation of resources to manage hypertension. *N Engl J Med* 1977;296:732-9.
9. Strandberg LR. Drugs as a reason for nursing home admissions. *Am Health Care Assoc J* 1984;10(4):20-3.
10. Maronde RF, Chan LS, Larsen FJ, Strandberg LR, Laventurier MF, Sullivan SR. Underutilization of antihypertensive drugs and associated hospitalization. *Med Care* 1989;27:1159-66.
11. Soumerai SB, Avorn J, Ross-Degnan D, Gortmaker S. Payment restrictions for prescription drugs under Medicaid: effects on therapy, cost, and equity. *N Engl J Med* 1987;317:550-6.
12. Ray WA, Federspiel CF, Baugh DK, Dodds S. Interstate variation in elderly Medicaid nursing home populations: comparison of resident characteristics and medical care utilization. *Med Care* 1987;25:738-52.
13. Federspiel CF, Ray WA, Schaffner W. Medicaid records as a valid data source: the Tennessee experience. *Med Care* 1976;14:166-72.
14. Schaffner W, Ray WA, Federspiel CF, Müller WO. Improving antibiotic prescribing in office practice: a controlled trial of three educational methods. *JAMA* 1983;250:1728-32.
15. Avorn J, Soumerai SB. Improving drug-therapy decisions through educational outreach: a randomized controlled trial of academically-based "detailing." *N Engl J Med* 1983;308:1457-63.
16. Department of Commerce, National Technical Information Service. Medicaid data as a source for postmarketing surveillance information. Vol. 1. Technical report. Research Triangle Park, N.C.: Research Triangle Institute, 1984.
17. Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. *J Am Stat Assoc* 1958;53:457-81.
18. Mantel N. Evaluation of survival data and two new rank order statistics arising in its consideration. *Cancer Chemother Rep* 1966;50:163-70.
19. Cox DR. Regression models and life-tables. *J R Stat Soc [B]* 1972;34:187-220.
20. Health Care Financing Administration, Office of the Actuary. Health care financing program statistics: analysis of state Medicaid program characteristics, 1984. Washington, D.C.: Government Printing Office, 1985. (HCFA publication no. 03204.)
21. Ray WA, Federspiel CF, Baugh DK, Dodds S. Experience of a Medicaid nursing home entry cohort. *Health Care Financ Rev* 1989;10(4):51-63.
22. Public Health Service, National Center for Health Services Research and Health Care Technology Assessment. Prescribed medications: a summary of the use and expenditures by Medicare beneficiaries. Research findings 3. Rockville, Md.: Department of Health and Human Services, 1989. (DHHS publication no. (PHS) 89-3448.)
23. Harrington C, Swan JH, Grant LA. Nursing home bed capacity in the States, 1978-86. *Health Care Financ Rev* 1988;9(4):81-97.
24. Hsiao WC, Sapolsky HM, Dunn DL, Weiner SL. Lessons of the New Jersey DRO payment system. *Health Aff (Millwood)* 1986;5:32-45.
25. Health Care Financing Administration, Office of the Actuary. Health care financing program statistics: analysis of state Medicaid program characteristics, 1986. Washington, D.C.: Government Printing Office, 1987:87-90. (HCFA publication no. 03249.)

Industry Headache

States Square Off Against Drug Firms In Crusade on Prices

Michigan's New Experiment Leads Pfizer and Others To Stage a Boycott

Vioxx Doesn't Make the Cut

Efforts by state governments to cut prescription-drug prices are sweeping across the nation, posing a serious challenge to the U.S. pharmaceutical industry's mighty lobbying machine—and to its profits.

This summer, Florida announced that drug companies participating in its lucrative Medicaid program would need to provide special rebates. Maine restricted Medicaid access to expensive drugs while separately threatening companies with price controls if they didn't offer discounts to residents who don't have drug coverage. And this morning, Michigan plans to release a list of lower-cost drugs whose prices other drug companies must match in order to receive preferential treatment from state drug programs.

Pharmaceutical companies are fighting back with lawsuits and advertising campaigns, and rushing to stamp out similar movements in Louisiana, Missouri, Indiana and Maryland.

But some in the industry say the number of cost-cutting states may be reaching a critical mass. "Alone, they can be picked off,

but if they stand together, they can win," says Diane Rowland, executive director of the Kaiser Commission on Medicaid and the Uninsured, a Washington-based health-policy think tank.

At stake are potentially billions of dollars in sales, not just to states and public-aid programs but also to the private health-



John Engler

insurance market, which often is influenced by new developments in state policy. Equally worrisome to the industry, the latest developments signal that the battle has shifted away from Washington—where pharmaceutical giants have cultivated great influence—and to state capitals around the country, where it can be harder to fight back.

Surprisingly, the most damaging salvos haven't come from regulation-minded Democrats but influential Republican governors with close ties to the White House, including the president's brother, Florida Gov. Jeb Bush, and Michigan's Gov. John Engler.

"The political winds have changed," says Arkansas' Medicaid director, Ray Hanley, who personally helps speed the change by passing word of new developments with a flurry of e-mails to his colleagues. "I've got all 50 Medicaid directors on one button," he says.

Adds Michigan's Gov. Engler: "Michigan will be a signal for other states and other states will follow."

The changing climate began as the economy sputtered early in the Bush administration, drying up states' tax revenues. This forced them to confront the escalating cost of pharmaceutical drugs under Medicaid, a federal- and state-funded health plan for the poor and disabled. States collectively are forecast to spend around \$25 billion buying Medicaid drugs during the current fiscal year. Last year their purchases represented about 12% of total industry sales.

States were also disappointed when Congress failed to pass a prescription-

*By Wall Street Journal staff reporters
Russell Gold in Lansing, Mich., Scott
Hensley in New York and Andrew
Caffrey in Boston.*

drug benefit in Medicare, a health plan for the elderly. While the states don't help foot the Medicare bill, as they do with Medicaid, most have programs to help the elderly pay for their prescriptions. For states, pharmaceutical drugs were no longer a footnote in their budgets; they were quickly becoming a major line item.

In July, Florida became the first state since federal Medicaid laws were overhauled in 1990 to extract additional price concessions from drug makers. Under federal law, pharmaceutical companies that sell to state Medicaid programs must offer them the same prices they give their most-favored customers. Florida took this a step further, generally requiring companies to offer rebates averaging around 6% on top of those already-discounted prices.

Michigan's experiment is potentially even more serious, because it expands well beyond Medicaid-funded drugs, and because it takes dead aim at drug companies' freedom to set prices. Instead of taking as a starting point the prices offered to companies' most-favored customers, the Michigan experiment seeks to drive all prices down to a low common denominator. A similar movement in Europe, known as "reference pricing," has savaged drug-company profits there.

In Michigan, it works like this: A committee of 11 doctors and pharmacists, meeting privately in a windowless basement conference room, chose so-called "best-in-class" drugs in 40 categories that would get special treatment in the \$1.1 billion the state spends each year on prescription medicines.

The selected drugs will be guaranteed a handsome slice of the state expenditures in both Medicaid and a state-funded pro-

Please Turn to Page A13, Column 1

States Clash With Drug Industry

Over Price Controls

Continued From First Page

gram for the elderly. Doctors can prescribe drugs that aren't on the list but only after justifying their decision in a call to a phone bank of pharmacy technicians—a requirement expected to discourage use of those drugs. Thus, all companies wanting to sell drugs under these programs risk losing market share unless they agree to slash prices to also win a spot on the preferred list.

