

medicaid
and the uninsured

**One State's Medicaid Managed Care Formulary
Operations: A Look at Pennsylvania, 2001-2002**

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kaiser commission medicaid and the uninsured

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Executive Summary

The importance of pharmaceutical treatment of acute and chronic diseases, and the increasing cost of prescription drugs have made drug benefits a critical issue in Medicaid health plans. Recent studies have looked at state implementation of formularies for the fee-for-service Medicaid population¹ or have compared potential cost savings of drug benefits in a carve-out model versus benefits inclusion in managed care contracting.² Proposals have been written to ensure that quality of beneficiary care is not compromised by cost containment measures.³ As more states consider implementation of formularies for even the most vulnerable groups of Medicaid beneficiaries, some physicians and advocacy groups have expressed concern that drug lists will restrict access and harm beneficiaries.

This report examines formulary implementation under mandatory Medicaid managed care in Pennsylvania between 2001 and 2002. These findings are based on reports from sentinel prescribing physicians, interviews with participating pharmacists, and calls from Medicaid beneficiaries to a statewide legal services helpline. They demonstrate the serious potential and actual consequences to beneficiaries when complex formulary systems fail, and the difficulties of creating cost effective systems with adequate monitoring and outcome evaluation. This report looks at one state during a yearlong period; formulary operations are likely to vary across states and programs and over time. It concludes with some observations and recommendations to improve formulary implementation.

Findings

- **Despite safeguards in managed care contracts, case reports indicate that beneficiaries were sometimes unable to obtain prescribed medications.** Managed care plans were sometimes in violation of federal Medicaid rules and contractual mandates, for example, disregarding the requirement for 24-hour turnaround time for prior authorization of medications. Managed care plans had inadequate infrastructure to administer formularies, including insufficient fax capacity to process prior authorization requests, too few staff available to answer consumer and provider inquiries; and inadequate training of health plan staff

responsible for administering the formulary system. Cases documented by sentinel physicians and legal services revealed the serious, and, in some cases, potentially life-threatening consequences of inadequate administrative infrastructure.

- **Retail pharmacies carried a large share of the responsibility for effective formulary operation but they underwent little or no monitoring to ensure compliance with plan policies or Medicaid law.** A consumer's chance of obtaining medication, a physician's chance of receiving notification of non-dispensed medication, or a health plan's chance of receiving notification of non-dispensed medication hinged upon the retail pharmacist's actions. This study found considerable variation in pharmacy practice pertaining to Medicaid formularies and, in some cases, little or no monitoring by the state, or the managed care organizations (MCOs) to which the pharmacies were contracted.
- **Health plan control over outpatient, but not inpatient formularies resulted in the inability of some seriously ill patients to obtain medications on discharge from inpatient facilities, putting them at risk of relapse and re-hospitalization.** Lack of formulary coordination meant that some patients were discharged from the hospital with prescriptions their health plan did not cover, jeopardizing their ongoing medical or psychiatric treatment.
- **The division of contracts and responsibilities into physical and behavioral health plans but the allocation of all pharmacy benefits to physical health plans resulted in special problems for the chronically mentally ill.** Physical health managed care organizations in Pennsylvania's Medicaid program are responsible for pharmaceuticals but behavioral health managed care companies are responsible for hospitalization and outpatient care. This division created opposing financial interests, and made it difficult for some chronically mentally ill patients to obtain their medications.
- **The existence of multiple plans and formularies and the absence of state requirements for formulary organization and presentation made it difficult for physicians to use formularies efficiently.** Providers received health plan

drug lists and updates in disparate fashion, including loose-leaf pages, pocket-sized books, wall posters and forms. This lack of uniformity complicated formulary use and comparisons.

- **Frequent, financially-driven formulary changes, combined with prior authorization and administrative requirements that lack clinical rationales, resulted in deep suspicion by physicians and consumers and poor stakeholder acceptance of formularies or preferred drug lists despite their potential for both cost savings and quality improvements.** Drugs that cycle rapidly on and off a formulary frustrate physicians and confuse beneficiaries. Requirements for repeated authorization for chronic medications create procedural barriers to access, and Medicaid beneficiaries' suspicions of second-class care are reinforced when they cannot obtain prescribed medications.

Observations on Improving Formulary Operations

- **Efficient pharmacy infrastructures are better able to meet the needs of patients, physicians and pharmacists while providing important safeguards to beneficiary access.** Formulary implementation is key to success because formulary operations, and not just content, can have clinical consequences. Rapid and easy access to necessary information and feedback of access problems or system failures could improve formulary operations and quality.
- **Monitoring retail pharmacy service delivery requires a joint effort of managed care organizations, retail pharmacy trade organizations, and state Medicaid agencies.** Retail pharmacies are a key but neglected component of Medicaid pharmacy policy and monitoring tools and activities should reflect the importance of these providers. The experience at the retail pharmacy level is likely to become even more important under the new Medicare prescription drug benefit.
- **Managed care organizations are in a position to lead and facilitate the inpatient-outpatient transition, including formulary coordination and other important aspects of care.** Discharge planning presents a unique opportunity

to manage care and not just costs, and pharmaceuticals should be included in health plan input into discharge planning. Ensuring a seamless transition between inpatient and outpatient access to medication is an important part of care management.

- **The high proportion of people with mental illness in the Medicaid population, the division in clinical care between physical and mental health providers, and the high cost of newer mental health drugs make it critical that Medicaid policy serves to coordinate physical and mental health care for those with chronic mental illnesses.** Mental illness is expensive to treat, but the consequences of treatment failures are even more costly. Coordination of care and continuity of treatment are critical for this population.
- **Uniform standards for organization, drug classification, and formulary presentation would promote ease of formulary use and comparison, particularly in states with multiple Medicaid managed care organizations.** Ideally, these standards would also exist at the federal level to encompass current and future Medicaid and Medicare drug benefits. Additionally, uniform templates for prior authorization could minimize confusion and improve provider participation and cooperation with formularies.
- **Stakeholder involvement in the development of Medicaid pharmaceutical policy could improve overall responsiveness and satisfaction.** By seeking input from providers and patients, states should be better able to construct systems that best meet the needs of all stakeholders.
- **Financial penalties assessed by states for violations of Medicaid law or contracts, or savings generated by changes in pharmaceutical policy administration could serve as the source of funds to improve prescription drug access and prescribing quality in the state.**

I. Introduction

The importance of pharmaceutical treatment of acute and chronic diseases, and the increasing cost of prescription drugs have made drug benefits a critical issue in Medicaid health plans. Recent studies have looked at state implementation of formularies for the fee-for-service Medicaid population⁴ or have compared potential cost savings of drug benefits in a carve-out model versus drug benefits included in managed care contracting.⁵ While states are understandably looking to contain drug cost growth, proposals have been written to ensure that quality of beneficiary care is not compromised by cost containment measures.⁶ As more states consider implementation of formularies for even the most vulnerable groups of Medicaid beneficiaries, some physicians and advocacy groups have expressed concern that drug lists will restrict access and harm beneficiaries.

This report examines formulary implementation under mandatory Medicaid managed care in Pennsylvania between 2001 and 2002. These findings are based on reports from sentinel prescribing physicians, interviews with participating pharmacists, and calls from Medicaid beneficiaries to a statewide legal services helpline. They demonstrate the serious potential and actual consequences beneficiaries face when complex formulary systems fail, and the difficulties of creating cost effective systems with adequate monitoring and outcome evaluation. This report looks at just one state during a yearlong period. Formulary operations are likely to vary across states and programs and over time, but the findings in this report can be instructive to other states with Medicaid managed care drug benefits. The report concludes with some observations and recommendations to improve formulary implementation.

Medicaid's Coverage of Prescription Drugs

Drug costs have been growing rapidly for all payors, including Medicaid. Pharmaceutical costs are now the third largest costs for Medicaid nationally,⁷ and the fastest rising costs.⁸ Medicaid serves a disproportionately high number of people with chronic disabling conditions, and low-income elderly who are sicker, and poorer than commercially insured beneficiaries, and who are high users of prescription drugs.⁹

Numerous studies have shown that pharmaceutical costs have risen both because more drugs are being prescribed, and the drugs that are prescribed are more expensive.¹⁰ Drugs may offer alternatives to more expensive services (e.g., expensive

oral antibiotics taken at home versus inexpensive intravenous medications requiring hospitalization) or may offer opportunities to prevent serious future complications of chronic conditions (e.g., maintenance medications for heart disease or diabetes). Demand for pharmaceuticals has also risen as a result of direct-to-consumer advertising and the extensive marketing efforts of the pharmaceutical companies.¹¹

Although pharmaceutical spending in the private sector has also increased at a rapid pace, much of the increase is passed on to the consumer.¹² In order to protect the vulnerable population served by Medicaid, states are unable to pass more than nominal costs on to beneficiaries and must therefore utilize other cost control mechanisms. All 50 states instituted some cost control mechanisms for drug costs for FY 2002-2003.¹³ Cost control mechanisms, detailed in earlier reports¹⁴ include generic substitution, utilization review, federally allowed drug exclusions, prior authorization for selected drugs, caps on the number of prescribed drugs per member/month, and the adoption of formularies which limit drugs available to the Medicaid population. In addition, many states, including Pennsylvania, include drug coverage as part of Medicaid managed care contracting, shifting the imposition of cost control measures to insurance companies and their pharmacy benefit manager (PBM) subcontractors.

Generic substitution is not enough to control Medicaid pharmaceutical costs as generics are not universally available and prices for both brand and generic drugs continue to rise.¹⁵ Of the top 50 drugs prescribed in the United States in 2002, 27 out of 50, or almost 50%, are available currently in generic formulations,¹⁶ including four drugs not available generically in 2002. States have reported varying levels of success with other commonly used strategies such as prior authorization or DUR. Other strategies, such as caps or limits on quantities have the potential to depress a significant proportion of necessary utilization.

Many Medicaid programs have turned to formularies or restricted drug lists to help manage drug utilization and stem rising drug costs. From the perspective of medical practice, formularies should disseminate relevant information regarding drugs of choice for particular medical conditions, based on medical evidence and cost effectiveness. Ideally, a physician seeing a patient with diabetes and high cholesterol could check a list, immediately learn the medications recommended by national treatment guidelines and their relative costs, and then make an informed prescribing decision.

Formularies

Despite the recent large and rapid expansion of formulary use in commercial and Medicaid plans, very few studies have been done on the clinical consequences of formulary policy or outcomes.¹⁷ There is no “gold standard” by which to assess formulary performance and outcomes. The American Society for Health System Pharmacists’ (ASHP) report “Principles of a Sound Drug Formulary System,”¹⁸ provides one framework for formulary decision-making and operations. One of the largest and most comprehensive studies of a formulary is that commissioned by the Institute of Medicine, reviewing the Veterans Administration formulary.¹⁹

All formularies are restrictive, since they do not include every available FDA-approved medication. However, the term “restrictive formulary” is often used to emphasize this limited nature. In the commercial market, formularies may be described as “open” or “closed”²⁰, or may have multiple tiers with varying co-payments. In order to preserve access for the poor, sicker population served by Medicaid, Medicaid law does not permit some of the cost and utilization controls used in the commercial market. Pennsylvania Medicaid MCO formularies are all closed formularies and none of them utilizes the small co-pays allowable under Medicaid.

