No. 01-188

In The
Supreme Court of the United States

Pharmaceutical Research & Manufacturers
of America,

Petitioner,

v.

Kevin Concannon, Commissioner,
Maine Department of Human Services, and
G. Steven Rowe, Attorney General of Maine,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

AMICUS CURIAE BRIEF OF LEGAL SERVICES ORGANIZATIONS REPRESENTING MEDICAID BENEFICIARIES IN SUPPORT OF NEITHER PARTY

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INTERESTS OF *AMICI CURIAE*

Amici represent low-income Medicaid beneficiaries in two states in which the type of drug formulary scheme with prior authorization/supplemental rebates at issue in this case has been implemented (Florida) or is about to be implemented (Connecticut).[1] These beneficiaries have a direct interest in this litigation because prior authorization, a necessary component of the scheme at issue, can result, and has resulted, in other states, in significant restrictions in access to prescription drugs for needy Medicaid beneficiaries. Although PhRMA has purported to represent the interests of Medicaid clients in this litigation, it is clearly motivated **not** by such concerns but by the profit interests of its members, and therefore it cannot adequately present the concerns of low-income Medicaid clients in the various states where the challenged scheme has been or is soon to be implemented. In addition, given the arguments being made by PhRMA, any decision on the legality of the Maine scheme will likely include an assessment of the impact of that scheme on Medicaid beneficiaries, such that the Court will benefit from hearing their perspective.

PRELIMINARY STATEMENT

This brief does not address the legality or illegality under the Medicaid Act or Commerce Clause of the Maine Rx scheme consisting of supplemental rebates and prior authorization imposed on Medicaid recipients with respect to those drugs manufactured by companies which refuse to pay them. Pharmaceutical manufacturers engage in a variety of practices designed to artificially inflate the prices of prescription drugs. States understandably seek to combat this

[1] Consent to the filing of this brief has been obtained from both parties to this litigation. No party or counsel for a party in this litigation has contributed to the writing of any part of this brief. No monetary contribution toward this brief has been provided by any entity other than *amicus curiae*.

trend, since a significant and growing proportion of their expenditures under their respective Medicaid programs are for prescription drugs. However, the particular state practice of prior authorization ("PA") has the direct consequence of restricting access to prescription drugs for Medicaid recipients, and the specific scheme at issue intentionally restricts access in order to induce drug manufactures to pay supplemental rebates precisely to avoid these restrictions.

As the Court has noted, in creating the Medicaid program, Congress recognized that "'these people are the most needy in the country and it is appropriate for medical care costs to be met, first, for these people.' " Schweicker v. Hogan, 457 U.S. 569, 590 (1982), quoting H.R. Rep. No. 213, 89th Cong., 1st Sess., 66 (1965). It is therefore important for the Court to recognize the potential harm to Medicaid clients when PA is imposed without due consideration of the interests, needs and special problems of Medicaid beneficiaries, as well as the protections for such beneficiaries intended by Congress.

To assist the Court, *amici* summarize the basic legal protections for Medicaid clients set forth in the Medicaid Act and describe some of the problems with PA for patients generally. They then discuss the particular problems for Medicaid clients created by PA, particularly as it has been imposed in some other states.

RELEVANT MEDICAID PROVISIONS

Congress adopted the Medicaid program in order to "furnish ... medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services...." 42 U.S.C. § 1396. With that overarching purpose, Congress has imposed strict and detailed requirements on state Medicaid plans in order to protect Medicaid beneficiaries, as set forth in 42

U.S.C. § 1396a. One of these requirements is that each state's Medicaid plan "provide such safeguards as may be necessary to assure that ... care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients." 42 U.S.C. § 1396a(a)(19).

Another important requirement applicable to all categories of services under Medicaid is that assistance under the Medicaid program "be furnished with *reasonable promptness* to all eligible individuals." 42 U.S.C. § 1396a(a)(8)(emphasis added). And related to this requirement is the mandate that the state plan "provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness." 42 U.S.C. § 1396a(a)(3). "Reasonable promptness" has long been held to apply to requests for individual services under Medicaid, as well as eligibility for Medicaid at large. See Ladd v. Thomas, 962 F. Supp. 284, 290-91 (D. Conn. 1997); Kessler v. Blum, 591 F. Supp. 1093 (S.D.N.Y. 1984). See also 42 C.F.R. §§ 435.906 and 435.930(a). Thus, in order to comply with these provisions, the administrative procedures of a state, including those with respect to any prior authorization system, must assure prompt access to all covered treatments under a given state's Medicaid program, and, if services are denied, must do so only pursuant to an individualized determination of medical necessity, and in compliance with due process requirements. See Weaver v. Reagan, 886 F.2d 194, 199-200 (8th Cir. 1989); Visser v Taylor, 756 F. Supp. 501, 507 (D. Kan. 1990); Jeneski v. Myers, 209 Cal. Rptr. 178, 189 (Cal. Ct. of App. 1985).