An early preview of the list shows that several of the biggest drug makers will be hit hard. Among pain relievers commonly prescribed for arthritis, for instance, generic ibuprofen and generic naproxen made the preferred grade, while the widely prescribed Celebrex, jointly marketed by Pfizer Inc. and Pharmacia Corp., and Vioxx from Merck & Co. didn't.

Although the state won't detail the potential savings, they appear to be large. According to Fred Ghannam, owner of Capitol Pharmacy, about one block from the state capitol building in Lansing, the retail price of a month's supply of generic prescription-strength naproxen is around \$21, while a comparable prescription for Celebrex is \$151.

Lumping the Old and the New

Drug makers complain that the program is flawed because bureaucrats lump old and new drugs together, declaring all medicines in a given category to be equivalent. This thwarts industry efforts to differentiate their newest wares—and, they say, gives them little incentive to spend money on research and development.

The industry's counterattack has been swift. Last Friday its trade association filed suit—the group's fourth against a state government in the past 16 months—seeking to block the Michigan program, scheduled to go into force in January. Meanwhile, six major drug companies refused to play by Michigan's new rules, declining to make any price concessions to guarantee a spot on the state's preferred list, or formulary, for those drugs not selected best in their class.

"We think they've gone too far," says Charles Hardwick, a senior vice president for government affairs at New York-based Pfizer, the world's largest pharmaceutical company, which declined to participate in the Michigan price-cutting program.

Early results from other states that have adopted programs less restrictive than Michigan's show both the potential upside for states and possible downside for companies that don't cut prices to get on the states' preferred lists of drugs.

Florida expects to save at least \$100 million this fiscal year. At the same time, sales to Medicaid of several drugs not on Florida's preferred list have plummeted: The market share of AstraZeneca's heartburn drug Prilosec in Florida dropped to 4% from 38% in the first three months since the preferred list went into effect, while Pre-

vacid, from TAP Pharmaceutical Products Inc., Lake Forest, Ill., saw its share rise to 65% from 43% over the same period.

Drug companies worry that doctors out of sheer habit will be more likely to prescribe Medicaid-preferred drugs to their non-Medicaid patients, as well. At Miller Drug of Bangor, Maine, which fills more than 1,000 prescriptions per day, pharmacists say they're seeing just such a trend. For instance, after Maine selected Madison, N.J.-based American Home Products Corp.'s Protonix as its preferred heartburn drug beginning this year, the medicine was dispensed for nearly 75% of Miller's Medicaid heartburn prescriptions, up from just 3% three quarters before. There was a smaller but still-noticeable increase for the rest of Miller's customers. Protonix was the dispensed drug for 13% of heartburn prescriptions, up from 3%.

The industry is fighting back most vigorously in the courtroom. As Michigan officials were developing their plan, the Pharmaceutical Research and Manufacturers of America, the Washington-based industry association known as PhRMA, filed a lawsuit against Florida in federal court in Tallahassee. The group argued that federal law allows states to limit access to Medicaid drugs only if they offer no clinical benefit, not if the manufacturer doesn't offer a large enough price cut. A hearing is scheduled for today.

"The state litigation is unique to the last few years, because states are becoming more aggressive in trying to regulate pharmaceutical prices," says PhRMA assistant general counsel Marjorie Powell.

So far, PhRMA has won only one case—killing a Vermont effort to use Medicaid to provide drug coverage for noneligible seniors. But the suits have had a chilling effect. Iowa and California are launching efforts to get drug companies to voluntarily offer discounts to seniors, partly because mandatory price-cut programs have sparked industry lawsuits. "If someone litigates—rightly or wrongly—it puts a stop to what you're doing. You cannot move forward," says Dr. Carol Kuhle, chairwoman of the nonprofit corporation Iowa created to run its new program.

The industry was slow to marshal forces to fight the Michigan program because state officials deliberately concealed what they were up to for several months.

Faced with Medicaid and other state-funded drug costs that doubled to \$1.1 billion over the past two years, state health officials needed to find \$42 million to plug a hole in their new budget and find some way to control escalating pharmaceutical costs long term. James Haveman, director of the community health department, which runs Medicaid, was convinced that Maine and Florida were heading in the right direction but wanted to go farther.

In June, he proposed to state lawmakers that the mandated price cuts be expanded beyond Medicaid to also cover the

state's senior drug-assistance program and other state-funded programs. But state Rep. Mickey Mortimer, chairman of a subcommittee handling this piece of the budget, balked. "I wanted to be sure we didn't put anybody at risk," he says, worried that patients would be denied access to needed drugs.

Novel Approach

With the budget at a standstill, Gov. Engler intervened, calling Mr. Mortimer and other top lawmakers to his office. Mr. Engler suggested a novel approach: pass a budget with broad language authorizing unspecified pharmacy practice changes by the end of September. In the meantime, state health officials would develop the specifics of the program. If Mr. Mortimer or his counterpart in the state senate didn't both like the resulting program, they would have a chance to block it. Within five minutes, a deal was struck.

During the three months he had to develop a plan, Mr. Haveman decided he didn't want to be slowed down by pharmaceutical companies applying lobbying pressure. He instructed his top deputies not to meet with or take phone calls from drug makers.

"I needed time to think and plan," says Mr. Haveman.

It was another lesson learned from other states, where intense industry lobbying had killed drug-rebate proposals. "The states have learned that if they are going to be able to negotiate deals and work against the drug companies, they have to do it behind closed doors," says Ms. Rowland of the Kaiser Commission. "If they do it in too open a way, they will be lobbied to death."

Industry officials were livid. "This was handled with speed and deception," says Stephen Scofes, the Lansing-based lobbyist for Eli Lilly & Co., Indianapolis, and Merck, who tried unsuccessfully to schedule a meeting with Mr. Haveman.

On Sept. 28, two days before the deadline imposed by the state budget, state health-department officials disclosed how its preferred list would be put together. Mindful that Florida's program had been sued by PhRMA for basing its list mainly on discounts offered by drug makers, Michi-

gan's lawyers suggested a different approach: A committee would justify its decisions based on clinical grounds. During three meetings, the committee scoured scientific journals and debated the benefits of drugs in 40 categories that account for the vast majority of state drug expenditures.

In early October, First Health Services Corp., a suburban Richmond-based subsidiary of First Health Group Corp., Downers Grove, Ill., contracted by the state to administer its pharmacy program, invited the companies to meetings in Richmond, Dallas and Lansing to tell them what discounts they would have to provide for their drugs to gain preferred status.

Drug companies say they were left in the dark during the crucial process that defined the categories of drugs and selected the so-called best-in-class drugs. "When we met with First Health Services, we discovered that, in fact, none of the terms of the agreements were open to negotiation," David Marin, an vice president for at Peapack, N.J.-based Pharmacia Corp., later wrote to state officials.

On Nov. 13, the day before lawmakers gave their final approval, Merck advised the state it would refuse to offer any rebates. Pfizer, Eli Lilly, Pharmacia, Johnson & Johnson, New Brunswick, N.J.; and Wyeth-Ayerst Laboratories, a unit of American Home Products, quickly followed.

On Nov. 30, PhRMA filed its lawsuit in state court in Lansing, alleging the way in which Michigan adopted the program violated the state constitution and state laws.