Pharmaceutical companies, physicians, and consumers have all protested the use of formularies as “interfering with the doctor-patient relationship.” Yet studies have shown that pharmaceutical company advertising and gifts unduly influence physician prescribing habits.²¹ Moreover, despite the existence of clinical guidelines supported by evidence, physicians are slow to follow these guidelines, particularly in prescribing.²² Payors, whether states or their managed care subcontractors, have a legitimate interest from both a quality and cost perspective, in assessing and influencing prescribing patterns. Numerous articles in the medical literature document the difficulties of changing prescribing patterns via education alone.²³ Formularies have a critical role to play in health policy, with their promise of optimal, rational prescribing.²⁴

Although uncertainties in the medical literature play a role in the determination of drugs of choice, a key problem in formulary creation is the wide array of similar medications manufactured by different pharmaceutical firms offering a variety of pricing schemes to government and private payors. While cost management is a key function, formulary design must reflect the needs of the populations the formularies will serve. An expensive medication used only in the elderly might appropriately require prior authorization in a formulary primarily serving a young, healthy population but the same

requirement in a formulary designed for the geriatric population would present a significant administrative burden to prescribers and a barrier to access for beneficiaries. This is critical when considering that the majority of pharmacy benefit manager (PBM) experience in formulary design is based on the needs of a healthy, employed population and not a Medicaid population including the elderly and disabled.²⁵

Rebates offered to states under fee- for -service Medicaid via the Federal rebate program are not available to contracted Medicaid MCOs²⁶, yet Medicaid MCOs have demonstrated significant cost savings via the use of restricted drug lists.²⁷ In addition, Medicaid MCOs, or their subcontracted PBM, are free to negotiate rebates from pharmaceutical manufacturers, usually trading price for a guarantee of market share. Thus cost, a legitimate consideration in formulary construction after safety and efficacy, becomes a driving force resulting in multiple formularies for the same population, and formularies are subject to frequent changes as the marketplace changes.

Pennsylvania

Pennsylvania includes almost all categories of Medicaid beneficiaries in its managed care plans²⁸, and requires that all beneficiaries living within designated geographic areas participate in its managed care program, HealthChoices, which enrolled 900,000 members at the time of the study.²⁹ In areas of the state that continue to have fee-for-service Medicaid, voluntary enrollment in managed care is sometimes an option. As of second quarter 2003, 25% of 194,000, or 48,500 eligible beneficiaries were enrolled in voluntary managed care, for a total statewide population of approximately 950,000 with pharmacy benefits via managed care plans.³⁰ All managed care enrollees in HealthChoices zones must choose a physical health plan, but they are automatically enrolled in a behavioral health MCO determined by county of residence. All pharmacy benefits for physical and behavioral health needs in these zones are administered via the physical health MCO.

Statewide, seven physical health MCOs had contracts with the state Medicaid office, the Office of Medical Assistance Programs (OMAP) in the Department of Public Welfare (DPW) at the time of the study. The provision of pharmaceutical services under managed care is governed by these contracts and by Act 68 of 1998 of the Pennsylvania code³¹ that applies to all MCOs in the state. All MCOs in Pennsylvania utilize formularies, and each utilizes a different formulary, making state oversight both critical and difficult. Act 68 requires that plans disclose and make public formularies, respond in

writing to requests for the formulary, and have in place an exceptions process that includes designated response times and appeal procedures.

HealthChoices contracts in the three geographic areas are essentially identical³² and allow the managed care organizations to utilize formularies subject to OMAP approval. The formulary must meet “the clinical needs” of the Medicaid population, and the MCO must allow access via an exception process to all pharmaceuticals in therapeutic categories covered by the Pennsylvania Fee for Service Program. The contract requires responses to prior authorization requests within 24 hours, written notification of denials to the beneficiary, and contains a provision for 72-hour supplies of medications for which there is an immediate need. Prior authorization requests of any kind are deemed automatically approved after 21 days if a denial has not been issued. These rights are clearly spelled out in handbooks that are provided to beneficiaries and providers, many of whom remain unaware of these regulations, due in part to the volume of information provided to both parties.

Although Federal Medicaid law exempts Medicaid MCOs from requirements governing coverage of outpatient drugs, Pennsylvania’s contracts include the beneficiary protections of 24- hour response to prior authorizations and 72-hour emergency supplies. The state has also added protections for renewal of chronic medications requiring prior authorization, requiring the dispensing of a 15-day supply. Criteria for prior authorization are not specified in the contract, but the HealthChoices’ contract has a definition of medical necessity utilized by plans, providers, and beneficiaries.³³ If an MCO beneficiary files an appeal of a denied ongoing service, and this includes prescription drugs, the beneficiary must be supplied with the medication until the grievance is resolved.³⁴

Within the Office of Medical Assistance Programs, the state has established core teams to act as liaisons with each managed care organization, field complaints from beneficiaries and providers, and monitor plan operations to ensure contract compliance. Although some reporting on HealthChoices is available to the public on the web and via the Medical Assistance Advisory Committee,³⁵ no public reports on formulary operations, outcomes, or monitoring are available.

Despite widespread concern, in Pennsylvania and elsewhere in the nation over formulary adequacy (i.e., the provision of an adequate array of medications in various classes, or medications especially appropriate to treat the conditions of the Medicaid population) the problems documented here did not result primarily from the drug lists

themselves, but from their implementation. Although there were important concerns regarding the removal of specific drugs from formularies during the time of the study³⁶, issues regarding formulary construction and adequacy are not the focus of this paper.

II. Study approach

This report is derived mainly from interviews and reports received from beneficiaries and providers in southeastern Pennsylvania. Initial data came from beneficiary calls to a statewide help line maintained by the Pennsylvania Health Law Project (PHLP), a statewide non-profit legal advocacy organization. At the initiation of the study, HealthChoices was limited to southeastern Pennsylvania (Philadelphia and four surrounding counties) and southwestern Pennsylvania (Pittsburgh and nine surrounding counties). Although helpline calls came from all areas, pharmaceutical access problems were disproportionately concentrated in southeastern Pennsylvania.

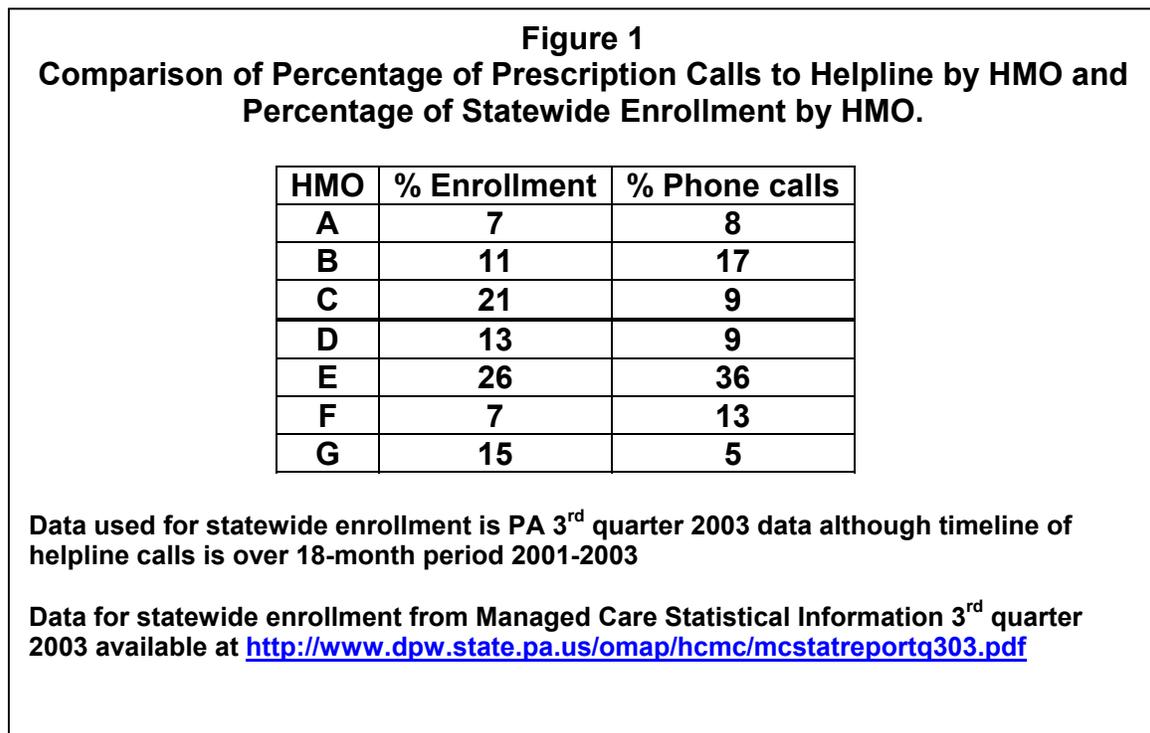
The majority of the data were collected between September 2001 and January 2002, with additional case reports collected through August 2002. The goal of the project was to identify whether the formularies within mandatory Medicaid managed care in Pennsylvania created access limitations, and to improve pharmaceutical access where problems were identified. The study was conducted using primary data collected through interviews and tracking, and secondary data sources, including the HealthChoices contract³⁷ and the National Health Law Program advocacy guide to Medicaid³⁸ which provided data on legal and contractual responsibilities of the state and the managed care organizations. Relevant legislation and published state data on Health Choices were also reviewed.

Interviews were conducted in two stages: preliminary interviews to determine provider perceptions of problems with pharmaceutical access, and subsequent detailed interviews and requests to monitor prior authorization requests. Additional interviews to obtain background information on the use and impact of managed care formularies were conducted with a staff member from the Pennsylvania Medical Society Drug Utilization Review Board, the agency contracted with the state to review HealthChoices formularies for adequacy, representatives from consumer advocacy “disease” groups (e.g. Mental Health Association), representatives of statewide physician organizations, and with former executives of Medicaid MCOs in Pennsylvania.

Because the study was part of the ongoing work of PHLP, there was frequent, ongoing contact with personnel in both staff and executive levels in the Office of Medical

Assistance Programs. This contact included efforts to resolve client problems received via the PHLP helpline, and emails and phone conversations regarding formulary policy. This contact confirmed that DPW was aware of problems in formulary administration and had made some efforts to solve these problems.³⁹

Medicaid beneficiary-level data were obtained by reviewing calls to the helpline of the PHLP.⁴⁰ PHLP runs a toll free helpline for low-income Pennsylvania residents. The helpline database was reviewed for all calls relating to pharmaceutical benefits and access in Medicaid managed care. Between September 11, 2001 and June 30, 2003 there were 4980 calls to the helpline, of which 354 pertained to prescription drug coverage. Calls pertaining to prescription drug problems, sorted by MCO, were not proportional to market share. (Figure 1)



These cases were reviewed to categorize types of access problems. For each of these cases, when appropriate, PHLP lawyers contacted the MCO and/or the Pennsylvania Office of Medical Assistance Programs to resolve the issue. Issues were resolved via phone mediation or representation at grievance hearings. No cases resulted in litigation.

Data from retail pharmacies were obtained by personal interviews with pharmacists working in the city of Philadelphia and its surrounding counties

(HealthChoices southeast), including chain pharmacies, independently owned pharmacies, and pharmacies specializing in servicing group homes and institutions for developmentally disabled children and adults. Ten pharmacists working in these diverse settings were interviewed. The Philadelphia Association of Retail Druggists, the trade organization of independent pharmacists, supplied copies of 118 problem reports submitted over three months from independent pharmacies to the Pennsylvania Office of Medical Assistance Programs. Of these, approximately 50% involved reimbursement issues to the pharmacy and 50% involved operational and communications issues with MCOs.

Additional pharmacy data were obtained from ongoing reports, via email or telephone, numbering approximately 50, over a one year period from independent pharmacies servicing Medicaid beneficiaries and from pharmacists working in an HIV program; three observational “field trips” by the author to independent and chain pharmacies; and pharmacists contacted by PHLP lawyers during investigations of helpline cases.

Data from physician prescribers were obtained by interviewing a diverse group of providers in the Philadelphia area regarding their experiences in obtaining prescriptions for HealthChoices members. A smaller group of physicians in the Pittsburgh area were contacted by email, confirming helpline data that suggested fewer problems in the southwest area.

Physicians were identified who were likely to see high percentages of sick Medicaid beneficiaries, either because of location or clinical specialty. Practices chosen had no prior contact with PHLP, and no history of complaints to the MCOs or the state. Initial contact, either by email, or phone, was made to medical directors of internal medicine teaching clinics in the Philadelphia area, three of whom agreed to monitor Health Choices prior authorization requests over a four month period (see appendix for form used). The author met with the medical directors of four Federally Qualified Health Centers (FQHC) in the Philadelphia region, two of which also submitted reports over the three-month period, and also with the medical directors of city and suburban community mental health centers. Physician practices and pharmacies were re-contacted following changes in MCO formulary procedures to ascertain the impact of MCO changes at the practice level. These repeated contacts included email, telephone, and in-person interviews.