Congress also provided that any system of prior authorization for prescription drugs under a fee-for-service Medicaid program must have specific protections, including a 24-hour

turnaround time on all requests for prior authorization, and an automatic three-day supply in emergency situations. 42 U.S.C. § 1396r-8(d)(5). However, as discussed below, these pharmacy-specific protections do not protect the thousands of Medicaid beneficiaries whose requests for non-formulary drugs are denied or who, because of confusion and ignorance of PA requirements, are unable to even initiate the PA process.

INHERENT PROBLEMS WITH PRIOR AUTHORIZATION

Prior authorization for prescription drugs is inherently problematic for patients for several reasons, most of which relate **not** to the prior authorization process itself, but to the failure of the process to even be initiated, owing to ignorance of the system and its details, among both patients and their doctors. Each of these problems for patients generally, whether or not they are covered under a Medicaid program, is discussed below.

First, Medicaid is not the only health insurance program that applies PA to prescription drugs. Each plan that imposes PA has sharply varying rules as to when it is imposed and how one requests PA. United States General Accounting Office, *PRESCRIPTION DRUG BENEFITS: Impact of Medicare HMOs' Use of Formularies on Beneficiaries*, GAO/T-HEHS-99-171, at 4 (July 20, 1999)(Statement of William J. Stanton before the Special Committee on Aging, U.S. Senate) (available on line at www.gao.gov). Physicians typically must deal with many health plans to run a practice. Many health plans have their own unique formulary, which is premised in part upon whatever current agreements the plan has made with specific drug manufacturers -- whichever drug is the least expensive in a given classification for that particular plan will tend to be on the formulary; the others in the classification will generally not be on the formulary. Id. at 3-4. Moreover, health plans change their formularies with some frequency

(generally, at least quarterly), based on the introduction of new drugs and, more importantly, renegotiation by each plan with the drug companies, based on the availability of new generic products and other issues. The number and sheer length of these drug formularies create enormous difficulty for physicians to keep track of which drugs are on which formularies in any given month or quarter. As a result, it is not uncommon for physicians to prescribe drugs which are not on the formulary of the insurance plan for a particular patient (assuming that the doctor even knows what plan is paying for the prescribed medication at the time it is prescribed) without first requesting the necessary PA.

Second, because patients in any health plan routinely obtain access to prescription drugs by presenting a prescription at the pharmacy, expectations are created that this is the manner in which one **should** proceed to obtain drugs prescribed by a physician. In fact, this procedure generally works for patients. However, in those cases in which PA is required because the drug is not on the formulary, but such authorization has not previously been obtained, the patient presents the prescription and it is not filled.

Third, when the prescription is denied at the pharmacy due to the lack of PA, this information is often not accurately communicated to patients such that they even know about the availability of PA, let alone the procedure to obtain it. The way that patients **might** learn of such authorization requirements is through the pharmacist, who types in the request for PA on his or her computer terminal. This computer is linked to the specific health insurer or HMO's pharmacy benefit management computer system. A "yes" or "no" to payment is automatically provided without any human intervention, based on the computer program run by the pharmacy benefit management company, and the pharmacist can convey to the patient the result so obtained. See

Hernandez v. Medows, Case No. 02-20964, 2002 WL 31060425, at *5 (S.D.Fla. Aug. 26, 2002)(Ruling Granting Class Certification). However, often the automatic computerized response indicates a rejection for lack of coverage, without indicating that the drug may, in fact, be obtained through PA. Particularly in this situation, the pharmacist is likely to suggest either out-of-pocket payment for the drug or that the patient contact his or her doctor to obtain a prescription for a different drug. The result is that the patient generally is presented with the choice of either direct payment or receiving no drug at all.