Both sides are taking risks. The six boycotting drug companies stand to lose market share to competitors that agreed to cut prices to get on the state's preferred list. But if doctors or patients balk because some of the six firms' most-prescribed drugs aren't included, that could force Michigan to back away from its program.

Whichever side prevails, says Arkansas' Mr. Hanley, other states are watching the battle closely, to help plot their next move. "If a huge state like Michigan can't do this, then smaller states like us probably can't either," he says. "I'm pulling for Michigan."

Injunction Blocks Michigan Medicine Law

By RUSSELL GOLD

Staff Reporter of THE WALL STREET JOURNAL

In a victory for the pharmaceuticals industry, a Michigan judge yesterday issued a preliminary injunction to block a state law that seeks price concessions from drug companies in exchange for inclusion on a list of preferred drugs.

The lawsuit was filed by the Pharmaceutical Research and Manufacturers of America, a Washington trade group. The group, known as PhRMA, opposes the growing number of state efforts to restrict access to prescription drugs as a way to control rising health-care costs.

Under the proposed Michigan program, doctors must call to seek permission to prescribe drugs that aren't on the state's preferred drug list. The preferred-drug law covers 1.6 million people in Medicaid and other state-funded health programs.

In his order granting the injunction, Ingham County Circuit Court Judge Lawrence M. Glazer ruled that the unorthodox manner of implementing the Michigan law—several prominent legislators were given what amounted to a veto over the policy after Gov. John Engler signed the law—violated the state constitution. The judge also was persuaded by arguments from several groups representing the mentally ill that restricting access to certain drugs could harm patients. The judge allowed those groups to join the lawsuit.

The Michigan Department of Community Health has filed an emergency appeal to the state appellate court and hopes to still be able to implement the preferred list on Jan. 14, as planned.

The state's preferred-drug list was developed by a committee of physicians and pharmacists who met last fall to select at least two "best-in-class" drugs in 40 different categories. These drugs would go on the preferred list. All other drugs would make the preferred list only if the makers cut their prices to equal the lowest-priced "best" drug. Several compa-

nies, including Pfizer Inc. and Merck & Co. refused to offer any price breaks.

The Michigan decision comes just days after a federal judge let stand a similar program implemented last year in Florida. Already, other states seeking budget savings are hoping to copy Florida. This week Colorado lawmakers plan to introduce a bill, modeled on Florida's program, to seek additional rebates for Medicaid drugs. The bill's sponsor, Sen. Penfield Tate, says he was encouraged by the Florida federal-court ruling. PhRMA has appealed the Florida case to the Eleventh U.S. Circuit Court of Appeals in Atlanta.

PhRMA was pleased with the Michigan ruling. Jan Faiks, assistant general counsel for PhRMA, says the preferred-drug list is harmful because it interferes with doctors' freedom to prescribe what they feel is the

most appropriate drug. "The state imposed itself between the patient and the doctor," she says. "We think that is of tremendous potential harm to the doctor-patient relationship and ultimately to the patient's health."

Mark Reinstein, vice president of the Mental Health Association in Michigan, one of the groups which joined the lawsuit, says the preferred list "was set up to deprive them [persons with mental illness] of access to certain drugs and that would hurt too many people."

Geralyn Lasher, a spokeswoman for the Michigan Department of Community Health, says if doctors want to prescribe a certain drug, the state law doesn't stop them. It just requires an extra effort. "If a drug is medically necessary, that is the drug a recipient will get," Ms. Lasher says. Michigan expected to save \$42 million this fiscal year from the program.

Wall Street Journal
January 8, 2002

Senior groups square off over Medicaid prescription program

By DEE-ANN DURBIN

03/12/2002

Associated Press Newswires

Copyright 2002. The Associated Press. All Rights Reserved.

LANSING, Mich. (AP) - Senior advocacy groups are taking opposite sides in the battle over the state's new prescription program for low-income patients.

The new state program, which took effect Feb. 1, allows doctors to prescribe only certain discounted medications to the 1.6 million patients who rely on Medicaid unless the doctors get state authorization for medications not on the list. The state expects to save around \$42 million this year with the program.

The Seniors Coalition, which has around 30,000 members in Michigan, came to the Capitol Tuesday to present lawmakers with a banner covered with signatures of seniors who oppose the prescription drug plan. Flora Green, the Seniors Coalition's national spokeswoman, said the program could harm seniors.

"The doctor-and-patient relationship has to be protected at all costs," said Green, 79, who lives in Utah. "How can someone who doesn't know me make a decision that supersedes my doctor?"

On the other side of the issue is the Michigan AARP, which has around 1.4 million Michigan members aged 50 and older. The AARP supports the program because it says the state must control prescription drug costs, which have reached \$1 billion per year.

"Prescription drug prices can be prohibitively expensive to those without drug coverage, and older persons tend to use more medications," Michigan AARP director Stephen Gools said in a news release.

"We believe the Michigan program is a sincere, effective attempt to insure that that state has the funds to provide prescription drugs to Medicaid recipients."

Green said she understood the need to control costs, but said the state should look for other ways to cut funding.

"Does anyone have the right to balance the budget on the backs of seniors?" she said.

The program is being challenged in court by a coalition of drug companies and mental health advocates. The Michigan Court of Appeals is expected to rule this spring on whether the program should remain in place. Both the Seniors Coalition and the AARP have filed briefs in that case. Meanwhile, state Sen. John Schwarz, R-Battle Creek, is sponsoring legislation that would require the state to place practicing physicians, pharmacists, drug company representatives and a patient advocate on the committee that decides which drugs are on the state list.

Gov. John Engler appointed the current members of that committee last fall without consulting the full Legislature. Drug companies weren't involved in the process.

"I question the wisdom of the present system," Schwarz said. "I believe it's really quite arbitrary."

But Schwarz, who is a surgeon, said he does support having a state list and requiring doctors to get permission before prescribing some drugs. Most health maintenance organizations have similar lists as a cost-saving measure, he said.

On the Net:

The Senior Coalition, <http://www.senior.org>

AARP, <http://www.aarp.org>

Michigan Department of Community Health, <http://www.mdch.state.mi.us>

April 9, 2002

Many on Medicaid Lack Drugs, Study Says

By ROBERT PEAR

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.

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.

Issue Brief

Findings from HSC



PRESCRIPTION DRUG ACCESS: NOT JUST A MEDICARE PROBLEM

by Peter J. Cunningham

While all state Medicaid programs provide outpatient prescription drug coverage, slightly more than one in four Medicaid patients ages 18-64 could not afford to fill at least one prescription in the last year, according to a new study by the Center for Studying Health System Change (HSC). A similar percentage of uninsured adults also had difficulty affording prescription medications. Faced with rapidly rising drug spending, many states have moved to control Medicaid prescription drug spending by imposing copayments, limiting the number of prescriptions and using other cost-containment methods. The study indicates that these state cost-control measures are contributing to Medicaid beneficiaries' prescription drug access problems. State and federal policy makers should keep in mind that the impact of these controls on Medicaid beneficiaries is likely to be greater than on privately insured people, given their higher need and lower incomes.'