Staff at two HIV centers, two nursing directors at large residential facilities for the developmentally disabled, and nurses and social workers delegated to obtain prior authorizations were also interviewed. Under HealthChoices, physical health MCOs are responsible for all medications, including behavioral health drugs, although behavioral health care is delivered via separate MCOs. Four senior medical directors from both behavioral health MCOs in HealthChoices southeast were interviewed. Requests to meet with pharmacy directors of the three HealthChoices southeast MCOs were declined by two MCOs. One pharmacy director agreed to a personal interview, accompanied by a medical director and the director of governmental affairs.

Four primary care sites in Philadelphia agreed to submit reports for three months on all Medicaid MCO prior authorization requests. A total of 58 reports were received, of which 55% involved MCO A, 26% involved MCO B, and 20% MCO C, roughly commensurate with market share. The total number of prescriptions written by these sites during this time is not known, but is clearly more than 58. More than 50 additional spontaneous reports were received in the course of the following nine months from previously interviewed practitioners who had declined to participate in regular reporting, but did send in “problem cases.” To protect patient confidentiality, patients were identified by initials only, without identifying data. Information obtained in this manner was used for study purposes only, and these patients did not become clients of PHLP nor was the state able to investigate these cases.

Overall, more than 150 case reports were obtained from the helpline, pharmacists, and physicians. Although the helpline calls represent complaints, and could be viewed as “loud” aberrancies, helpline calls on other issues have served as early warning signs of health care access and delivery issues in Pennsylvania.⁴¹ Significantly, although documented problems represented a small number of total dispensed prescriptions⁴² under HealthChoices, the problems in formulary operations separately reported by beneficiaries, pharmacists, and physicians were extremely similar and formed recognizable patterns.

III. Findings

1. Despite safeguards in managed care contracts, beneficiaries were often unable to obtain prescribed medication in the required time.

Pennsylvania's Medicaid managed care contract requires plans to make a decision whether to approve or deny a request for medication within 24 hours of the request, and it requires written denial notices to be issued to the beneficiary within 24 hours of the presentation of the prescription to the pharmacy. A request can consist of a prescription presented to a pharmacy, or an authorization request from a physician's office prior to an attempt to fill a prescription.

During the monitoring period of the study, health plans did not comply with this requirement on numerous occasions, either by failing to respond at all, or by long delayed responses. Physician offices reported response times of 13 days to one month or longer. For example, a nurse at a residential facility for 122 developmentally disabled adults reported that in October 2001 she had over 50 outstanding prior authorization requests dating back as far as July, despite a contractual agreement mandating automatic approval for requests not responded to within 21 days.⁴³

Physician offices reported learning that beneficiaries had not received medications at follow-up visits that were intended to assess medication efficacy. Feedback mechanisms to alert physicians to their patient's inability to obtain medications failed because of problems at the plan and retail pharmacy levels. When their prescriptions were denied, patients often assumed they had no recourse and simply had to do without the medication. Although provisions of the contract state that all prior authorization requests older than 21 days are deemed approved, lack of provider and beneficiary awareness of this protection, and the

Inability to obtain blood thinner on time is life-threatening

A 40-year-old man needed to stop his oral blood thinner (anticoagulant) and switch to an injectable medication, prior to a surgical procedure. The Medicaid managed care plan did not respond to three separate prior authorization requests, despite fax confirmations. When the drug was finally approved, 24 hours after its intended start date, the patient never received the medication because the approval mandated use of a mail order pharmacy. The patient stopped his oral medication, and went five days without any anticoagulant until the date of his surgery, placing his life at risk.

effort required to enforce it, made the rule meaningless for beneficiaries whose requests were lost or otherwise unanswered. Finally, medications were sometimes delayed even after approval, because plans did not contact physicians, pharmacies, or beneficiaries when prescriptions were approved, and because of delays or errors in entering the approvals into computerized pharmacy systems.⁴⁴

This study documents several cases where approval of essential medications was delayed days to months with potential health and life-threatening consequences. Examples of medications included:

- Injectable medication for multiple sclerosis
- Cholesterol medications for patients with HIV
- COX-2 inhibitors (arthritis, pain medication) for patients who met formulary criteria for prior authorization
- Oral chemotherapy for breast cancer
- Erythropoietin (shots for anemia) for kidney failure patients
- Anti-convulsants for epilepsy
- Oral medications and insulin for diabetes
- Mood stabilizers for patients with bipolar disease
- Antibiotics needed to prevent gangrene and possible foot amputation in a beneficiary with diabetes⁴⁵
- Medication to improve circulation⁴⁶

Many factors at the physician, plan, and pharmacy levels contributed to these delays. Physicians often paid little attention to formularies, rarely requesting authorization prior to writing a prescription, and assuming that a pharmacy or plan would notify them if the prescription could not be filled. Not all physicians writing prescriptions for plan members are credentialed by the plan⁴⁷, or have a relationship with the plan, leaving them uninformed about the plan formulary. Non-affiliated doctors include emergency room physicians, inpatient physicians, or non-participating physicians seeing Medicare dual-eligibles.

Although lack of adherence to the 24-hour turnaround requirement was the most striking of the contract violations, concerns were found in two other major areas as well. First, the requirement that physicians review all medication denials did not appear to be always fully met. Although physicians signed all denial letters (in a stamped signature format), some letters contained formulaic/multiple choice denial rationales that

suggested that the prior authorization request had not been carefully reviewed.⁴⁸ Meetings with officials from one MCO confirmed the usual process of having pharmacy technicians review prior authorization requests, identify the issues, and pass them on for physician review with suggested plans of action. The MCO declined to say, in an interview, the number of such letters a physician reviewer examines in one day, or the training given to physicians in such positions.

Second, 72-hour medication supplies for which there is an “immediate need” were not always dispensed. One plan acknowledged failures to dispense 72-hour supplies of medications whose smallest packaging was larger than a 3-day supply. Although many examples were found of beneficiaries’ inability to obtain 72-hour supplies of medications, differing explanations from pharmacists and plans made clarification of this issue extremely difficult.

Limited fax server capacity, insufficient telephone personnel, and the appearance⁴⁹ of cursory review at the medical director level meant that administrative hurdles were means of limiting the use of drugs requiring prior authorization. These hurdles had real and immediate effects on beneficiaries, some of whom were not physically or emotionally able to wait at pharmacies, return to get prescriptions, or send others, such as family members, to pick up prescriptions with uncertain availability. Administrative barriers on both ends of the transaction played a significant role. Physicians often used clerical personnel with little or no clinical training to communicate with MCOs, decreasing accurate transmittal of appropriate information. The use of personnel at the plan level who lacked training and knowledge in pharmacy to answer telephone requests resulted in poor communications with providers.⁵⁰ During the study period, physician offices documented the need to send faxes several times, despite having fax confirmations of successful sends. If they realized the problem, and called, they were simply told to fax again, rather than being offered an immediate telephone conversation with a plan pharmacist who could handle the request.

Physicians and pharmacists documented long telephone hold times once phones were answered. Of 60 reports received from medical practices identifying problems with prior authorization, over 50% (32) reported needing telephone contact one or more times per prescription, and all reported wait times that ranged from 5 to 40 minutes (average 15-20). The total wait time for these 32 prescriptions was 595 minutes or almost ten hours of telephone time. A pharmacy in a low income neighborhood in Philadelphia needed to call an MCO four times in two hours, with each call lasting 12-15 minutes, or

one hour out of four spent on hold.⁵¹ These wait times negatively impact patient access. One chain store pharmacist commented to the author, “I don’t have time to call for a welfare patient.”⁵²

During the study period, although scattered helpline reports were received from beneficiaries in all plans, problems were initially concentrated in just a few plans. One of these changed PBMs during the study, improving telephone access to prescribers and pharmacies, and streamlining procedures for renewals of chronic, previously approved medications. This led to a dramatic decrease in the number of beneficiary and physician complaints, suggesting that plan operations, and not the formulary concept – or even the particular formulary – was the primary problem.

2. Contractual obligations and managed care policies hinge on actions at the retail pharmacy level without monitoring to ensure compliance.

The existence of multiple health plan formularies creates an enormous administrative and fiscal challenge to pharmacists. Whether a pharmacist faced with a computer-generated denial or a request for additional information chooses to question a beneficiary, call a physician, or call the MCO can have a significant impact on whether the beneficiary receives the medication. Interviews with pharmacists, calls to the PHLP helpline, physician reporting, and direct observation in pharmacies found numerous problems at the retail pharmacy level which affected whether a needed prescription was obtained. Medicaid beneficiaries are particularly likely to receive prescriptions for non-

formulary medications, because the physicians they see – in emergency rooms, in

teaching hospitals, in clinics that utilize part time providers – are less likely to be aware of formularies, and less likely to be available to pharmacists when prescriptions need clarification or adjustment.

A Tale of Two Pharmacists

A beneficiary with HIV presented a pharmacist with a prescription for a fungal infection. The pharmacist handed back the prescription saying, “Your plan doesn’t cover this.” Worried about her health, the patient called her physician, who contacted the pharmacy. A different pharmacist acknowledged they had no record of the prescription, entered it into the computer, confirmed coverage, and dispensed the medication.

Large variations in business decisions at the retail pharmacy level impacted a beneficiary's ability to receive medication.

Pharmacists have discretion regarding whether to call PBMs, health plans or physicians to clarify, change, or improve their ability to dispense a given prescription. Although a pharmacist's knowledge of Medicaid regulations is one factor in these decisions, other factors are largely business decisions: reimbursement, pharmacy staffing, number of customers in the store, and general level of customer service provided.

Two examples of the range of problems and their impact on beneficiaries illustrate the possibilities:

- A physician reported seeing a patient who had been unable to get arthritis medication for one month, despite notification that prior authorization had been granted. The patient's pharmacist told her the prescription "would not go through" despite multiple attempts on different days. A phone call to the plan by PHLP discovered the prescription had been written for "34 days" but prior authorization had been granted for "one month," generating a computer mismatch that rejected the prescription. *Had the pharmacist made a call initially, the beneficiary would have received the medication.*
- A beneficiary on potassium supplementation had the dosage increased mid-month from one to two pills per day. The prescription was rejected at the pharmacy as an "early refill," even though it was a new prescription and a dosage change. The pharmacist called the MCO to get override permission to dispense. *Had the pharmacist not made the call, the medication could not have been dispensed.*

Pharmacists, primarily those in independent pharmacies, sometimes declined to dispense medications to Medicaid beneficiaries (when the pharmacy accepted Medicaid generally) when reimbursement dropped below their wholesale cost, although beneficiaries may not have been aware of this reason and may have believed the drug was ineligible. Pharmacists documented refusals⁵³ to fill medications used to treat HIV, arthritis, schizophrenia, depression, diabetes, cancer pain, and blood clots. This was reported only in independent pharmacies, whose wholesale costs fluctuate to a greater extent than regional or national chains. Chain pharmacists are unaware of their employer's wholesale costs, and thus this is less likely to be an issue for them.

Pharmacists faced administrative barriers similar to those found in physician offices.

Retail pharmacists reported different beliefs, and therefore confusion, regarding appropriate after-hours call numbers and availability of pharmacy personnel. In 2001, one plan closed its pharmacy department at 3:00 PM on the day before Thanksgiving and remained closed until Monday. Although plans stated they had a 24/7 on-call pharmacist for problems, retail pharmacists did not believe, or were not aware, they could reach anyone but a telephone clerk without override power.

Previously reported long telephone wait times led some pharmacists to ask beneficiaries to return hours or days later, and others to fill prescriptions and work on overrides later. However, this kind of “random discretion” puts beneficiaries at the mercy of the individual pharmacist, and the number of customers standing at the counter.

Multiple PBMs with different computer programs allow pharmacists varying degrees of control to override drug interaction problems, early/vacation refills, etc, adding to the confusion of when a phone call will make a difference. Pharmacists had both praise and criticism for differing systems that prevented overrides for which they felt able to make decisions, or allowed dispensing of potentially dangerous duplicate medications.