Fourth, because some commercial plans use a "closed" formulary, under which non-listed drugs are simply unavailable, the physician may not know that non-listed drugs are available for Medicaid patients through PA. Even if he or she is aware that a non-formulary drug is available through PA through a particular plan, the physician will often change to a different drug which is on the formulary in order to avoid going through a burdensome PA process, see *Report on Prescription Access Hotline (April 22- June 14, 2002), Final Statistical Report* (Mental Health Association in Michigan and Michigan Association for Children with Emotional Disorders), June 24, 2002, at 1-3 ("Michigan Final Statistical Report")(Lodging with the Court), see also David Mechanic, *Are Patients' Office Visits with Physicians Getting Shorter?*, 334 New Eng. J. Med., Jan. 18, 2001, at 198-204 (the mean duration of a doctor's office visit in 1998 was 18.3 minutes per patient). In fact, this is a primary goal of the HMOs in using formularies. While in many cases such self-censoring by physicians does not cause patient harm, it can create health problems where the alternative formulary drug is not as effective as the drug that the physician would have prescribed if it were readily available without PA, or it causes side effects or adverse drug interactions not present with the originally prescribed non-formulary medication. Id. at 2.

PARTICULAR PROBLEMS CREATED FOR MEDICAID BENEFICIARIES BY THE IMPOSITION OF PRIOR AUTHORIZATION

The above description of the problems with PA apply to patients generally. However, in the case of the typical middle income enrollee in a commercial HMO, there are several options available to obtain a prescription drug, when the enrollee's plan rejects the pharmacy's claim for payment: (1) he or she can pay up-front to obtain the PA-only drug and try to get reimbursed later; (2) he or she will generally have a sufficient educational level and skills to follow through with the doctor or the insurance company, to obtain authorization for the drug the doctor originally prescribed; (3) after approval is obtained, he or she will have transportation to readily return to the pharmacy to obtain the prescription.

It has been suggested in the course of this litigation that PA is not that burdensome for Medicaid patients, as it is often applied in the commercial employer-based health insurance context. However, the circumstances are significantly different for Medicaid recipients. Collectively, these circumstances mean that PA creates qualitatively different obstacles to access than for middle-income employer-based insurance participants. Peter J. Cunningham, *Affording Prescription Drugs: Not Just a Problem for the Elderly*, (Center for Studying Health System Change), Research Report No. 5, at 4, 7 (April 2002)(hereinafter, "Cunningham")(available on line at www.hschange.org). It is therefore imperative that states proceed with great caution when implementing PA schemes for Medicaid recipients.

First, individuals qualify for Medicaid only if they fall into one of the specific categories of low income individuals covered by this program. The primary categories under which poor people can qualify for Medicaid are being elderly, blind or permanently and totally disabled,

being a pregnant woman, or being a member of a family with minor children. 42 U.S.C. § 1396a(a)(10)(A)(i) and (ii). However, the most basic requirement is that the individual have both a very low-income and very few assets. As this Court has noted, "[i]n structuring the Medicaid program, Congress chose to direct those limited funds to persons who were most impoverished and who – because of their physical characteristics – were often least able to overcome the effects of poverty." Schweicker v. Hogan, 457 U.S. at 590. Over half of adult non-elderly Medicaid recipients, including individuals who qualify because they are in families with minor children, have incomes below the federal poverty level. Cunningham, at 4. For those receiving Medicaid because they are elderly, blind or disabled, in 45 states their income must be at or below 74 per cent of the federal poverty level. The Henry J. Kaiser Family Foundation, *State Health Facts Online,* 50 State Comparisons, Medicaid and CHIP, Medicaid Eligibility Levels for Other Enrolled Groups, available online at http://www.statehealthfacts.kff.org. Thus, in almost all cases, Medicaid beneficiaries lack the resources to pay up-front at the drug store to obtain a prescribed drug rejected for lack of PA. See Dodson v. Parham, 427 F. Supp. 97, 108 (N.D. Ga. 1977); Stephen B. Soumerai, et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia,*" New Eng. J. Med., Sept. 8, 1994; 331: 650-655, at 650 (hereinafter, "Effects of Limiting Medicaid Drug-Reimbursement"). This means that the Medicaid patient who is denied access at the pharmacy counter to a prescribed medication will walk out, not only without the originally prescribed drug, but with **no drug at all**, in the vast majority of cases.