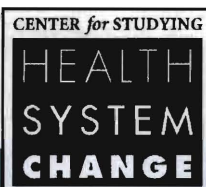
Nonelderly Have Problems Affording Drugs

While recent federal and state policy debates have focused on the prescription drug needs of the elderly in Medicare, many nonelderly adults also have problems affording prescription medications. According to HSC's 2000-01 Community Tracking Study Household Survey, nonelderly adults enrolled in Medicaid and those who are uninsured have the most problems affording prescription drugs—more than one out of four people in both groups did not get at least one prescription drug in the past year due to the cost. This is in sharp contrast to those in Medicare and those with employer-sponsored private insurance (see Figure 1).

The fact that adults with Medicaid coverage have problems affording prescription drugs is surprising. Medicaid is designed to ensure access to affordable medical care for the poorest and sickest Americans, and all state Medicaid programs provide drug coverage for most beneficiaries.² The wide gap in access to prescription drugs between nonelderly Medicaid enrollees and those with employer-sponsored coverage stands in contrast to other types of care. For example, people with Medicaid are more similar to those with employer-sponsored coverage in terms of unmet medical needs, having a usual source of care and contact with a physician in the past year.

Low Income, Poor Health Compound Problems

Despite the assistance Medicaid brings, beneficiaries' low incomes put them at much higher risk of being unable to afford prescription drugs. Half of nonelderly adult Medicaid beneficiaries have incomes below the federal poverty level, or \$8,590 for a single person in 2001 (see Table 1); three-quarters have incomes below 200 percent of poverty. By contrast, only 3 percent of people with employer-sponsored health coverage have incomes below the poverty level, while 14 percent have incomes below 200 percent of poverty.





State efforts

to control Medicaid

prescription drug

spending appear

to contribute to the

access problems

experienced by

Medicaid patients.

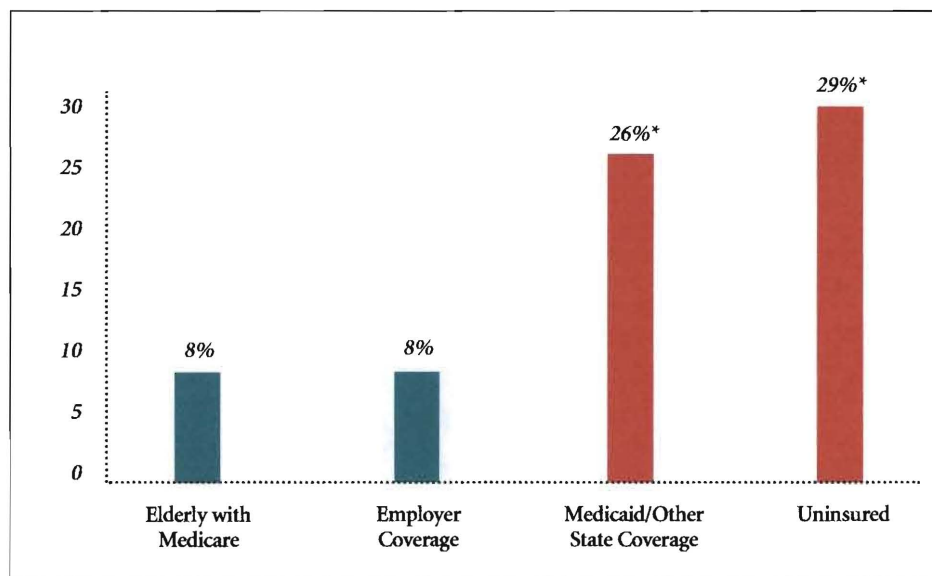
Web Exclusive



A more detailed analysis on this topic can be found in Research Report No. 5, "Affording Prescription Drugs—Not Just a Problem for the Elderly," available online at www.hschange.org.

Figure 1

Percent Not Obtaining Prescription Drug Due to Cost



* Difference from elderly with Medicare is statistically significant at $p < .05$ level.

Note: The categories of employer coverage, Medicaid coverage and the uninsured include adults ages 18-64.

Source: Community Tracking Study Household Survey, 2000-01

Medicaid beneficiaries also tend to be in poorer health. More than half of nonelderly adult beneficiaries are living with at least one chronic condition, such as diabetes, heart disease or depression, and more than one in four has two or more such conditions. In contrast, fewer than one-third of people with employer-sponsored coverage have a chronic condition, and only 10 percent have two or more conditions.

Cost barriers are greater for people living with chronic conditions across all categories of insurance coverage (see Table 2). Especially striking is the high proportion of Medicaid beneficiaries and uninsured people with chronic health conditions who report being unable to afford prescription drugs. Perhaps most troubling, more than 40 percent of Medicaid patients with two or more chronic conditions reported not obtaining prescription medications because of cost.

Thus, low incomes and high prevalence of health problems put adult Medicaid beneficiaries at high risk for experiencing problems in affording prescription medications. The study shows that these characteristics largely explain the wide gap between

Medicaid and privately insured persons when it comes to affording prescription medications. But why has Medicaid—which was designed to narrow this gap—failed in this one critical aspect of care?

Cost Containment Linked to Access Gaps

State efforts to control Medicaid prescription drug spending appear to contribute to the access problems experienced by Medicaid patients. In the past few years, many states have implemented a variety of methods to control escalating Medicaid prescription drug spending. These methods attempt to control spending by influencing physicians' prescribing patterns and patients' drug use.

Although methods vary from state to state, the most common include imposing nominal copayments, setting dispensing limits that restrict the number of prescriptions, mandating substitution of generic drugs for brand-name drugs, requiring prior authorization for certain drugs and issuing step-therapy protocols that require physicians to

Table 1
Health and Income Characteristics by Insurance Type (ages 18-64)

	MEDICAID/OTHER STATE COVERAGE	UNINSURED	EMPLOYER- SPONSORED COVERAGE
PERCENT WITH INCOMES BELOW POVERTY	50%	26%	3%
PERCENT WITH INCOMES BETWEEN 100% AND 200% OF POVERTY	25	30	11
PERCENT WITH 1 CHRONIC CONDITION*	23	14	20
PERCENT WITH 2 OR MORE CHRONIC CONDITIONS*	29	6	10

* Conditions asked about in the survey include diabetes, arthritis, asthma, chronic obstructive pulmonary disease, hypertension, coronary heart disease, cancer, benign prostate disease, depression and other serious medical problems that limit usual activities.

Note: Estimates reflect the percentage who responded "yes" to the following question: "During the past 12 months, was there any time you needed prescription medicines but didn't get them because you couldn't afford it?"

Source: Community Tracking Study Household Survey, 2000-01

Table 2
Percent Not Obtaining Prescription Drugs Due to Cost, by Insurance Coverage and Chronic Condition Status for Nonelderly Adults (ages 18-64)

	NO CHRONIC CONDITIONS	1 CHRONIC CONDITION*	2 OR MORE CHRONIC CONDITIONS*
ALL PERSONS AGES 18-64	10%	17%**	25%**
EMPLOYER-SPONSORED COVERAGE	6	11**	15**
MEDICAID AND OTHER STATE COVERAGE	16	26**	41**
UNINSURED	23	48**	61**

* Conditions asked about in the survey include diabetes, arthritis, asthma, chronic obstructive pulmonary disease, hypertension, coronary heart disease, cancer, benign prostate disease, depression and other serious medical problems that limit usual activities.

** Difference from persons with no chronic conditions is statistically significant at $p < .05$ level.

Note: Estimates reflect the percentage who responded "yes" to the following question: "During the past 12 months, was there any time you needed prescription medicines but didn't get them because you couldn't afford it?"