Beneficiaries often reported presenting prescriptions for which they had been told that prior authorization had been granted, but for which the pharmacist received a computer rejection. There are several possible reasons for this inconsistency, including data entry delays at the health plan, data entry mismatch, and misinformation, but sorting out the problem requires time and initiative on the part of the pharmacist, efforts that are not consistently made. Numerous independent reports from pharmacists, physicians, and the PHLP helpline confirmed this as a problem.⁵⁴

Some prescriptions did not require physician prior authorization, but required a pharmacist to call to obtain approval. In several such situations, pharmacists returned the prescriptions to the beneficiary, confusing the beneficiary and the physician. One MCO required this of smoking cessation products, but did not notify physicians, beneficiaries, or pharmacists of this logistical hurdle.⁵⁵

The enormous variability in options, completely dependent on the pharmacist’s interest in advocating for the patient, keeping the customer, willingness to call physicians, etc. has very different implications for beneficiaries. Beneficiaries who receive partially filled prescriptions, or who do not receive the medication at all, may have difficulty understanding why. Limited English proficiency, mental and physical disabilities, low educational level, and other characteristics of the Medicaid population

make it less likely that beneficiaries will understand why they do not get a medication, and less likely they will contact their physician if they fail to obtain prescribed medication.

*Beneficiaries were unable to obtain contractually mandated emergency supplies of medications*⁵⁶

Although all HealthChoices MCOs stated they had automatic override codes to allow pharmacists to dispense medications, pharmacists regularly reported difficulties with override codes that required phone calls to the plans. If the medications were expensive, or if they were presented on weekends or holidays when the MCO/PBM had no one covering the pharmacy department, pharmacists were reluctant to dispense without guarantee of payment. Numerous reports were received from pharmacists of an inability to dispense medications where the smallest available supply was more than 72 hours worth (eye drops, skin creams), and other medications, because they could not reach the MCO, could not get an override code to work, or were denied permission to dispense. Pharmacists had no guidelines to determine whether a customer had an “immediate need” and were not in a position to ask for medical information at a public pharmacy counter or to make that judgment, and thus assumed by default that all prescriptions should have a 72-hour supply dispensed. No interviewed pharmacist could recall ever being able to use a code for a 15-day supply. Numerous reports to the helpline and physicians offices cited “cut-offs” of previously approved chronic medications when the prior authorization had expired, yet beneficiaries were unable to obtain a 15-day supply. Among the medications for which we documented 72-hour supply problems were psychiatric medication for a child discharged that day from an inpatient facility; blood pressure and leukemia medications, both ongoing, for a beneficiary whose previous managed care plan went bankrupt and left HealthChoices; asthma medication and eye drops for an allergic reaction.

Many pharmacists were unaware of HealthChoices contract requirements. Interviews with pharmacists employed by large chains, some of whom work shifts in different stores, confirmed that they relied solely on computer messages for information on dispensing.⁵⁷ Two callers to the PHLP helpline, both of whom had filled prescriptions in high-income neighborhoods, asked for assistance after they were charged for emergency supplies of ongoing medications whose prior authorization had expired. Pharmacists were denied permission to dispense and beneficiaries feared being without cardiac medication and paid for the supply.⁵⁸ In many cases, although we were able to

document that 72-hour and 15-day supplies were not dispensed, it was impossible to accurately determine whether the problem lay with the retail pharmacy or the MCO/PBM. Both pharmacists and beneficiaries reported that some beneficiaries declined 72-hour supplies, fearful of running out of medication, of starting medication they could not finish, or of being unable to return to the pharmacy. In HealthChoices, when these prescriptions are not filled at all, the plans receive no notification of the failed prescription, and thus are unable to follow-up with either the physician or the beneficiary.

Plans had variable quality assurance programs to follow-up on 72-hour prescriptions. One plan reviewed its pharmacy data to ensure that denied prescriptions were followed by the prescribing of formulary medications for the condition, but noted that despite active outreach attempts, physicians often failed to return their phone calls.⁵⁹

3. Health plans control outpatient, but not inpatient formularies in both physical and mental health facilities. Seriously ill patients are unable to obtain medications on discharge from inpatient facilities, putting them at risk of relapse and re-hospitalization.

Lack of coordination between inpatient and outpatient care is not a problem limited to Medicaid, or the public sector, but its effect is most pronounced among those least able to advocate for themselves, least able to obtain physician appointments on discharge, and with the least continuity of care between hospital and outpatient settings. The sickest and most vulnerable

Multiple sclerosis untreated for 60 days

A 22 year old man with newly diagnosed multiple sclerosis was discharged from a rehab facility with a prescription for an injectable medication used only for multiple sclerosis. The prescription was denied at the pharmacy because it required prior authorization. The hospital physician, who wrote the prescription, had no relationship with the MCO and refused to complete prior authorization requests. The patient did not see his primary care physician until 22 days later, at which time prior authorization was requested and denied because the MCO required a hospital discharge summary, which was not yet available. Continued advocacy on the part of the primary care physician resulted in approval almost 60 days after the drug was prescribed.

beneficiaries – those recently in the hospital – may be at highest risk of missing medication. Pennsylvania Medicaid beneficiaries were particularly at risk for problems

resulting from lack of care coordination because of the large number of primary care physicians and community psychiatrists who do not care for their patients in the hospital, and the large number of teaching hospitals where interns and residents, oblivious to formularies and health systems, write for discharge medications. This disconnect leads to examples such as the beneficiary with schizophrenia whose violent behavior led to an involuntary commitment, but who was unable to obtain, for more than a week after discharge, the medication with which he was treated in hospital;⁶⁰ a resident in a facility for mentally retarded adults who, after being denied a non-formulary medication, required hospital re-admission;⁶¹ and a diabetic woman with an infected foot, at risk of amputation, who went without medication for over two weeks. (See appendix case 7)

4. The division of contracts and responsibilities into physical and behavioral health plans but the allocation of all pharmacy benefits to physical health plans results in particularly severe problems for the chronically mentally ill.

Chronically mentally ill patients have difficulty obtaining medications, as opposing financial interests in the system create substantial barriers. Physical health MCOs in Pennsylvania's Medicaid program are responsible for all pharmaceuticals including psychiatric medications, but behavioral health MCOs are responsible for outpatient care and hospitalization. Thus, in the ongoing discussion over whether expensive pharmaceuticals prevent even more expensive hospital care, there is no unified

responsible party.

Long wait for the right drug

A psychiatrist sought prior authorization in July for a mood stabilizing drug after a beneficiary had failed three formulary medications. The community mental health center supplied the patient with samples on a trial basis. In January, after a prolonged period with no written response, a nurse telephoned and was told she needed to wait for a denial letter. When she informed the plan that she had sent multiple requests since July, she was put through to a pharmacist who approved the drug.

Psychiatrists caring for Medicaid beneficiaries are credentialed and communicate with behavioral health MCOs but have no contractual or other relationship with the MCOs paying for the prescriptions they are writing. This disconnect discourages the implementation of structures promoting quality assurance in prescribing practices.

Several other factors combine to make pharmaceutical benefits for the chronically mentally ill a difficult health policy and economic issue. The very high cost of newer psychiatric

medications is now accompanied by controversies in the medical/scientific literature regarding appropriate utilization of these medications, including whether they have fewer side effects, whether they should be first choice drugs, and whether they lower overall care costs by decreasing hospitalization.⁶² Yet the initial scientific excitement over these medications, and heavy pharmaceutical marketing and educational campaigns to beneficiaries and their consumer organizations on the benefits of these new drugs make it difficult to “return” to older medications without accusations of inferior care for poorer or vulnerable populations. Controversies in the medical literature on the appropriate use of newer anti-depressants and anti-psychotics in the pediatric population and the relative role of medications, paid for by physical health MCOs, and therapy, paid for by behavioral health MCOs⁶³ further complicate treatment decisions for beneficiaries, providers, and payors.

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Psychiatrists caring for Medicaid beneficiaries are credentialed and communicate with behavioral health MCOs but have no contractual or other relationship with the MCOs paying for the prescriptions they are writing. These dichotomies foster pre-existing distrust and discourage structures to promote quality assurance in prescribing practices.

Several other factors combine to make pharmaceutical benefits for the chronically mentally ill a difficult health policy and economic issue. The very high cost of newer psychiatric medications is now accompanied by controversies in the medical/scientific literature regarding appropriate utilization of these medications, including whether they have fewer side effects, whether they should be first choice drugs, and whether they lower overall care costs by decreasing hospitalization.⁶⁴ Yet the initial scientific excitement over these medications, and heavy pharmaceutical marketing and educational campaigns to beneficiaries and their consumer organizations on the benefits of these new drugs make it difficult to “return” to older medications without accusations of inferior care for poorer or vulnerable populations. Controversies in

the medical literature on the appropriate use of newer anti-depressants and anti-psychotics in the pediatric population and the relative role of medications, paid for by physical health MCOs, and therapy, paid for by behavioral health MCOs⁶⁵ further complicate treatment decisions for beneficiaries, providers, and payors.

In addition to scientific and economic controversies, other factors converge to make formularies particularly difficult for mentally ill beneficiaries and their prescribing physicians. The nature of the illness presents the first barrier. A beneficiary whose medical problem involves thought processing may not be able to negotiate complex rules and systems, and may not be easily convinced that the blue generic pill is the same as the green brand name he received last month. More than with other types of illness, perception may drive reality.

Differences in responses and side effect profiles to medications within the same class, such as selective serotonin reuptake inhibitors for depression, or atypical antipsychotics for schizophrenia make psychiatrists and patients very reluctant to consider same class drugs as equivalents. Formularies, and especially Medicaid managed care formularies, have considered same class drugs equivalent because they have been shown to be equally effective, despite different side effect profiles.

Finally, formularies constructed for adults may not apply to pediatrics. Community standards of use and in particular the use of drugs in the pediatric population often diverge rapidly from original FDA approval, placing community practice at odds with formularies, and leaving no scientific “gold standard” for prescribing. Recent evidence regarding pharmaceutical manufacturers’ withholding of information on drug trial results in children highlights the difficulties faced by physicians, MCOs, and the parents of ill children as they try to understand economic and treatment issues.

Psychiatrists interviewed for this study shared the frustrations of their medical counterparts with regard to managed care administration but expressed additional concerns regarding the failure of state initiated safeguards to guarantee psychiatric input into formularies managed by the physical health MCOs.

In HealthChoices Southeast, a regional pharmacy and therapeutics (P & T) committee had representation from the two participating behavioral health MCOs, practicing psychiatrists from the community mental health system, and members of the state Office of Mental Health and Substance Abuse Services (OMHSAS). However, committee members stated that physical health MCOs either did not send representatives to these meetings, or sent representatives without decision-making

power, and changed their behavioral health formularies without consulting the committee designed to act as an advisor in these matters. Changes cited during this time included the initiation of step therapy or fail first mandates for SSRIs. A letter from the pharmacy director of one MCO, responding to these charges, noted that they had no obligation to follow committee recommendations.⁶⁶

Medical directors of both behavioral health MCOs involved in HealthChoices SE discussed lack of input into formulary decisions. A psychiatrist and substance abuse expert with an administrative position in a behavioral health MCO stated in an interview that he believed he was on the pharmacy and therapeutics committee of one of the physical health MCOs, but that he had not been invited to a meeting in more than one year.⁶⁷

These controversies over appropriate prescribing of behavioral health drugs lead to frequent prior authorization requests. An overtaxed community mental health system, often staffed by part-time psychiatrists and limited support staff restrict the abilities of the staff to submit prior authorizations and follow-up if no response is received (see case at the beginning of this section). During the time period of the study, beneficiaries with mental illness, their psychiatrists, and pharmacies all reported numerous problems with behavioral health medications, reflecting both the issues around these drugs, and the high proportion of Medicaid beneficiaries with behavioral health diagnoses.

A final problem affecting the behavioral health beneficiaries affects those living in state regulated community living arrangements or Title 6400 Group homes. These facilities operate under additional regulations regarding the dispensing of pharmaceuticals, including packing into blister packs, and dispensing in units of “weeks” rather than “one month.” Pharmacies serving these institutional providers reported problems converting prescriptions from 30-day supplies to 4-5 week supplies, both in obtaining prior approval, and in obtaining appropriate reimbursement, because of discrepancies in the absolute numbers of pills dispensed. For medications requiring prior authorization, every change – including a packaging change if a beneficiary goes home for the weekend – required an additional prior authorization in a system already overburdened and unable to respond to prior authorizations in a timely manner.