Second, Medicaid clients are sicker than the general population, with a significantly higher incidence of chronic disease. See Schweicker, 457 U.S. at 590; Vargas v. Trainor, 508

F.2d 485, 489 (7th Cir. 1974); Cunningham at 4. More than one-fourth of adult non-elderly Medicaid beneficiaries have multiple chronic conditions, compared to less than 10% of such individuals with employer-based coverage. Cunningham at 4. Further, it is projected that, between now and 2010, the increase in the Medicaid enrollment rate for the blind and disabled will be twice that for all other enrollees. United States Department of Health and Human Services, *"A Profile of Medicaid, Chartbook 2000"*, p. 18, Figure 1.5, available online at http://cms.hhs.gov/charts/medicaid/2Tchartbk.pdf. Since Medicaid patients have a statistically lower level of health, given their poverty and disproportionate representation of individuals with chronic disease, Cunningham, at 4, 7, their health can quickly decline, with the physician who prescribed a drug to arrest such decline not even knowing that his or her prescribed treatment is not being applied. Indeed, previous restrictions on Medicaid beneficiaries' access to prescription drugs imposed in the past by other states have resulted in increased emergency mental health services and increased institutionalization (often irreversible), both increases incurred at state expense. Soumerai, *Effects of Limiting Medicaid Drug-Reimbursement*; Stephen B. Soumerai, et al. "*Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*," New Eng. J. Med., 1991; 325:1072-1077.

Third, literacy skills are disproportionately lower for Medicaid recipients than for the population at large. See New York City Unemployed and Welfare Council v. Brezenoff, 742 F.2d 718, 722 (2d Cir. 1984). As such, information about the details of PA and how to obtain it is less likely to be effectively communicated to such recipients by a pharmacist who has received a computerized message that a drug cannot be filled and correctly identifies the cause as lack of PA.

Fourth, even if they speak English, receive accurate information from the pharmacist about the PA process, and make obtaining the prescribed drug a priority, Medicaid recipients are much more likely to lack the resources to take affirmative steps to negotiate a complicated PA process after a rejection at the pharmacy occurs, assuming that they are advised of this option by the pharmacist. See Goldberg v. Kelly, 397 U.S. 254, 264 (1970); Vargas, 508 F.2d at 489-90; Ortiz v. Eichler, 616 F. Supp. 1046, 1062 (D. Del. 1985), aff'd 794 F.2d 889 (3d Cir. 1986). Even such basic tasks as making a long-distance phone call to the pharmacy benefit management company are difficult, since many Medicaid recipients lack the resources to make long-distance calls and a substantial number do not even have telephones. If they are employed, they often work in service jobs which will not allow them to take time off during the day to make these necessary calls and receive return calls.

Fifth, more Medicaid recipients lack private transportation, and are physically disabled, than the general population. They thus encounter significant difficulties in simply returning to the pharmacy to obtain a PA-only drug, even if they are able to negotiate the PA process and PA is finally obtained. The initial trip to the pharmacy may be one that had to be specially arranged; it may be days before they can arrange another to pick up the prescription which is finally authorized.

These special obstacles for Medicaid clients have largely been ignored by states which have implemented PA. The way that the states have so far implemented PA, tied to formularies in particular, has not worked well for Medicaid recipients.

In Florida and Michigan, two states that have implemented PA in order to obtain supplemental rebates, the short history of such implementation has seen a disturbingly wide-

spread level of interference with access to basic medical care. For example, low-income Medicaid patients in Florida are routinely turned away at the drug store without access to needed prescriptions, because the prescribed drug was not on the formulary and required PA, and yet the physician, not having known that the drug required PA, simply wrote a prescription for it without seeking PA. According to documents provided by the State of Florida in pending class action litigation filed by Medicaid beneficiaries, with respect to Florida's procedures for PA, as well as its "four brand limit" imposed on these beneficiaries:

> Defendant's own statistics demonstrate that over *35,000 [Medicaid] recipients in a single recent month were denied coverage* of their prescription drugs or the opportunity for a hearing, including *21, 974 recipients who received no drug at all in the same therapeutic class*. These numbers exclude those recipients who were denied their prescription claims due to the generic substitution payment policy and those who eventually did receive their doctor's prescription after an unknown period of delay.

Hernandez, 2002 WL 31060425, at *3.

In Michigan, doctors who request PA for their Medicaid patients are routinely denied authorization. In response to this experience, patients are often switched by their Medicaid doctors from non-formulary to formulary drugs, even though the second drug is far less effective than the first for that particular individual.[2] Michigan Final Statistical Report at 2. Michigan Medicaid recipients are routinely denied approval for drugs on which they have been stabilized for months or even years, causing deterioration in their health status. For recipients treated with complex medication regimens, denial of even one drug and substitution with another can have immediate adverse consequences because of negative interactions between medications.

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[2] Medicaid recipients are entitled to all medically necessary medications, with the exception of a few narrow categories of excluded drugs set forth in federal law. 42 U.S.C. § 1396r-8(d)(4)(D). A client may only be limited to a formulary medication if it is equally effective in treating that particular member's medical condition. See Jeneski, 209 Cal. Rptr. at 189; Visser, 756 F. Supp. at 507.