Source: Community Tracking Study Household Survey, 2000-01

try lower-cost drugs before prescribing more costly alternatives.³

Individually, these cost controls do not appear to significantly affect beneficiaries' access to prescription drugs. Most states, however, have implemented more than one cost-control measure, and the study shows that when multiple cost-control

measures are implemented, beneficiary access to prescription drugs is affected to a much greater extent (even after controlling for beneficiary characteristics and other community, state and regional factors). For example, beneficiaries in states that have implemented four or five cost-control measures were about twice as likely to

report cost barriers as those living in states with either one or no cost-control policies (see Figure 2).

States that implement multiple cost-control methods may be much more aggressive in trying to control Medicaid prescription drug spending. Not only would the cumulative effects of implementing these policies curtail access to a greater degree than any single method, but the individual methods themselves also may be more stringent (e.g., higher copayments, stricter dispensing limits) in states that are trying more aggressively to control spending. While greater Medicaid savings may be realized, an unintended consequence of aggressive cost-control policies might be a reduction in beneficiary access to needed prescription drugs.

Policy Implications

While the recent policy debate has focused on expanding prescription drug coverage for senior citizens enrolled in Medicare, the HSC study suggests that policy makers should not ignore the difficulties many nonelderly patients face in affording drugs, especially those who are uninsured or enrolled in Medicaid.

The importance of prescription drugs in medical care is growing as both the number of people using prescription drugs and the number of prescriptions per user are increasing.⁴ Expenditures for prescription drugs now account for about 11 percent of personal health care expenses, up from about 6 percent in 1988.⁵ The importance and cost of prescription drugs in medical care are likely to increase in the future with the development of new drug products, including those from the still-nascent biotechnology field. As drug products increase in both importance and cost, policy makers will be confronted with the challenge of making medications affordable and accessible to all Americans.

Many states currently are experiencing Medicaid budget shortfalls, and state officials often point to rising Medicaid prescription drug spending as a major cause. If these pressures continue or worsen, states may become even more aggressive in their efforts to control prescription drug expen-



Data Source

This Issue Brief presents findings from the 2000-01 Community Tracking Study Household Survey, a nationally representative telephone survey of the civilian, noninstitutionalized population, supplemented by in-person interviews of households without telephones to ensure proper representation. The survey contains observations on a total of about 60,000 persons. The sample for this study is based on 39,000 adults ages 18-64, including about 1,800 who are in Medicaid or state coverage. The response rate for the survey was around 60 percent.

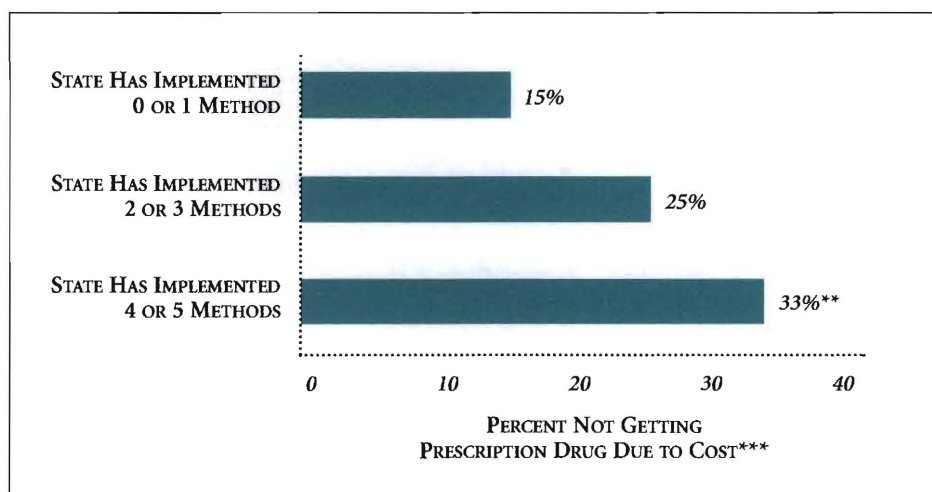
ISSUE BRIEFS are published by the Center for Studying Health System Change.

President: Paul B. Ginsburg
Director of Public Affairs: Richard Soriano
Editor: The Stein Group

For additional copies or to be added to the mailing list, contact HSC at:
600 Maryland Avenue, SW
Suite 550
Washington, DC 20024-2512
Tel: (202) 554-7549
(for publication information)
Tel: (202) 484-5261
(for general HSC information)
Fax: (202) 484-9258
www.hschange.org

Figure 2

Summary of Effects of State Medicaid Cost-Control Methods on Beneficiaries' Access to Prescription Drugs*



* These methods include copayments, limits on the number of prescriptions, mandatory substitution of generics for brand-name drugs, preauthorization requirements and step-therapy requirements.

** Difference from persons in states that have implemented 0 or 1 requirement is statistically significant at $p < .05$.

*** Estimates reflected regression-adjusted means that control for beneficiary characteristics and other community, state and regional factors.

Note: Sample includes persons ages 18-64 enrolled in Medicaid or state coverage programs.

Source: Community Tracking Study Household Survey, 2000-01

ditures, further restricting beneficiary access. While some may view these cost-control methods as consistent with those used by many private insurers, public officials should keep in mind that the impact of these methods on Medicaid beneficiaries is likely to be greater given their higher need and lower incomes. ●

Notes

1. This Issue Brief is based on Research Report No. 5, "Affording Prescription Drugs—Not Just a Problem for the Elderly," which can be found at www.hschange.org.
2. While prescription drugs are an optional benefit under Medicaid, all 50 states and the District of Columbia now offer such coverage.
3. Schwalberg, Renee, et al., *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights*, Kaiser Commission on Medicaid and the Uninsured (October 2001); Bruen, Brian K., *States Strive to Limit Medicaid*

Expenditures for Prescribed Drugs, Kaiser Commission on Medicaid and the Uninsured (February 2002).

4. Merlis, Mark, "Explaining the Growth in Prescription Drug Spending: A Review of Recent Studies," report prepared for the U.S. Department of Health and Human Services, Conference on Pharmaceutical Pricing Practices, Utilization, and Costs (August 2000).
5. Levit, Katherine, et al., "Inflation Spurs Health Spending in 2000," *Health Affairs*, Vol. 21, No. 1 (January/February 2002).

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25

- - - - -

:

PHARMACEUTICAL RESEARCH AND :
MANUFACTURERS OF AMERICA, :

Plaintiff, :

-vs- :

File No.

01-94627-AZ

MICHIGAN DEPARTMENT OF COMMUNITY :
HEALTH, :

Defendant. :

=

10
11

12

13

--

14
15

18
17
18
19

20
21
22

23

24

25

2

1 THE COURT: Good afternoon. Be seated,
2 please.

3 In 2000 the Michigan Supreme Court, as we all
4 know, decided the case of Blank versus Michigan
5 Department of Corrections, 462 Michigan 103. In that
6 case the Department of Corrections had promulgated a set
7 of rules without the approval of what was then known as
8 the joint committee on administrative rules, a body
9 appointed by both houses of the legislature consisting
10 of members of the legislature.

11 The legislature had enacted in 1977 a statute,
12 Public Act 108, which required the approval of that
13 joint committee on administrative rules before any
14 executive agency could promulgate rules which would have
15 the force and effect of law.