5. The existence of multiple plans and formularies and the absence of state requirements for formulary organization and presentation make it difficult if not impossible for physicians to efficiently utilize formularies when prescribing.

Pennsylvania Medicaid managed care formularies are presented to prescribers and beneficiaries in multiple electronic and printed formats. The clarity and availability of this information to beneficiaries can impact their choice of plans, and the presentation of the information to prescribers affects their ability to follow a formulary and choose a drug. Although the HealthChoices contract specifies that formularies must contain drugs from all therapeutic categories and subcategories and subclasses and subcategories covered under the fee for service program, it does not specify the system or nomenclature to be used to assess compliance.⁶⁸ The result is a bewildering array of drug lists that prevents comparisons and confuses prescribers, most of whom participate in multiple insurance plans.

Finding a migraine drug

A beneficiary with migraine headaches wishes to know if the medications she has been on will be covered by her new MCO. In 2000, only four of the seven plans had formularies with an index. Migraine medications were variously listed in formularies under neurologic medications, musculo-skeletal agents, pain and inflammatory disease, or central nervous system disease. Only one plan out of seven cross referenced the medications or listed a medication in multiple categories if it had multiple uses.

Although some of these problems have been remedied since the time of this study, the formularies presented several barriers to quick and easy consultation. The physical formats of the seven plans included 8.5 by 22 inch wall posters with text on both sides, pocket-sized books, and larger bound books that could be inserted into three ring notebooks. One plan had no complete formulary, but only a series of memos. These physical formats were impractical for easy office use by clinicians or by beneficiaries. They presented different display and storage problems (wall space, pockets, bookshelves) complicating access to them at the point of use. None of them allowed for integration of formulary changes within the original format, resulting in quickly outdated references. At the time of this study, none of the formularies was available in electronic format.⁶⁹

Seven Medicaid MCOs (two plans are part of the same corporate organization and have identical formularies) presented their data in six diverse drug classification schemes. Although most utilized an adaptation of the proprietary system of the American Society of Health System Pharmacists (ASHP), some used alphabetic categories, and

others numeric. Not only did numerical categories vary across plans, but categories with similar names, such as “central nervous system” contained different medications. They placed identical drugs in different categories within the formularies making it difficult for consumers or clinicians to locate medications.

Printed formularies were inconsistent in their use of an index or table of contents. Only three of the six formularies were indexed by generic and brand name. Moreover, despite the importance of encouraging generic prescribing, not all HealthChoices printed formularies were designed to educate and promote their use. One printed formulary used only brand names. They did not include a guide to over-the-counter (OTC) medications that are covered under the program, although use of these medications is clearly cost effective and medically safe. Several plans did include a few OTC drugs in the formulary body, or brief descriptions of OTC coverage, and one plan referred users to the PA [legal] Code, an unfamiliar source to HealthChoices physicians and beneficiaries. OTC drug coverage is critical in Medicaid formularies, because Medicaid, but not commercial insurers, covers selected OTC formulations when a beneficiary has a written prescription.

The formularies’ use of confusing and inconsistent terminology to describe restrictive practices constituted an impediment to physician and beneficiary use of, and understanding of, formularies. At the time of the study, plans used prior authorization, managed drug limitations (MDL), quantity limitations (QL), first choice, fail first, and step therapy to refer to restrictions on prescribing. If a plan requires a patient to fail drug A before they will allow drug B, whether it is called first choice, step therapy, or fail first, is a matter of marketing a pharmacy benefit, not a matter of medical prescribing. Prior authorization was required both for non-formulary drugs, and for some drugs appearing on the formulary, without clarification of the difference in these categories.

Only one out of six printed formularies used the format as a means to educate physicians about national guidelines or other safe prescribing practices. None offered information or references explaining formulary choices.

6. Formulary changes with financial but not clinical rationales, combined with prior authorization and administrative requirements that lack a clinical basis, result in deep suspicion by physicians and consumers and poor stakeholder

acceptance of the entire concept of formularies or preferred drug lists despite their potential for both cost savings and quality improvements.

The Formulary Battleground

“I can’t be bothered to ask for prior authorization. It’s not my job.”

-Specialist physician, Pennsylvania Medicaid program, to PHLP lawyer

“Doctors ignore our notification of the need to renew prior authorization. We know they are disgusted with managed care.”

-Pharmacy and medical director, Pennsylvania Medicaid MCO

Physician and beneficiary acceptance of formularies as cost effective quality tools that improve health outcomes has not yet been achieved in most health systems.⁷⁰ Although physicians have repeatedly stated that they prescribe based on scientific principles and not because of pharmaceutical company marketing, numerous studies have shown otherwise.⁷¹ Reliable estimates are that the pharmaceutical companies spend between \$12-15,000 per doctor per year on marketing. The addition, in recent years, of direct-to-consumer (DTC) marketing, has increased patient demand for recognizable brand name drugs touted by celebrities or TV advertising. Given the strength of these influences, systems that foster physician and patient distrust create a serious obstacle to successful formulary implementation and acceptance. Insurance companies and PBMs, with complex systems and payment denials, are less likely to be believed than pharmaceutical representatives who come bearing gifts.

While it has been argued that physicians simply don’t like to be told what to do, and how to prescribe, there are additional reasons for physician dislike and distrust of formularies. For example, during the two years of the study, several MCOs changed their formularies multiple times, including, in one case, twice in one year. These changes included adding, and then removing, particular drugs within a class, requiring physicians to switch patient medications even if patients were doing well. Although plan medical directors, in one case, originally stated that patients would not be required to change drugs, requests to maintain beneficiaries on their original drugs were denied.⁷² For many physicians, these denials contradict sensible prescribing practices.

Plans required physicians or pharmacists to submit prior authorization requests every month, or every three months for chronic medications whose indications and necessity did not change. Examples at the time of the study included proton pump inhibitors recommended by gastroenterologists, and medications for epilepsy patients. Pharmacists needed to call one MCO monthly for any beneficiary requiring more than two bottles of insulin/month and for insulin pens even if they were previously authorized with refills. These requests were rarely denied if the pharmacist or physician office took the time to call, supporting provider belief that the requirement was merely an administrative hurdle.

Despite the existence of a state mandated regional pharmacy and therapeutics committee for behavioral health drugs, MCOs repeatedly disregarded its recommendations, supporting the belief that MCO decisions are made purely on an economic basis.

MCO representatives cite a range of prescribing practices among their member physicians. Although they acknowledged their ability to evaluate individual physicians based on these practices, they defended their need to implement policies based on the practices of the worst prescribing physicians. Beneficiaries may be confused and frustrated when they cannot obtain the medication the physician prescribed and/or the one on television. Although all three groups have a potential common interest in making a formulary system work, it is difficult to overcome the shortcomings of the present system to begin to consider this goal.

V. Conclusions and recommendations

Despite the problems detailed in this report, the formulary concept – the creation of lists of cost effective drugs of choice for medical conditions appropriate to the population served – is critical as states and the Federal government seek to implement pharmaceutical coverage as part of government sponsored health programs.⁷³ Essential to the success of such programs will be improved education regarding pharmaceuticals and prescribing at the physician and beneficiary level, “image improvement” public relations efforts for the formulary concept, methods of formulary construction that stakeholders believe are fair, and monitoring of formulary implementation at the administrative level.

Policy recommendations include the following:

1. Safeguards in managed care contracts or in state run prescription benefit programs must be linked to well run administrative infrastructures that serve the needs of beneficiaries, pharmacists, and physicians. This infrastructure includes 24/7 phone or computer access for pharmacists and physicians, knowledgeable personnel at the physician and pharmacist level, and adequate personnel for quick turnaround of requests and problems, consistent both with state contracts and with standards of quality care. Well-publicized user hotlines to report problems may be useful for ongoing monitoring. Sentinel practices, including private practices, teaching settings, and safety net providers can be engaged to participate in the monitoring process. The prior authorization process of managed care organizations, or of states with Medicaid formularies, needs to be monitored not only with data from the plans or pharmaceutical benefit managers, but also from physician and pharmacy providers. Potential key breakdown points, such as those identified in this report, should be used to develop templates for assessing a managed care organization or PBM's ability to administer a pharmacy program according to contractual obligations and federal and state law.

States should be encouraged to team up with experienced researchers in the field to look at clinical consequences of problems in formulary implementation. As we have shown, formulary operations, and not just content, have clinical consequences. It is critical to know if delay or inability to access medications resulted in hospitalization, relapse, or other adverse quality consequences. This cannot be done on an anecdotal level, and should be looked at by researchers familiar with Medicaid formularies and health policy.⁷⁴

2. Monitoring services at retail pharmacies requires a joint effort of managed care organizations, retail pharmacy trade organizations, and state Medicaid agencies.

Retail pharmacies are a key but neglected component of Medicaid pharmacy policy and states must develop monitoring instruments that reflect the importance of these providers. Suggestions to improve services include on-line trainings for contracted pharmacists, computer generated beneficiary rights to be included when any prescription cannot be filled as written, and computer systems that allow for transmission of unfilled prescriptions to PBMs and MCOs who can then contact the prescriber. Pharmacists need 24/7 access to knowledgeable personnel who can approve or clarify rejected transactions.

Multiple plans with differing service hours, phone numbers, PBM intermediaries, and formularies hinder beneficiary access to medication. Just as no formulary can anticipate every clinical situation, no computer program can anticipate every prescribing scenario. Pharmacists need to be able to exercise clinical judgment, and to clarify prescriptions with physicians and plans. Adequate support systems, including override codes and 24/7 telephone access are needed to ensure the goal of quality prescription service.

Clear quality assurance programs must be developed by MCOs or PBMs to identify and follow-up on prescriptions unable to be dispensed. Medicaid MCOs in Pennsylvania have audited pharmacies for financial discrepancies but neither the MCOs nor the state have looked at the influences of pharmacies in care delivery and outcomes. The pressure from PBMs and MCOs in the commercial arena to switch beneficiaries to mail order pharmacies has implications for Medicaid beneficiaries. Particular problems include, but are not limited to, limited English proficiency, safety of mailboxes and neighborhoods, storage of 90-day supplies, and time delays in ordering and receiving prescriptions. These issues need to be examined outside the commercial competition debate between retail and mail order pharmacies. Pharmaceutical policy researchers will need to develop innovative methods to examine this neglected area.⁷⁵

3. Managed care organizations should be leaders and facilitators of the inpatient-outpatient transition, not only with respect to formulary but to all aspects of care.

In Pennsylvania, some Medicaid MCOs perform daily concurrent reviews of hospitalized patients to evaluate medical necessity for hospitalization. These nurse reviews could be used to pinpoint potential care disconnects at the point of discharge, anticipate medication problems, speak to attending physicians, or transmit information to pharmacy systems to allow temporary supplies of medications following hospitalization. Hospitalizations are “red flags” for the sickest, most at-risk beneficiaries and require creative efforts at intensive case management. Discharge planning presents a unique opportunity to manage care and not just costs, and pharmaceuticals should be included in discharge planning considerations.

4. High drug costs for newer mental health drugs, the high proportion of people with mental illness in the Medicaid population, and the division in medicine between physical and behavioral health providers make it critical that Medicaid

policy serves to coordinate care for those with chronic mental illness. Separating prescribing and fiscal responsibility, as Pennsylvania has done, exacerbates these difficulties. Psychiatrists need input into formulary creation, but also need to be held accountable for prescribing practices. Coordination at the state and MCO level is needed to prevent beneficiaries from being denied therapy and behavioral approaches by the behavioral health MCO, or drug treatment by the physical health MCO, as MCOs seek to shift care and financial responsibility.

Many states, mindful of these difficulties, have exempted all mental health drugs from formularies.⁷⁶ Although this addresses many of the concerns of psychiatrists and patients, it also exempts them from the prescribing scrutiny being applied to other disciplines, and places few checks on the commercial influences of the pharmaceutical companies. A combination of treatment guidelines⁷⁷, audits for polypharmacy (patients on excessive numbers of psychotropic drugs), and decreased administrative hurdles for prior authorization and non-formulary medications would address concerns of physicians and advocates.