In Florida, a federal district court has recently recognized due process concerns in the implementation of PA, as it is required under 42 U.S.C. § 1396a(a)(3) and 42 C.F.R.§ 431.200, et seq., see Goldberg, 397 U.S. at 267-68. As explained in the recent class certification decision in Hernandez:

> With a minor exception, the failure to provide such notice and hearing is uniformly being applied against all members of the Plaintiff class [Florida Medicaid beneficiaries].... Typically, this happens when recipients receive prescriptions from their physicians and then go to a pharmacy to get the prescription filled, and are rejected by a state actor for any number of reasons under Florida's complicated Medicaid law. Such claims are decided immediately by the state actor and the pharmacist receives an electronic message stating whether the drug is covered and therefore whether the claim will be paid, suspended, or denied... *When coverage is denied for whatever reason, there are no provisions for recipients to receive a written notice in either the Florida Statutes or in the current or proposed administrative rule on the prescription drug coverage.*

Hernandez, 2002 WL 31060425, at *5 (emphasis added).

CONCLUSION

The members of PhRMA have largely brought upon themselves the push by the states to impose prior authorization on their products, as the companies' practices are sharply driving up the states'-costs under their respective Medicaid programs. While the states are rightly taking action to address this growing problem, the Court must not lose sight of the fact that the protections for Medicaid beneficiaries provided in the Medicaid Act are designed to protect the health of the most vulnerable members of our society-- **not** the profits of drug companies.

In its decision below, the First Circuit ruled for Maine, but cautioned that its decision "was without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the

prior authorization requirements 'as applied.' " PhRMA v. Concannon, 249 F.3d 66, 78 (1st Cir. 2001). Since that time, several states have in fact implemented supplemental rebate/PA schemes, solely for the purpose of saving money. *Amici* believe it is important for the Court to be aware that, where supplemental rebates have been linked with prior authorization requirements, significant harm has befallen Medicaid recipients. They have been denied reasonably prompt access to prescription drugs because of difficulties inherent in the administration of a Medicaid formulary program which exists in the midst of dozens of similar programs, each with its own unique requirements for authorization of excluded drugs. *Amici* therefore exhort the Court to recognize the special obstacles to health care access facing Medicaid recipients under supplemental rebate/PA schemes and the caution with which states must proceed if they seek to implement such schemes.

Dated: September 20, 2002

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REPORT ON PRESCRIPTION ACCESS HOT-LINE

April 22 – June 14, 2002

Mental Health Association in Michigan
Michigan Association for Children with Emotional Disorders

June 24, 2002

Final Statistical Report

I. Introduction

In February of this year, the Michigan Department of Community Health began using pharmaceutical prior authorization with Medicaid-fee-for-service recipients and certain other state-funded health care populations. On April 1, Medicaid HMO enrollees were brought into the program for their mental health medications.

The state's prior authorization effort is being challenged in court by four mental health-related organizations and three individual service consumers. The matter presently rests with a Michigan Court of Appeals panel.

To develop a better picture of what is happening across the state under prior authorization, the Michigan Association for Children with Emotional Disorders and the Mental Health Association in Michigan began a toll-free phone line April 22 for receiving consumer and provider complaints about the program. These organizations were assisted in this "prescription access hot-line" by the Michigan Partners for Patient Advocacy and the National Alliance for the Mentally Ill of Michigan.

The hot-line ran for eight weeks, through June 14. During that period, the hot-line's existence was promoted through word-of-mouth communications; two weeks of radio and/or newspaper advertising in three counties (Genesee, Ingham and Saginaw); and a June 9 print ad in one Oakland County newspaper.

This document provides information on hot-line results for its eight-week period, April 22 – June 14. Despite the limited means for marketing, 455 calls were received, from 50 different counties, in those eight weeks. Consumers or their family members made 360 of the calls (79%), while 95 calls (21%) were received from health care providers. Our report on these contacts is divided into three parts: (i) A narrative summary of key overall statistical results; (ii) A tabular presentation of those statistical results; and (iii) Excerpts from a number of the phone calls received. (Over the course of four reports published on the hot-line, we have provided excerpts from 72 separate calls.)

The results show that Michigan's current prior authorization program suffers from serious deficiencies and is not working well. Many consumers have experienced dangerous medication delays and/or been switched off drugs through which they were stable. At the same time, providers are incurring tremendous expenses to deal with the new layers of bureaucracy and problems that have been created. Several assurances from the state about program procedures have not proven to be true.