16 A three-member plurality of the Michigan
17 Supreme Court was joined by a fourth member, which thus
18 constituted a majority of the Supreme Court in holding
19 that the legislative veto over rules proposed by an
20 executive agency is inherently a legislative function
21 and is thus subject to the enactment and presentment
22 clauses of our state constitution, and this is true
23 whether the veto is exercised by the entire legislature
24 or something less than the entire legislature, such as,
25 in that case, a joint committee.

30th JUDICIAL CIRCUIT COURT
333 South Capitol Avenue Suite C Lansing, MI 48933

1 The Supreme Court further held that the
2 statute in question delegated to that joint committee
3 authority to perform what the Supreme Court recognized
4 as essentially legislative acts and that the essence of
5 this was the committee's ability to, quote, exert a
6 policy-making effect equivalent to amending or repealing
7 existing legislation, close quote, and, quote,
8 therefore, such actions are subject to the enactment and
9 presentment requirements of our 1963 constitution, close
10 quote. I'm quoting there from page 117, footnote eight,
11 and page 119 of the Blank decision.

12 Turning to the case before the Court today,
13 section 2204(1) requires the Department of Community
14 Health to submit proposed changes in its so-called
15 pharmacies' policies for non-HMO Medicaid recipients and
16 certain others, to the chairs of the relevant senate and
17 house appropriations sub-committees. There's nothing
18 unconstitutional about the requirement of submitting
19 that information. But subsection three gives those
20 chairs 30 days to veto any such changes in those
21 policies, and if those chairs do veto those policies,
22 those policies may no longer be executed.

23 This violates the Michigan constitution in
24 exactly the same manner and for exactly the same reason
25 as 1977 Public Act 108 was declared to do so in the

1 Blank case.

2 The Defendant argues that even if this
3 requirement is unconstitutional, it is moot because the
4 veto was not exercised within 30 days and cannot now be
5 exercised. But the fact that the chairs of the
6 committees did not disapprove of these changes does not
7 make the issue moot, in my opinion. The power of the
8 chairs, and in certain circumstances the senate and
9 house leaders, to disapprove these changes must
10 necessarily have been taken into account in designing
11 the changes. It is impossible to find out all of the
12 formal and informal communications which may have taken
13 place between these legislators and/or their staffs on
14 the one hand, and the people in the department who were
15 working on these policies on the other hand. But to
16 presume that there were no such communications defies
17 common sense. In other words, once the chairs had the
18 veto, it is clear that the wishes of the chairs, either
19 expressly communicated or inferred, would have to be
20 taken into account in designing the changes. This to me
21 taints the entire plan and makes it an unconstitutional
22 exercise.

23 In addition, I agree with the Plaintiffs that
24 the Defendant has failed to cite any substantive
25 statutory authority for the recovery of so-called

1 supplemental rebates. No where has the Defendant cited
2 or quoted any federal or state statute which authorizes
3 a state agency to require a rebate in addition to or
4 beyond that expressly authorized in section
5 1396R(C) (1) (c) (i) of the Social Security Act. To me
6 that section of the Social Security Act merely
7 recognizes that states may, if properly authorized by
8 their legislatures, create their own programs -- not
9 federal programs -- which result in lower prescription
10 drug prices. However, the section of the federal act
11 which has been cited by the Defendant does not and
12 cannot authorize states to do so. This can only be done
13 by the respective state legislatures through duly
14 enacted state statutes. So the department does not have
15 the authority to require supplemental rebates.

16 I agree with the Defendant that the so-called
17 veto provisions of section 2204(3) would be severable
18 under the tests laid out in MCL 8.5. That is to say,
19 although it is invalid, the rest of the statute is not
20 permeated with it. However, as I have said earlier, it
21 is my view that once this veto was granted, it must
22 necessarily have resulted in the executive department
23 taking into account the actual or presumed views of the
24 chairs of the respective sub-committees, and this taints
25 the entire exercise.

1 Now, as to the granting of an injunction. I
2 have said this morning that time constraints have not
3 allowed the Court to hear the separate motion of the
4 Intervening Plaintiffs for preliminary injunction.
5 However, I believe that I may take judicial notice of at
6 least some of the Intervening Plaintiffs' needs and
7 characteristics.

8 It is indisputable that disadvantaged persons
9 who are in need of continuing medical services which
10 involve prescription drugs will be affected by these
11 programs. The system of telephone appeals to a
12 technician and then to a pharmacist and then to a
13 physician, only during business hours, will undoubtedly
14 result in delays in the dispensing of the medications
15 which physicians judge to be medically necessary, and
16 this is putting the best face on it as described by
17 counsel for the Defendants. To me this constitutes
18 irreparable harm to those patients who would be so
19 affected.

20 I have not ruled that preapproval per se is
21 unlawful or unconstitutional. Indeed, it is expressly
22 authorized by the appropriations act. However, I may
23 take into account realistic expectations as to the
24 effects the preapproval process will have in determining
25 whether the unconstitutional provisions make it

1 necessary under the applicable standards for me to grant
2 the injunction.

3 The patients will be dramatically and
4 immediately affected in their personal health. The harm
5 to the state will be monetary. Thus, the balance of
6 prospective harms favors the Intervening Plaintiffs. In
7 saying this, I do not in any sense intend to make light
8 of what I believe we all know is a very serious fiscal
9 and budgetary situation for the state government, but
10 under my view of the constitutional and statutory
11 issues, I believe that the Plaintiffs are much more
12 harmed in this case, and that is to say, the Intervening
13 Plaintiffs, than the Defendant, and they are most likely
14 to prevail for the reasons I have already stated. Thus,
15 under the standards which I must follow, the injunction
16 must issue, and I will issue it.

17 I will ask that the attorneys for the
18 Plaintiffs get together and draft an appropriate
19 injunction with approval as to form by the Defendants,
20 not to be unreasonably withheld.

21 MS. MARSDEN: Your Honor, at this time we
22 would like to make an oral motion for a stay of the
23 preliminary injunction pending emergency appeal to the
24 Court of Appeals.

25 THE COURT: Response?

30th JUDICIAL CIRCUIT COURT
333 South Capitol Avenue Suite C Lansing, MI 48933

1 MR. MARSAC: We oppose that, Your Honor. I
2 think what the State is asking for is that they be
3 allowed to proceed with what the Court has already
4 determined to be an unconstitutional format. I think to
5 stay the proceedings at this point -- to stay the
6 issuance of the injunction would allow them to proceed
7 and engage in conduct that would render irreparable
8 injury to the parties, and I think it would be totally
9 inappropriate under the circumstances. It would
10 undermined the Court's order.

11 MR. CODY: We would join in that, Your Honor.

12 THE COURT: You may seek a stay from the Court
13 of Appeals along with your emergency appeal.

14 MS. MARSDEN: Your Honor, I have prepared a
15 proposed order denying stay. May I present it for your
16 signature?

17 THE COURT: Yes. Also seek approval as to
18 form.

19 MS. MARSDEN: Yes.

20 THE COURT: I want you also all to get
21 together this afternoon and try to get an injunction
22 batted out that I can sign it so that is not a barrier
23 to the State's ability to pursue this appeal.

24 MS. MARSDEN: Thank you, Your Honor.

25 THE COURT: And if that proves impossible, I

30th JUDICIAL CIRCUIT COURT
333 South Capitol Avenue Suite C Lansing, MI 48933

1 may have to consider an emergency motion tomorrow
2 afternoon. In other words, although I obviously feel
3 that I've made the correct decision, I don't want to do
4 anything to hobble the State's ability to see if the
5 Court of Appeals, and ultimately the Supreme Court, may
6 disagree.