States need to search out, and fund, “best practice” initiatives and model treatment programs that include community resources in education, employment, and housing, all of which may be as important as pharmaceuticals in the management of mental illness.

5. States with multiple Medicaid managed care organizations, with or without fee-for-service Medicaid, should have uniform standards for organization, drug classification, and presentation of the formulary to promote ease of use and comparability. Preferably, these standards would also exist at the Federal level to encompass current and future Medicare drug benefits.⁷⁸ Advocates of electronic prescribing have called for similar standards.⁷⁹ Contracts should include standards for online access to formularies and their rationales, consistent with the transition to electronic prescribing and the level of electronic based data transmission currently required by states, their contractors, and physicians. Uniform templates for prior authorization of pharmaceuticals would minimize confusion and improve physician participation.

A true “drugs of choice” formulary would mean that each state would have only one formulary, identical across all plans, with reference pricing or drugs of choice listed

by price when they are otherwise considered equal. This is unlikely in the near future for multiple reasons.

Clinical rationales for all drugs subject to prior authorization or other prescribing limitations must be available to prescribers and consumers.⁸⁰ This provides an educational function for both patients and physicians, and clarifies whether decisions are being made on a clinical or cost basis. Such information could be available online to physicians, as a printout with a denial letter to physicians, and as a printout at an appropriate literacy level to beneficiaries. This has the potential to change prescribing habits, or allow reasonable appeals based on a common knowledge base. It also has the potential to educate beneficiaries about medical conditions and pharmaceuticals.

Examples for online policy benefits exist in the commercial arena.⁸¹

6. States need to seek creative methods to involve physicians and consumers in the development of Medicaid pharmaceutical policy. Although the engagement of large pharmaceutical firms in the design of commercially available formularies is generally accepted as inevitable, primary system users with an interest in quality and efficiency are less often at the table. In the public sector, balancing the need for open processes and transparency while minimizing the influence of pharmaceutical companies has proved challenging.

States need to devise ways to unite consumers and physicians with the state as purchasing agency to meet the pressures presented by large pharmaceutical firms. For formularies to be successful, physicians and beneficiaries must believe that they arise from an impartial and professional process centered on health care outcomes, not that they are the creations of parties with overwhelmingly financial interests.⁸² Formularies must meet the needs of the populations they serve, with data regarding age and disease demographics included in formulary construction.

Strategies could include generic educational “detailing” to physician offices, public relations campaigns to beneficiaries on drug safety and generic drugs, and involvement of traditional “disease organizations”⁸³ in promoting safe prescribing and generic drugs. Currently, major pharmaceutical companies, whose available financial resources are considerably larger than those of most states, pay for almost all pharmaceutical educational programs.⁸⁴ The pool of money for generic detailing, and physician and consumer education could be enlarged by state cooperation with commercial insurers, business purchasers of prescription plans, and physician

organizations who share the same interest in quality and cost effective prescribing. Although the consumer target may be different, the physician targets are similar.

In the long run, a national panel, on the model of the Oregon panel, is needed to review evidence-based studies, and peer reviewed literature to construct a listing of available medications, therapeutic usefulness, and overall value in treatment plans.⁸⁵

7. Financial penalties assessed by states for violations of Medicaid law or contracts, or savings generated by changes in pharmaceutical policy administration, should go into a fund to improve prescription drug access and prescribing quality in the state. States currently considering changing to systems that involve managed care or formularies should explicitly target savings from these changes to remain in the area of health care access for its population.

Appendix A

Pennsylvania Health Law Project 924 Cherry St. Philadelphia PA 19107
215-625-3663 Fax: 215-625-3879 HELP line: 1-800-274-3258

HealthChoices Monitoring Form

Initials _____ Age _____ Date of request _____ Date of resolution _____

Health Plan: MCO 1 MCO 2 MCO 3

Service: Medication DME or Nursing – go to separate page

Medication/dosage _____

Indication _____

Or: attach copy of faxed request to HMO with patient's name blacked out

Problem:

- Not on formulary
- On formulary with PA
- Dosage limit
- Dosage form not available (pediatric, liquid)
- Renewal of previously approved med
- Medication not dispensed by pharmacy/no notification

Action:

PA called date_____ approved_____ denied_____

PA faxed date_____ return fax date_____ app_____denied_____

And/or: Attach copy of approval/denial with *name blacked out*

To get service approved the prescriber/nurse/social worker/office staff (circle all relevant) had to: check all that apply

consult provider handbook

speak to plan medical director

consult plan formulary

write letter of medical necessity

speak to neighborhood pharmacist

complete special forms
estimated time _____ minutes

speak to plan pharmacy rep

participate in grievance/fair hearing

spend ___minutes on the phone

Did HMO respond within 24hours Yes No

reminder call necessary? X1 x2 more?

Did you seek prior authorization before giving Rx to patient?

after Rx denied to patient.

How did you hear of the problem?

patient pharmacist HMO prior experience with issue other

Did the pharmacist initially dispense:

72 hour supply 14 day supply

None, notified prescriber none, did not notify prescriber

unknown

Results:

- Patient obtained medication as prescribed after above noted authorization
- Patient obtained only 72 hour supply
- Patient obtained only 14 day supply
- Patient did not obtain prescribed medication in appropriate time frame
- Patient prescribed/obtained alternative equivalent medication (from prescriber perspective)
- Patient prescribed/obtained alternate medication less desirable from prescriber perspective
- Medication denied; prescriber or patient gained beneficial clinical knowledge from denial
- Patient referred to Pennsylvania Health Law Project for assistance

This patient would be willing to have his/her name used or give additional information in an effort to demonstrate barriers to care and improve the health care system

yes no didn't ask

Thank you very much. Additional comments:

Appendix B

Sample cases from the study

The following actual cases demonstrate problems cited in the report, including inadequate fax and telephone support at the plans, delays in issuing approval or denial for prior authorizations, errors in data entry resulting in inability to obtain medication, delays at retail pharmacies, and inpatient/outpatient care disjunction because of pharmacy issues.

Inadequate fax server and telephone capacity:

Case 1

A practice submitted a prior authorization for erythropoietin injectable for a patient in renal failure. The initial prior authorization was submitted October 15, 2001. The patient's son went to pick up the medication from the pharmacy, and was told by the pharmacist that the MCO denied receiving a fax prior authorization request. This medication is critical for renal failure patients. The problem was not resolved until November 12, 2001.

Case 2

On October 11, 01 a practice faxed a request for Maxalt 10®, a migraine medication, to an MCO. A follow-up telephone call by the practice on October 14, 2001 revealed that the MCO denied receiving the fax. The information was re-faxed again on October 14, again with fax confirmation of transmission. A repeat follow-up phone call to resulted in a claim that the fax was not received. A third fax was sent on October 22, 2001. Attempts by the office nurse to contact the MCO following this fax resulted in multiple repeat busy signals. The nurse gave up and the patient did not receive the medication.

Case 3

A client called the PHLP Helpline in February 2002 because of inability to obtain a cardiac medication, despite his physician's repeated attempts to obtain prior authorization. The physician office had documentation of five separate fax requests to the MCO, without response. The physician gave up.

Case 4

A patient with metastatic breast cancer required Xeloda®, an oral medication requiring prior authorization. The initial request was faxed to the MCO on September 28, 2001 (a Friday), after the office was notified by the pharmacist that he was unable to dispense any medication. The physician's office followed up with a phone call on three successive days before the medication was approved the following week.

Case 5

A 65-year-old woman called PHLP after her physician had been trying unsuccessfully for three months to obtain prior authorization for Pletal®, a medication used to treat poor circulation in the legs. The physician had documentation of faxes sent once, a week later, and 3 weeks later. On a phone call from the physician office to the MCO, the office staff member was told by an MCO employee, that the MCO was "busy and understaffed". A non-physician MCO employee suggested the physician try a different medication. The beneficiary called PHLP and filed a grievance. Counsel at PHLP called Pennsylvania DPW liaison for the MCO. The state liaison reported that she had met with the MCO and they acknowledged "glitches" in their response to prior authorizations and faxes. The MCO approved the drug after being called by the state Medicaid office.

Failure to comply with the 24 hour requirement for response to prior authorizations

Case 6

A psychiatrist submitted a prior authorization for Ambien® 10mg (a sleep medication that is less addictive than those on the formulary) for a very agitated patient who had just been discharged from the psychiatric hospital. The request was submitted on May 29, 2002, as indicated by the HMO in their denial letter. The denial letter was mailed bulk mail on June 13, 2002, as indicated by the postmark and postage on the envelope, and was received by the physician on June 17, 2002. The agitated woman never received the medication. In a subsequent letter to the physician, the HMO said they could "not explain the delay."

Case 7

A diabetic was hospitalized with a foot infection placing her at risk for amputation. She had an allergy to the first choice medication, and her only chance to prevent amputation was a new, expensive medication, linezolid. The patient was discharged home with a linezolid prescription, which was denied at the pharmacy because it was non-formulary.

Her infectious disease consultant immediately faxed a request for the drug. Neither the patient, nor the infectious disease consultant was aware of the 24-hour requirement, and the pharmacy did not dispense an emergency supply. No response was received. When the physician learned the patient was without medication, he again requested the medication. This time, on receiving no response, he placed a phone call to the MCO, demanding to speak with a medical director, who immediately approved the request. The patient, in danger of losing her foot, went without antibiotics for more than two weeks.

The consequences of hospital/outpatient disconnect

Case 8

A beneficiary with schizophrenia was discharged from a psychiatric hospital following involuntary commitment after he attacked a woman in a bookstore. He had previously had side effects from multiple formulary medications, and was discharged on Abilify®, a nonformulary medication. However, the medication was rejected at the pharmacy and the hospital physician would not complete prior authorization requests. His outpatient psychiatrist submitted a prior authorization, which was initially lost, re-submitted one week later, and rejected by the plan. The psychiatrist succeeded in reaching a medical director, who approved the medication after the beneficiary went more than a week without medication.

Problems with communication and operations at retail pharmacies

Case 9

An anti-fungal medication for a beneficiary discharged after a partial lung removal repeatedly showed up on the pharmacy computer as a rejection requiring “prior

authorization” despite the beneficiary’s belief that this had been obtained. After repeated calls from the physician and pharmacist, the pharmacist was told that even with prior authorization, the pharmacist is required to call for the claim to go through. The beneficiary went two weeks without critical medication.

Cases 10 and 11

Two pharmacists reported an inability to fill prescriptions for the anti-depressant Zoloft® 100mg after it was removed from several HealthChoices formularies with the provision that beneficiaries previously stabilized on the medication could remain on it. One pharmacist reported he was told the patient needed to try and fail generic Prozac® and the second was told the HMO would contact the physician to change the medication. Pharmacists were denied permission to dispense, despite the fact that Zoloft 100mg is not a starting dose, making it likely this was a continuing, rather than a new prescription, and that stopping Zoloft suddenly has medical consequences. Under the HealthChoices contract, pharmacists should be allowed to dispense 15 days of continuing medications.

Case 12

A patient required a brand name of diltiazem, because of problems swallowing the pill size of the generic formulation. She received authorization for six months, despite this being a chronic medication for which the need will not change. In June of 2001, the medication was denied at the pharmacy because the prior authorization had run out. Neither the patient nor the physician received prior notice of the need to submit a new prior authorization request. According to the pharmacist, his computer prompts did not offer him the chance to dispense a 15-day supply for a chronic medication. He dispensed a 30-day supply, for which the patient paid cash because she was afraid to stop her heart medication. This case, which also included multiple unanswered fax requests, required legal intervention.

Case 13

A PCP prescribed Levaquin® for a urinary tract infection in a homebound elderly woman on 11/3/01. The family called the physician 9 days later to report that the prescription had been denied at the pharmacy and they had received no medication. The

physician did not receive a denial letter and the family did not receive a 72-hour supply as required under the HealthChoices contract.

Case 14

A patient presented a prescription for Ketorolac® 10mg #15 (pain medication) that was rejected because it exceeded plan limits. The pharmacist called the MCO and was unable to get an authorization, despite the fact that the patient had been told that one was in the system. The pharmacist asked the patient to call her MCO. The patient returned the next day, saying she had talked with the plan and was told that everything was in order and the prescription would go through. The pharmacist submitted the prescription, which was again rejected. After 20 minutes on the phone he was able to fill the prescription.