Virtually every health care-related organization in the state has called for major revision (if not abolishment) of the prior authorization program. The outcomes of our hot-line's eight-week history suggest that these recommendations have been totally on track. We hope Michigan's legislative and executive branches will choose to take remedial action.

II. Narrative Highlights – Prescription Access Hot-Line Statistics

April 22- June 14, 2002

A. Consumers/Families

There were 360 calls from consumers (or family members about consumers). These were categorized according to the primary nature of the complaint: (i) Confusion about Program Procedures; (ii) Medication Delay, Denial or Switching without Negative Consequences; or (iii) Medication Delay, Denial or Switching with Negative Consequences. As can be seen in the tabular statistical presentation (next section), **239 of the 360 calls, or 66%, reported Medication Delay, Denial or Switching with Negative Consequences**. Examples of negative consequences were circumstances such as: subsequent hospitalization; required new medication not working as effectively as previous drug; forced switching to a product causing allergic or other negative reaction; reduced ability to perform Activities of Daily Living; going several days, or even weeks, without any medication at all; forced switching to a product form (such as tablet, chewable or liquid) which the consumer could not tolerate; and loss of continuity upon discharge from a hospital (i.e., hospital physicians/patients are not under prior authorization, but have to deal with it immediately upon discharge).

Consumer/family calls came in from 46 different counties. As would be expected based on two weeks of media advertising in Genesee, Ingham and Saginaw, those three counties produced the highest numbers. Among remaining counties, Jackson and Shiawassee had the greatest representation.

Consumer/family callers were given the option of stating the health condition(s) being experienced by the consumer. Among those electing to identify the condition(s), the category containing the most number of citations was Mental Health/Neurological, with 62 mentions (46 Mental Health; 16 Neurological). This was followed by Cardiovascular Disease with 59 mentions.

Consumer/family callers were also given the option of stating the drug(s) involved in the consumer's prior authorization difficulties. Among those choosing to identify the drug(s) involved, there were 219 drug citations, covering 67 distinct products. (We have verified that every one of these 67 specific drugs is, in fact, on the state's prior authorization list for the program which began in February. This is a strong indicator that the hot-line has succeeded in capturing calls from people affected by the new program, and not some other manner of preauthorization such as a private insurance plan.) Analyzing the particular drugs mentioned by category shows that the two classes of pharmaceuticals most often involved in prior authorization difficulties were pain medications and anti-depressants. These results support two of the potential problems many parties have raised about the new program: (i) It has no recognition of or allowance for the value of off-label prescriptions, which is how many pain medicines are used by physicians; and (ii) Mental health medications are among the most difficult to manage effectively, with

the persons taking them highly sensitive to changes in regimen and routine, and especially vulnerable for resulting problems.

Demographically, the consumers who called (or about whom family members made contact) were predominantly Caucasian, female and enrolled in Medicaid fee-for-service (as opposed to a Medicaid HMO). All nine age categories we created, from 0-5 through 75 and above, were represented, ranging from a low of 3% of cases in the 0-5 group to a high of 25% of cases age 45-54. Nearly half of all cases (45%) were between the ages of 35 and 54.

B. Providers

There were 95 calls from providers. As expected, Ingham, Saginaw and Genesee were among the counties producing the most calls. Jackson County, however, provided the second-highest number of calls, behind Ingham.

Callers were asked how many consumers in the provider's practice were affected by the new program. The predominant response, from half of all callers, was that more than 100 consumers were affected. More than 75% of callers reported that at least 26 consumers in the practice were affected.

Provider calls were categorized according to the primary nature of the complaint: (i) Too Much Time Required to Seek Authorization; (ii) Forced to Do Additional Patient Follow-Up; (iii) Process Too Confusing/Difficult; and (iv) Problems in Multiple Categories or Other Areas. Thirty-six percent of providers said there is *Too Much Time Required to Seek Authorization.* Another 15% said they were *Forced to Do Additional Patient Follow-Up.* **Thus, over half of all providers cited as a primary complaint that the program was making them take actions which were highly time-consuming.** Additionally, 29% of providers were in the *Other/Multiple Complaint* category. Thus, the proportion of providers concerned with the amount of time lost (and the considerable expense that goes with it) was almost assuredly well beyond 50%.

III. Tabular Statistical Data – Prescription Access Hot-Line

April 22 – June 14

A. Consumers/Families

During the period April 22 – June 14, 360 consumers or family members called.