7 MS. MARSDEN: Your Honor --

8 THE COURT: No dispute as to form on this
9 order of denying motion for stay?

10 MR. MARSAC: I don't believe so, Your Honor.

11 THE COURT: All right.

12 MR. CODY: None, Your Honor.

13 MS. MARSDEN: Your Honor, if I might suggest
14 now, and this, perhaps, would simplify matters, I would
15 not be opposed to an order saying that the injunction is
16 issued for the reasons stated by the Court, and then we
17 don't have a problem agreeing to the verbiage, and we'll
18 get a copy of the transcript. I think that's the
19 easiest way.

20 MR. MARSAC: Your Honor, we have an order that
21 we had attached to our motion. Perhaps counsel ought to
22 take a quick review of that and advise the Court whether
23 it's acceptable.

24 THE COURT: You folks take a look at that and
25 see if you can agree on something. I'll be in my

30th JUDICIAL CIRCUIT COURT
333 South Capitol Avenue Suite C Lansing, MI 48933

1 chambers in the foreseeable future. If you cannot
2 agree, then, as I say, tomorrow you can seek emergency
3 relief some time late in the morning, early afternoon.

4 I will give you back this order denying the
5 motion to stay, which I've signed. I think I have the
6 court file in my office. No, here it is. The clerks
7 downstairs on the first floor will be happy to take
8 this.

9 MS. MARSDEN: Thank you very much.

10 THE COURT: Anything else?

11 MR. MARSAC: That's all. We'll work on the
12 order.

13 THE COURT: Thank you.

14 (Whereupon hearing concluded at 3:16 p.m.)

15 * * *

16
17
18
19
20
21
22
23
24
25
30th JUDICIAL CIRCUIT COURT

333 South Capitol Avenue Suite C Lansing, MI 48933

CURRENT 2003 BUDGET LANGUAGE

Page 49

- 14 Sec 1627 . (1) The department shall use provisions specified under Section 1927 of title XIX of the social security act, 42 U.S.C. 1396r-8, to secure quarterly rebates from pharmaceutical manufacturers for drugs dispensed to participants in state-funded programs.
- 19 2) for products distributed by pharmaceutical manufacturers not providing quarterly rebates as listed in subsection (1), the department may require preauthorization for prescriptions dispensed to participants in state-funded programs.

AMEND SEC. 1627 OF THE 2003 BUDGET BILL TO READ AS FOLLOWS:

Sec. 16287 . (1) The department may negotiate with pharmaceutical manufacturers to obtain the same level of quarterly rebates as specified under Section 1927 of title XIX of the social security act, 42 U.S.C. 1396r-8 for drugs dispensed to Medicaid recipients enrolled in managed care plans and to participants in the following state-funded programs: Elderly Prescription Insurance Coverage Program (EPIC), MI Family, Children With Special Health Care Needs, Wayne County Pluscare and MI Department of Corrections.

2) Products of pharmaceutical manufacturers that provide quarterly rebates pursuant to subsection (1), shall be made available in the Medicaid program and to the participants in the programs listed in subsection (1) without prior authorization or other restrictions.

SENATE BILL No. 1101

February 13, 2002, Introduced by Senators Gougeon, Schwarz, Johnson and Smith and referred to the Committee on Appropriations.

EXECUTIVE BUDGET BILL

A bill to make appropriations for the department of community health and certain state purposes related to aging, mental health, public health, and medical services for the fiscal year ending September 30, 2003; to provide for the expenditure of such appropriations; to create funds; to provide for reports; to prescribe the powers and duties of certain local and state agencies and departments; and to provide for disposition of fees and other income received by the various state agencies.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

PART 1

LINE-ITEM APPROPRIATIONS

1 (2) When carved-out of the capitation rate for managed care
2 recipients, the pharmaceutical dispensing fee shall be \$3.77 or
3 the pharmacy's usual or customary cash charge or the usual charge
4 allowed by the recipients's medicaid HMO, whichever is less.

5 (3) The department shall require a prescription copayment for
6 medicaid recipients except as prohibited by federal or state law
7 or regulation.

8 Sec. 1624. An additional \$20,000,000.00 in tobacco settlement
9 funds are hereby appropriated to the elder prescription insurance
10 coverage program if the state budget director certifies that the
11 federal funds appropriated to that program are unavailable and
12 that sufficient tobacco settlement revenue is available to finance
13 this appropriation.

14 Sec. 1627. (1) The department shall use provisions specified
15 under section 1927 of title XIX of the social security act, 42
16 U.S.C. 1396r-8, to secure quarterly rebates from pharmaceutical
17 manufacturers for outpatient drugs dispensed to participants in
18 state-funded programs.

19 2) For products distributed by pharmaceutical manufacturers
20 not providing quarterly rebates as listed in subsection (1), the
21 department may require preauthorization for prescriptions
22 dispensed to participants in state-funded programs.

23 Sec. 1631. The department shall require copayments on dental,
24 podiatric, chiropractic, vision, and hearing aid services provided
25 to Medicaid recipients, except as prohibited by federal or state
26 law or regulation.

27 Sec. 1641. An institutional provider that is required to
28 submit a cost report under the medical services program shall

SB 1101, As Passed Senate, March 20, 2002

Senate Bill No. 1101

75

1 Medicaid, unless subsequent consultation with the prescribing physician
2 indicates otherwise.

3 Sec. 1624. (1) An additional \$20,000,000.00 from the tobacco set-
4 tlement trust fund is appropriated to the elder prescription insurance
5 coverage program for fiscal year 2002-2003 if the state budget director
6 certifies that the federal funds appropriated to that program are
7 unavailable and that sufficient tobacco settlement revenue is available
8 to finance this appropriation. As used in this section, "tobacco settle-
9 ment revenue" and "tobacco settlement trust fund" mean those terms as
10 defined in section 2 of the Michigan trust fund act, 2000 PA 489,
11 MCL 12.252.

12 (2) None of the tobacco settlement or other state restricted revenue
13 appropriated by the department to the EPIC program in fiscal year
14 2001-2002 shall lapse.

15 (3) The department shall place any funds that would have lapsed in a
16 reserve account for the sole purpose of providing revenue to fund the
17 EPIC program during fiscal year 2002-2003, in the event the proposed fed-
18 eral revenue to enhance EPIC program funding is not available.

19 (4) If the proposed federal funds become available, the reserved
20 tobacco settlement funds may either be lapsed to the tobacco settlement
21 trust fund or the Medicaid trust fund.

22 Sec. 1627. (1) The department may negotiate with pharmaceutical
23 manufacturers to obtain the same level of quarterly rebates described in
24 section 1927 of title XIX, 42 U.S.C. 1396r-8, for drugs dispensed to
25 Medicaid recipients enrolled in managed care plans and to participants in
26 the eligible programs.

S06627'02 (S-1)

SB 1101, As Passed Senate, March 20, 2002

Senate Bill No. 1101

76

1 (2) The program described in subsection (1) shall meet all of the
2 following:

3 (a) The rebates shall be payable for drugs dispensed to Medicaid
4 recipients enrolled in managed care plans only upon written confirmation
5 by the United States secretary of health and human services that the
6 rebates are not included in computing the manufacturer's best price as
7 defined in section 1927(c)(1)(C) of title XIX, 42 U.S.C. 1396r-8.