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¹ Bernasek C, Farkas J, Felman H et al. Case study: Michigan's Prescription Drug Benefit. Kaiser Commission on Medicaid and the Uninsured. January 2003. Also Bernasek C, Mendelson D, Padrez R, Harrington C. Oregon's Medicaid PDL: Will an Evidence-Based Formulary with Voluntary Compliance Set a Precedent for Medicaid? Kaiser Commission on Medicaid and the Uninsured. January 2004, and Bernasek C, Harrington C, Ramchand R, Mendelson D. Florida's Medicaid Prescription Drug Benefit: A Case Study. Kaiser Commission on Medicaid and the Uninsured. February 2002. All available at www.kff.org

² Beronja, N, Menges, J, and Park, C. Analysis of pharmacy carve-out option for the Arizona Health Care Cost Containment System. Center for Health Care Strategies. November 2003. Available at www.chcs.org

³ Somers S and Perkins J. Model Prescription Drug Prior Authorization Process for State Medicaid Programs. Kaiser Commission on Medicaid and the Uninsured April 2003. Available at www.kff.org

⁴ Bernasek C, Farkas J, Felman H et al. Case study: Michigan's Prescription Drug Benefit. Kaiser Commission on Medicaid and the Uninsured. January 2003. Also Bernasek C, Mendelson D, Padrez R, Harrington C. Oregon's Medicaid PDL: Will an Evidence-Based Formulary with Voluntary Compliance Set a Precedent for Medicaid? Kaiser Commission on Medicaid and the Uninsured. January 2004, and Bernasek C, Harrington C, Ramchand R, Mendelson D. Florida's Medicaid Prescription Drug Benefit: A Case Study. Kaiser Commission on Medicaid and the Uninsured. February 2002. Available at www.kff.org

⁵ Beronja, N, Menges, J, and Park, C. Analysis of pharmacy carve-out option for the Arizona Health Care Cost Containment System. Center for Health Care Strategies. November 2003. Available at www.chcs.org

⁶ Somers S and Perkins J. Model Prescription Drug Prior Authorization Process for State Medicaid Programs. Kaiser Commission on Medicaid and the Uninsured April 2003. Available at www.kff.org

⁷ Beronja, N, Menges, J, and Park, C. Analysis of pharmacy carve-out option for the Arizona Health Care Cost Containment System. Center for Health Care Strategies. November 2003. Available at www.chcs.org. Also Bruen B and Ghosh A. Medicaid prescription Drug Spending and Use. Kaiser Commission on Medicaid and the Uninsured. June 2004 provides an excellent recent review of this topic. Access at www.kff.org. Managed care cost statistics for Pennsylvania for the years of this study can be found online at the website of the Pennsylvania Office of Medical Assistance Programs. The website www.dpw.state.pa.us/omap/hcmc/omaphcmci.asp allows access of Physical Health Databooks for the HealthChoices zones, with per member per month costs based on category of medical assistance.

⁸ Mello M, Studdert D, and Brennan T. The pharmaceutical industry versus Medicaid – limits on state initiatives to control prescription-drug costs. *New England Journal of Medicine* 350(6):608-613. February 5, 2004.

⁹ In 2002, 63% of Pennsylvania mandatory managed care beneficiaries were young women and children (TANF and TANF related categories) and 33% were SSI with and without Medicare. However, the average per member/per month costs paid by the state to managed care (with variance by region) was \$150/month for TANF and related populations, and \$642/month for those on SSI without Medicare. Available at www.dpw.state.pa.us/omap/hcmc/HCPHUpdate703.pdf

¹⁰ Wallack SS, Thomas C, Hodgkin D, Ritter G. Recent trends in prescription drug spending for insured individuals under 65 and age 65 and older. Waltham, Mass.: Schneider Institute for Health Policy, July 30, 2001. Similar information in Cloutier, M and Golenski, J. Rx Health Value offers three recommendations and cost research. *Journal of Managed Care Pharmacy* Vol 7 (1) January-February 2001. Also National Institute for Health Care Management Foundation (NIHCM): Factors Affecting the Growth of Prescription Drug Expenditures. July 1999. Available at www.nihcm.org

¹¹ In 2000 advertising expenditures for Vioxx® (an arthritis drug) totaled \$160 million, more than Budweiser (\$146 million), Pepsi (\$125 million) and Nike (\$78.2 million). Rosenthal MB, Berndt ER, et al. Promotion of prescription drugs to consumers. *New England Journal of Medicine*. 346:498-505, Feb 14, 2002.

¹² Siwolop, Sana. As drug benefits fall, workers need a strategy. *New York Times* October 5, 2003. Also Huskamp HA, Deverka PA, et al. The effect of incentive-based formularies on prescription-drug utilization and spending. *New England Journal of Medicine*. 349(23):2224-2232. December 2003

¹³ Testimony of Diane Rowland to a subcommittee of the U.S. House of Representatives Oct 8, 2003. "Challenges facing the Medicaid program in the 21st Century." Available at www.kff.org

¹⁴ Medicaid and the Prescription Drug Benefit. Kaiser Commission on Medicaid and the Uninsured Policy Brief September 2002. Available at www.kff.org

¹⁵ Out of Bounds: Rising Prescription Drug Prices for Seniors. Families USA publication No.03-106 July 2003. Available at www.familiesusa.org

¹⁶ Available at <http://www.rxlist.com/top200.htm>

¹⁷ For a discussion of this see Soumerai S. Benefits and risks of increasing restrictions on access to costly drugs in Medicaid. *Health Affairs* 23(1):135-146 January-February 2004. Also MacKinnon N and Kumar R. Prior authorization programs: a critical review of the literature. *Journal of Managed Care Pharmacy* Vol 7(4):297-302. July/August 2001.

¹⁸ "Principles of a sound drug formulary system". From the American Society of Health System Pharmacists. Available at www.ashp.org. The ASHP defines a drug formulary as a "continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacies, and other experts in the diagnosis and/or treatment of disease and promotion of health." A formulary system is "an ongoing process whereby a health care organization...establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population."

¹⁹ Available at www.nap.edu/books/0309069866/html. This study provides an excellent framework for looking at the construction and operation of formulary systems. It concluded that the VA formulary was not overly restrictive, and made some suggestions for improvement.

²⁰ Closed formularies allow only those drugs listed. All other medications require prior authorization. Open formularies may allow non-listed drugs to be covered but at a higher co-pay. Tiered formularies group drugs into two or more tiers, with increasing levels of beneficiary responsibility for drug cost.

²¹ Chren MM, Landefeld CS. Physicians' behavior and their interaction with drug companies. *Journal of the American Medical Association*. 1994; 271:684-689. Also Orlowski JP and Wateska L. The effects of pharmaceutical firm enticements on physician prescribing patterns. *Chest*. 1992; 102:270-273. Other data and references available at www.nofreelunch.org

²² The treatment of high blood pressure illustrates this. Despite years of clear national guidelines from a Joint National Commission, recommending a sequence of drugs that begin with inexpensive generic medications, physicians continue to prescribe expensive brand name medications from newer classes that should be third and fourth line choices. Siegel D, Lopez J. Trends in antihypertensive drug use in the United States. Do JNC-V recommendations affect prescribing? *Journal of the American Medical Association* 1997; 278:1745-8.

²³ Jacoby, A. A qualitative study to explore influences on general practitioners' decisions to prescribe new drugs. *British Journal of General Practice* February 2003. 53(487):120-5. Also Grimshaw JM. Changing provider behavior: an overview of systematic reviews of interventions. *Medical Care* 01-AUG-2001; 39(8 Suppl 2): II2-45.

²⁴ Rucker, TD. A public-policy strategy for drug formularies: preparation or procrastination? *American Journal of Health System Pharmacy*. 56(22):2338-2342 Nov 15 1999

²⁵ Comments from an interview with a former executive director of a Medicaid MCO September 2001

²⁶ For a summary of Medicaid payment for prescription drugs: Bruen B. Medicaid and Prescription Drugs: An Overview. Kaiser Commission on Medicaid and the Uninsured October 2000. and Bruen B and Ghosen A. Medicaid Prescription Drug Spending and Use. Kaiser Commission on Medicaid and the Uninsured. June 2004. Available at www.kff.org

²⁷ See reference 2

²⁸ Nursing home residents are excluded, as are beneficiaries with longer than 30 day stays in acute care facilities, but residents of residential treatment facilities, boarding homes, and all Medicaid categories were included at the time of this study.

²⁹ www.dpw.state.pa.us/omap/hcmc/omaphcmcgeninf.asp

³⁰ For a brief summary see www.dpw.state.pa.us/omap/hcmc/HCPHUpdate703.pdf. More detailed data is also available at www.dpw.state.pa.us/omap and looking at the physical health data books for each geographic area.

³¹ The regulations can be accessed at www.pabulletin.com/secure/data/vol31/31-23/1032.html. The act is Act 68 of 1998 (P. L. 464, No. 68) (40 P. S. §§ 991.2001--991.2361) and can also be found at www.pacode.com/secure/data/028/chapter9/chap9toc.html

³² HealthChoices standard agreement, available at

www.dpw.state.pa.us/omap/hcmc/hcagr/hcagrtoc.asp

³³ It specifies that a service is medically necessary if the service or benefit will or is reasonably expected to prevent the onset of a condition, illness, or disability, reduce or ameliorate the physical, mental, or developmental effects of a condition, illness, or disability or assist the individual to achieve or maintain maximum functional capacity in performing daily activities. HealthChoices Standard Contract Section II. Definitions, Medically Necessary, available at www.dpw.state.pa.us/omap/hcmc/hcagr/pdf/2004StandardContract.pdf

³⁴ Health Choices Southeast Contract p.38 Section B.2 Prior authorization of services. Available at www.dpw.state.pa.us/omap/rfp/sephnote/seagreement.pdf

³⁵ www.dpw.state.pa.us/omap/hcmc/mcstatreportq402.pdf

³⁶ During the study period, several MCOs implemented fail first policies for anti-depressants, or removed particular anti-depressants from the formulary, despite protests voiced by the state psychiatric society and the mental health association. One MCO also decreased the choice of the cholesterol lowering medications, forcing physicians and beneficiaries to change drugs despite good responses to current therapy.

³⁷ Available at www.dpw.state.pa.us/omap/hcmc/hcagr/hcagrtoc.asp

³⁸ *An Advocate's Guide to the Medicaid Program* 2001 edition. National Health Law Program. June 2001. Available through NHelp www.healthlaw.org

³⁹ This information was obtained at a formal meeting between officials of DPW and PHLP in December of 2002, called to discuss the findings of this report.

⁴⁰ During the time of the study the author was on staff at PHLP permitting access to the helpline.

⁴¹ For example, calls to the helpline regarding problems in personal care boarding homes resulted in an extensive report by PHLP, the attention of the state Auditor General, and subsequent regulatory reform proposals. During the time period of this work, an MCO changed its PBM, leading to data transfer errors and medication denials. Calls to the helpline alerted PHLP, and the MCO, to the problem and cooperative work led to quick resolution.

⁴² DPW officials reported, at a meeting in December 2002, that the largest MCO dispensed 400,000 prescriptions/month.

⁴³ HealthChoices Standard Agreement Section V. Part B. Program Requirements/Prior Authorization of Services. Available at

<http://www.dpw.state.pa.us/omap/hcmc/hcagr/pdf/2004StandardContract.pdf>

⁴⁴ Multiple cases were identified in which pharmacists were unable to dispense medications for which patients and physicians had been told prior authorization was granted. This was especially true in a plan which ran its own pharmacy system, but used a PBM only for electronic data transmission and billing. This extra step resulted in delays of hours to days, presenting access problems for beneficiaries unable to return frequently to pharmacies.

⁴⁵ See case 7 in Appendix B

⁴⁶ See case 5 in Appendix B.

⁴⁷ When plans enroll physicians as part of their network, they review their qualifications, including certification and licensure, and certify to their members that these are physicians whose credentials have been reviewed and approved. These physicians have a contractual relationship with the plan. However, beneficiaries may also be seen by non-participating physicians, as explained in the text. These physicians may have adequate credentials with the state and with physician organizations but they do not have a contractual relationship with the plan.