1) *Type of Problem Experienced with Prior Authorization (PA):*
Confusion about Program Procedures - 24 (6.67%)
Delay, Denial or Switch of Medication; No Negative Consequences Reported - 97 (26.94%)
Delay, Denial or Switch of Medication; Negative Consequences Reported - 239 (66.39%)

2) *County of Residence for Consumers Affected by PA*
Calls representing 46 counties. Most frequent were:
Genesee - 53
Ingham - 52
Saginaw - 39
Jackson - 20
Shiawassee – 16

3) *Health Conditions of Consumers Affected by PA*
Among callers specifying consumer health condition(s), most frequently cited were:
Mental Health/Neurological – 62 {Mental Health – 46; Neurological – 16}
Cardiovascular - 59
Arthritis - 39
Gastrointestinal – 34
Diabetes - 30
Asthma - 29

4) *Medications Involved for Consumers Affected by PA*
Among callers specifying the particular drug(s) involved, 67 individual drugs were mentioned at least once (219 total mentions), crossing 24 classes from DCH's listings. The most cited categories were:
Analgesics (pain medication) – 67 mentions
Anti-depressants – 35
Gastrointestinal - 26

The most cited individual drugs were:
Prilosec (gastrointestinal) - 20
Ultram (analgesic) - 14
Oxycontin (analgesic) – 12
Zocor (cholesterol) and Celebrex (analgesic) - 11 each
Vicodin (analgesic) – 10
Zoloft (anti-depressant), Ambien (sedative-hypnotic) and Vioxx (analgesic) – 9 each

5) *Demographic Info on Consumers Affected by PA*
74.5% Female; 81% Caucasian; 45% age 35-54; 29% Medicaid HMO (remainder Medicaid fee-for-service or other State program)

B. Providers

During the period April 22 – June 14, 95 providers called.

1) *County in Which Provider Located*
Calls representing 33 counties. Most frequent were:
Ingham - 16
Jackson –10
Saginaw - 6
Genesee - 5
Oakland - 5
{NOTE: Putting consumers and providers together, calls came in from 50 different counties.}

2) *Number of Consumers in Provider's Practice Who Are Affected by PA*
>100 = 48 (50.53%)
51-100 = 11 (11.58%)
26-50 = 13 (13.68%)
10-25 = 8 (8.42%)
<10 = 10 (10.53%)
N.R. = 5 (5.26%)

3) *Type of Problem Experienced with PA*
Taking Too Much Time – 34 (35.79%)
Too Difficult/Confusing – 18 (18.95%)
Forced to Do Additional Patient Follow-Up – 14 (14.74%)
Other or Multiple Categories – 28 (29.47%)
No Complaint; Expressing Support for State's Program – 1 (1.05%)

IV. Excerpts from Calls to Prescription Access Hot-Line

..*Health care provider from Ingham County:* Some of the patients cannot get the medication that they have been on for years. Medicaid is saying that we have to try them on other drugs before we can put them back on the medicines that they were originally on. Where is the sense in switching them from drug to drug just so that you can put them back on the drug that they were taking in the first place?

..*Woman from Genesee County, calling about her 72-year-old grandmother:* She went to pick up her medication, and they told her that it is not covered anymore, that she is going to have to switch to a generic brand. She has had problems with switching medications before. Her medicine (Cardizem) is what works best for her; she has been on these pills for a very long time.

..*Health care provider from Kent County:* Most of our patients are on psychotropic drugs. We now have to get approval for these from Medicaid HMOs. It's like a circus with this stuff, going around and around in circles, trying to find out who is supposed to be responsible for pre-authorizations. One client needs Risperdal [which is on the state's preferred drug list], and I had a run-around with an HMO about it. They wouldn't approve the prescription the doctor wanted; they changed the milligram strength and dosage time for the medication without our agreement. Are they even allowed to do this?

..*Female consumer (age not given) from Wayne County:* The state says I don't need approval for Zoloft because I was taking it on March 1. Well, my doctor has written Zoloft prescriptions for me since March 1, and they've been rejected. This drug helped me for a long time. What's up with Medicaid saying I can have it, and then it's rejected?

..*Health care provider from Clare County:* My first problem or concern is time spent away from my patients. I have had to put in extra time to do what is required for this program. Second of all, my patients have had to wait, some up to a month, to get their medication. That is very nerve-wracking to the patients and to me because they are calling me all the time. I have to tell them I'm sorry, I have to go by what I'm told to do.