8 (b) The rebates shall be payable for drugs dispensed to participants
9 in each of the eligible programs only upon written confirmation by the
10 United States secretary of health and human services that the rebates
11 paid for each eligible program are not included in computing the
12 manufacturer's best price as defined in section 1927(c)(1)(C) of title
13 XIX, 42 U.S.C. 1396r-8.

14 (c) The per unit rebate amount reported by each participating phar-
15 maceutical manufacturer to the state for purposes of this section shall
16 be maintained in confidence and used only for purposes of administering
17 this program, and shall not be disclosed in a form that reveals directly
18 or indirectly the rebate amount for a specific drug or rebates payable by
19 a pharmaceutical manufacturer.

20 (3) Pharmaceutical manufacturers that provide quarterly rebates pur-
21 suant to subsection (1) for all of their products dispensed for all par-
22 ticipants in all eligible programs shall have all of their products made
23 available without prior authorization or other restrictions in the
24 Medicaid program, except for those drugs for which the department
25 required prior authorization during fiscal year 2000-2001 and except for
26 those drugs dispensed to Medicaid recipients enrolled in health plans.

SB 1101, As Passed Senate, March 20, 2002

Senate Bill No. 1101

77

1 (4) As used in this section, "eligible programs" means the following
2 programs funded by this state: the elder prescription insurance coverage
3 program, MIFamily or its predecessor programs, children's special health
4 care services, Wayne County pluscare, and any medical care program oper-
5 ated by the department of corrections or another state facility.

6 Sec. 1628. It is the intent of the legislature that if the savings
7 for Medicaid pharmacy rebates exceed the amount budgeted in this act, the
8 savings shall first be used to offset any increase in pharmacy costs
9 above that budgeted in this act and then to support and expand coverage
10 under the EPIC program.

11 Sec. 1630. Medicaid adult dental services, podiatric services, and
12 chiropractic services shall continue at not less than the level in effect
13 on October 1, 1996, except that reasonable utilization limitations may be
14 adopted in order to prevent excess utilization. The department shall not
15 impose utilization restrictions on chiropractic services unless a recipi-
16 ent has exceeded 18 office visits within 1 year.

17 Sec. 1631. The department shall require copayments on dental, podi-
18 atric, chiropractic, vision, and hearing aid services provided to
19 Medicaid recipients, except as prohibited by federal or state law or
20 regulation.

21 Sec. 1633. From the funds appropriated in part 1 for auxiliary med-
22 ical services, the department shall expand the healthy kids dental pro-
23 gram statewide if funds become available specifically for expansion of
24 the program.

25 Sec. 1634. (1) From the funds appropriated in part 1 for ambulance
26 services, the department shall continue the 5% increase in payment rates

Corporate Affairs
Pfizer Inc
209 North Walnut, Suite C
Lansing, MI 48933
Tel 517 485 8301 Fax 517 485 8525
Email bill.howe@pfizer.com



C. William Howe
Manager
State Government Relations

April 8, 2002

*Dr. David Tandy
Director, College Scholars Program
1101 McClung Tower and Plaza
Knoxville, TN 37996*

Re: Ms. Hannah Michelle Kiser

Dear Dr. Tandy:

The purpose of this letter is to provide you with my assessment of Ms. Hannah Kiser's performance during her internship with Pfizer's Michigan Office of State Government Relations. I also want to take this opportunity to express my sincere appreciation to you and the other members of the College Scholars Senior Project Committee for your willingness to consider and ultimately approve Ms. Kiser's participation in the Pfizer Internship program from January 2, 2002 through April 19, 2002.

In the various administrative positions that I have occupied within the public and private sectors during the past thirty years, I have had the opportunity to supervise over sixty interns and can state, without hesitation, that Ms. Kiser is the most professional and responsible intern I have ever had the opportunity to supervise. Certainly, her excellent performance is a tribute to herself, your individual educational efforts and the University of Tennessee.

Ms. Hannah Michelle Kiser

To the extent possible, I endeavor to allow an intern to become a part of the team effort within the office to accomplish our assigned tasks and responsibilities. I attempt to assign intern responsibilities commensurate with the intern's abilities, personality and work ethic to provide them with the best experience possible. In this regard, Ms. Kiser's completion of a number of diverse and difficult tasks has been truly impressive.

I believe Ms. Kiser has gained significant knowledge of the critical business issues impacting the pharmaceutical industry, the challenges involved with impacting public policy issues through legislation and the difficulty as well as the importance of building and maintaining grassroots relationships.

Although you are aware of Ms. Kiser's activities through her submission of weekly reports, I think it worthy of reiterating the significance of what Ms. Kiser has accomplished:

- Initiated contact and developed relationships with voluntary health associations and senior center representatives in Detroit, Grand Rapids and Lansing areas in an effort to build a grassroots coalition to impact public policy legislation*
- Assisted with the coordination and planning of a meeting of over 30 organizations concerning Medicaid/Medicare related issues.*
- Provided significant contributions to Pfizer's team effort to develop power-point presentations pertaining to the Pfizer Share Card prescription medication program and the adverse impact of the Medicaid Prescription Drug "prior authorization" policies*
- Completed numerous professional, informative and effective presentations to a variety of audiences concerning Pfizer's Share Card prescription medication program and the adverse impact of the Medicaid Prescription Drug "prior authorization" policies*

Page 3

Hannah Michelle Kiser

- *With limited guidance, successfully solicited the participation of various voluntary health and senior center organizations to serve as the Board of Directors for the Seniors for Prescription Drug Fairness coalition*
- *Served as the coordinator of the Prescription Drug Fairness coalition through facilitating email and conference call communications, preparing agendas for Board meetings, securing the necessary bank documents and serving as an ongoing informational resource for coalition members*
- *Functioned as a primary contact for internal Pfizer personnel and consultant firms engaged in an effort to influence the public policy issue relating to the Medicaid "prior authorization" program through the legislative process*

Additionally, Ms. Kiser's dedication, exceptional analytical talents, professional and effective oral and written communication skills and aptitude for quickly assimilating salient issues from significant amounts of data are very impressive. A very intelligent individual with excellent problem solving abilities which, combined with her compassionate understanding of others, has been a tremendous asset to Pfizer during her internship.

Thank you for the opportunity to have Ms. Kiser participate in our Pfizer internship program, as she certainly is a remarkable young woman who possesses skills and abilities beyond her years.

Sincerely,



C. William Howe

Manager

State Government Relations

Works Cited

Cunningham, Peter J. "Prescription Drug Access: Not Just A Medicare Problem." Center for Studying Health System Change April 2002 <<http://www.hschange.org/CONTENT/429>>.

Durbin, Dee-Ann. "Senior Groups Square Off Over Medicaid Prescription Program." AP Newswires 12 Mar. 2002.

Gold, Russell, Scott Hensley, and Andrew Caffrey. "States Square Off Against Drug Firms in Crusade on Prices; Michigan's New Experiment Leads Pfizer and Others To Stage a Boycott." New York Times 7 Dec. 2001: A1.

Gold, Russell. "Injunction Blocks Michigan Medicine Law." Wall Street Journal 8 Jan. 2002: A4.

Pear, Robert. "Many on Medicaid Lack Drugs, Study Says." New York Times 9 Apr. 2002: A22.

Soumerai, Stephen B., "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes." The New England Journal of Medicine 325 (1991): 1072-1077.