⁴⁸ One MCO's criteria allowed use of a COX-2 inhibitor for arthritis if the beneficiary was on warfarin, an anticoagulant. Despite two clear notations in a prior authorization request that the patient was indeed on warfarin, the denial letter stated that "criteria were not met." The letter then reviewed the criteria, including that the patient must be on warfarin, suggesting that the reviewer had not carefully read the prior authorization request. Although the prescribing physician could have appealed the case, few physicians are knowledgeable about appeals processes or willing to take the time to do so. This beneficiary called PHLP and obtained the medication with legal services help. However, she required a lawyer to obtain medication for which she met the MCO's own criteria.

Another beneficiary had trouble swallowing and her physician requested the smallest available generic or brand name formulation of the needed medication. The request was denied with a checked off reason "generic must be used" without addressing the beneficiary's problem or request. It was resolved after the physician appealed.

⁴⁹ See cases reviewed in footnote 47

⁵⁰ A pharmacist requested authorization for 3 bottles of insulin, (which is measured in "units" or "cc"), but was given an authorization for milligrams by a telephone operator, who said, when corrected by the pharmacist, "well I don't know." Interaction directly observed in neighborhood pharmacy by Gene Bishop, MD.

⁵¹ Direct observation in a neighborhood pharmacy by Gene Bishop, MD.

⁵² Interview with suburban pharmacist conducted by Gene Bishop, MD.

⁵³ Documented in problem reports to their trade organization, with copies supplied to the author.

⁵⁴ Two (of many) examples may help to demonstrate the problem. A beneficiary made two trips to a pharmacy on two different days to obtain a non-narcotic pain medication which had been prior authorized but not correctly entered into the computer. Not until the second day did the pharmacist spend the 20 required minutes on the phone that allowed him to dispense 15 pills. A beneficiary received 72 hours of an anti-depressant and her physician obtained prior authorization. When she returned 3 days later the pharmacist did not have approval. He was only able to dispense after multiple phone calls to the MCO and the intervention of the pharmacy director.

⁵⁵ A physician reported a phone call from a patient stating that the pharmacy could not dispense the prescribed smoking cessation medication because it needed prior authorization. She then called the MCO, who stated it did not, and sent the patient back to the pharmacy, who said they could not dispense. Assiduous detective work finally revealed that the pharmacist must call even though the prescription does not require prior authorization, although the plan had not communicated this information.

⁵⁶ The HealthChoices contract in effect at the time of this study is available at <http://www.dpw.state.pa.us/omap/rfp/sephnote/seagreement.pdf>. It required that if a beneficiary's prescription for a new medication could not be filled at a pharmacy because of the need for prior authorization, the beneficiary must be provided with "at least a 72-hour supply of the new medication if there is an immediate need for the medication." Immediate need, and the determination thereof, was not defined.

⁵⁷ Interview with DD, RPh. then working for a hospital pharmacy. She had no knowledge of Medicaid regulations, despite serving Medicaid customers, and stated that in her previous job at a large national chain she had received no training in Medicaid regulations and was told to rely on computer prompts.

⁵⁸ Few studies have looked at retail pharmacy operations and decisions. A study in California looking at the implementation of a new law offering discounts to low income Medicare beneficiaries showed chain pharmacies were more likely than independents to be aware of the discount. However, pharmacist discretion also played a role in this study. Only 75% of pharmacies complied with the California program, and only 45% did so without prompting by the study “customer.” Lewis JH, Schonlau M et al. Compliance among pharmacies in California with a prescription drug discount program for Medicare beneficiaries. *New England Journal of Medicine* 346:830-835 March 14, 2002.

⁵⁹ Meeting between Gene Bishop, MD and medical and pharmacy directors of one HealthChoices MCO, February 8, 2002.

⁶⁰ Case reported in interview with a community psychiatrist.

⁶¹ Reported by RN from residential treatment facility.

⁶² Geddes J, Freemantle M et al. Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta-regression analysis *British Medical Journal*, Dec **2000**; 321: 1371 - 1376.

Also, Shitij Kapur and Gary Remington Atypical antipsychotics *British Medical Journal*, Dec **2000**; 321: 1360 - 1361.

⁶³ Well after the time period of this report, safety issues regarding antidepressants and children were raised in the medical literature and the lay press. For example “Combination aids depressed youth”, *New York Times* August 18, 2004 and “Antidepressant study seen to back expert” by Gardiner Harris, *NYT* August 20, 2004. In 2003 the FDA issued an advisory regarding the use of the antidepressant Paxil® in patients under 18 years of age, and subsequent warnings have been issued for other anti-depressants. The clear implications of these studies, supporting increased talk therapy and decreased medication use, have significant consequences for the payors of therapy and pharmaceuticals.

⁶⁴ Geddes J, Freemantle M et al. Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta-regression analysis. *British Medical Journal*, 321: 1371 - 1376. December 2000.

Also, Shitij Kapur and Gary Remington. Atypical antipsychotics. *British Medical Journal*, 321: 1360 - 1361. December 2000.

⁶⁵ Well after the time period of this report, safety issues regarding antidepressants and children were raised in the medical literature and the lay press. For example “Combination aids depressed youth”, *New York Times* August 18, 2004 and “Antidepressant study seen to back expert” by Gardiner Harris, *New York Times* August 20, 2004. In 2003 the FDA issued an advisory regarding the use of the antidepressant Paxil® in patients less than 18 years of age, and subsequent warnings have been issued for other anti-depressants. The clear implications of these studies, supporting increased talk therapy and decreased medication use, have significant consequences for the payors of therapy and pharmaceuticals.

⁶⁶ Copy of letter given to the Gene Bishop, MD.

⁶⁷ The MCO in question stated that its committee meets regularly every three months, and includes all members – that is, it does not meet in subcommittees by specialty. This discrepancy was unable to be explained.

⁶⁸ HealthChoices standard contract Exhibit G accessible online at <http://www.dpw.state.pa.us/omap/hcmc/hcagr/pdf/HCStandAgreeExhibitG.pdf>

⁶⁹ This has since changed, but as of 2004 only some are available electronically, despite the fact that pharmacies, PBMs, and the MCOs transmit all information regarding prescriptions electronically.

⁷⁰ A recent article showed considerable variability in physician acceptance of formularies, depending on the percentage of managed care patients in their practice, and number of formularies with which they had to consult. The more formularies physicians had to consult, the more negatively they felt about formularies in general.

Landon B, Reschovsky JD, and Blumenthal D. Physicians views of formularies: implications for Medicare drug benefit design. *Health Affairs* Jan-Feb. 2004 volume 23(1) :218-226.

⁷¹ see endnotes 21, 22, and 23.

⁷² In a conversation between the author and a medical director of an MCO, the medical director acknowledged that beneficiaries whose cholesterol was well controlled on the “old” formulary medication should remain on that medication, because a change would require a dose change, additional doctor visits, and additional laboratory tests. However, once the formulary change was implemented, prior authorization requests to the MCO to maintain well controlled patients on the old medication were denied by the MCO.

⁷³ In April, 2004, a Federal appeals court upheld states’ abilities to utilize formularies to control costs when it upheld the Michigan preferred drug list and ruled against the Pharmaceutical Research and Manufacturers of America who tried to argue that the formularies limit access and force beneficiaries to accept inferior alternatives. Reported in the *New York Times*, April 2, 2004. More importantly, the Medicare Modernization Act of 2003 requires expanded government participation in the prescribing process, including incentives for electronic prescribing. In August 2004 the Center for Medicare and Medicaid Services published proposed rules in the Federal Register for the new Medicare drug benefit, and revised regulations appeared in January 2005. These regulations address some of the issues detailed in this study.

⁷⁴ See a similar call in Soumerai, SB. Benefits and risks of increasing restrictions on access to costly drugs in Medicaid. *Health Affairs* 23 (1): 135-146.

In the same issue, Hoadley JF. The need for independent research on prescription drugs . *Health Affairs* 23 (1) 244-249, argues for data separate from pharmaceutical companies that would allow improved buy-in from multiple stakeholders. The issue was also addressed previously in Lexchin J. Effects of restrictive formularies in the ambulatory care setting. *American Journal of Managed Care* 8(1): 69-76. January 1 2002.

⁷⁵ Morrison RS, Wallenstein S, Natale DK et al. We don’t carry that – Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New England Journal of Medicine* 342 (14):1023-1026. April 6, 2000. This article surveyed pharmacists in New York City, and compared their locations with census and crime data. They demonstrated that not only were pharmacies in nonwhite areas less likely to carry medications to treat severe pain, but also that the given reasons for this included additional paperwork and monitoring associated with these drugs. The study supports the findings in our study that pharmacists are making independent business decisions with significant health outcome consequences for their customers.

⁷⁶ Oregon, for example

⁷⁷ The influence of pharmaceutical companies is widespread, even in the development of treatment guidelines. In the 1990’s, ten drug companies underwrote an effort in Texas to develop treatment guidelines for schizophrenia, campaigning among state officials to utilize the most recent generation of anti-psychotic drugs. In Pennsylvania, Pfizer and Janssen contributed \$14,000 into an unauthorized state bank account used by state mental health officials for travel, meals, and expenses at a time when the drug makers were seeking state business. *New York Times*, “Making Drugs, Shaping the Rules” by Melody Petersen, Feb 1, 2004 and *Philadelphia Inquirer*, “State account draws ethics scrutiny” by John Sullivan, Feb 17, 2004

⁷⁸ The need for a model drug nomenclature and classification system was put forth as early as 1967 by a Task Force on Prescription Drugs convened by then President Lyndon B. Johnson. One of its members, T. Donald Rucker, retired professor of pharmacy administration, stated that “the cost effectiveness of implementing this idea [nomenclature and classification system] is unlikely to be exceeded by any other recommendation from any source.” (personal communication, March 8, 2002) Rucker’s experience on the task force is recounted in Rucker TD. The HEW Task Force on Prescription Drugs: An Insider’s Perspective. Originally published in

1989 and republished in Journal of Research in Pharmaceutical Economics Vol. 10 No.2/3 2001 The Haworth Press.

⁷⁹ Electronic Prescribing: Towards Maximum Value and Rapid Adoption, Report of the eHealth Initiative. Available at www.ehealthinitiative.org

⁸⁰ This is in contrast to secretive policies of PBMs, who claim that choice of drugs is proprietary information. Consumer groups and labor unions have resorted to lawsuits to discover coverage rules, as referenced in Kleinke JD. Access versus Excess: Value-based cost sharing for prescription drugs. Health Affairs 23(1):34-47 January-February 2003

⁸¹ As an example, see the online formulary policy of Aetna at www.aetna.com. By going to FAQs or clinical policy bulletins, it is possible to view the rationale for choosing drugs, or the overall view of formulary policy. Aetna is clear that the financial considerations they receive from manufacturers are a factor in formulary construction, but they also provide medical references to justify their choices. A consumer or physician may disagree, but it is at least possible to understand the basis of the decision.

⁸² The Oregon health plan, attempting to institute an evidence based formulary with input from stakeholders, is the best (and possibly only) example thus far of this approach. See the description in "Oregon's Medicaid PDL: Will an evidence based formulary with voluntary compliance set a precedent for Medicaid?" Bernasek C, Mendelson D, Padrez R, Harrington C.. Kaiser Commission on Medicaid and the Uninsured. January 2003. Available at www.kff.org

⁸³ For example, the Arthritis Foundation, the Mental Health Association, the Heart Association, and many others, most of whom receive substantial unpublicized funding from pharmaceutical companies. These disease foundations, speaking as the "consumer voice," see pharmaceutical representatives as their allies in fighting restrictive formularies. A staff member of one such foundation admitted to the author, in a personal conversation, that a pharmaceutical company had drafted a letter her organization sent to a state Medicaid organization. She saw this as an in-kind contribution from a donor.

⁸⁴ The Oregon program, referred to above, found itself financially unable to carry out this portion of its plan.

⁸⁵ This argument has been eloquently stated by T. Donald Rucker many times over many years, most recently in the article referenced in footnote 21, but any of his articles make significant contributions to the current discussion on formularies and prescribing practices.

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