..*41-year-old woman from Jackson County:* I have multiple sclerosis and other problems. I'm allergic to a lot of different medications. The doctor had me on Nexium, and it worked perfect. Now they have me on Prevacid, and it is not working. I talked to my doctor, and he said he couldn't do anything about it because of Medicaid. Now they have to check all the medications I get to make sure they are approved.

..*Health care provider from Metro Detroit:* We have elderly patients who need the soluble form of the drug. That form is supposed to be grandfathered in if someone was already on it. But just try to get a continuation prescription through for a client! You can't.

..*Woman calling about her husband (county not given):* He has congestive heart failure, COPD, asthma and diabetes. He was taking Glucotrol, and was able to regulate his sugar to where it stayed down. Most of the time he only had to take two pills a day. But now he is on glyburide, and he has to take six pills a day to keep the sugar down near normal. And then he was using Combivent for his breathing, and he can't get that anymore through Medicaid, and the medicine they substituted just doesn't do it. If you've got a medicine that's working for you, what's the use in changing it?

..Health care provider from Ingham County: We have numerous patients that have been on the same medication for over five years. Now the medication they've been stable on is not part of the Medicaid formulary. It would have been nice to let people continue with what they were taking. This is tremendously time-consuming and anxiety-provoking for patients, doctors and staff.

..63-year-old woman from Genesee County: I have osteoporosis, and Medicaid was paying for the medication. All of a sudden, Medicaid decided they were not going to pay for it anymore. I have not been able to pay for it, so I have no medication. I am in constant pain all of the time.

..Health care provider from Jackson County: They tell me I have to get a pre-authorization for these medicines. Having to call every 2-3 months to get the same meds pre-authorized is just very frustrating. One woman has just been cut back from the dosage the doctor prescribed for her. They want to give her a lower dosage to take less times a day than the doctor ordered.

..56-year-old man from Gratiot County: I can't tell you how many high blood pressure medicines I've been on, probably at least 10. None of them controlled my blood pressure until I went on Accupril. Now Medicaid says that I can't have Accupril; that I have to start all over again with all these other medications. Medicaid acts as though Medicaid recipients are non-participants in society.

..Health care provider from Ingham County: It's a lot more time-consuming for us to have to call for authorizations for each patient, and they don't last for an extended amount of time. We're constantly having to call to keep up on them. They are not good for six months to a year like the state said would be the case. When we get authorizations, they're only for a small amount of time.

..61-year-old woman from Wexford County: I was on Celebrex. They said I have to take another brand. I'm in so much pain that it's unbelievable. I didn't have this problem with Celebrex. Medicaid shouldn't have the right to tell me what I need for pain. How do they know how I feel? {**NOTE:** Call received June 5. Because the consumer is over age 60, she is not supposed to need prior authorization for Celebrex. This is yet another illustration of the chaos in the field from a badly designed and poorly implemented program.}

..Health care provider from Saginaw County: It is taking up too much of our time with all the paperwork. We've had to hire two additional people just to keep up with it.

..34-year-old woman from Eaton County: I have a medicine that has to be pre-authorized, and I have not taken it for two months because the authorization is not getting done, even though it helps with my condition. One of my other drugs, I have seen on the Medicaid list that it doesn't have to be approved, but the pharmacy said it requires pre-authorization, and they wouldn't give it to me. I am not very happy. The doctor knows what's best for us, not someone else.

60-year-old woman from Ogemaw County: I am having problems with my medications; getting them turned down. Every time my doctor orders me a medication, they turn it down. Then he tries to get me something else, and sometimes it takes two weeks to get an answer. Sometimes the pain is so bad that I can't think straight; it just takes over my whole body. This policy is unreal. The doctors don't have time to play with all this paperwork. They have to see patients.

Health care provider from Jackson County: We have been going by the list they gave us. Even though we're following the list, the prescriptions are still coming back rejected. They're telling us they won't approve certain medications because of the milligram dosage. They will only approve lower dosages. And most of the lower dosages of these meds don't help anybody. We have patients that are diabetics who have been controlled for some time. Now we're told to switch their meds, and when we do their diabetes goes haywire on them. This is just too frustrating and taking up too much of our time.

CERTIFICATION OF SERVICE

This is to certify that today, the 20th day of September, 2002, I, Sheldon V. Toubman, caused to be served three true and correct copies of the Amicus Curiae Brief of Legal Services Organizations Representing Medicaid Beneficiaries In Support of Neither Party by U.S. Postal service, first class mail, postage prepaid, upon the following counsel of record:

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